A Blinded Evaluation of the Effectiveness and Efficacy of the MyHealthyPregnancy Application Statistical Analysis Plan

This study will evaluate the effectiveness and efficacy of the MyHealthyPregnancy App, an app designed to reduce preterm birth risk. This study will use observational cohort data collected at the University of Pittsburgh Medical Center between September of 2019 and February of 2022.

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Emily Grayek, Baruch Fischhoff

1. Description of the study

MyHealthyPregnancy (MHP) was developed using decision science principles to help prevent preterm birth. An observational cohort trial was conducted at the University of Pittsburgh Medical Center starting in September of 2019 until February 2022. This trial compares the effectiveness of MHP to usual care for pregnant people who delivered at the University of Pittsburgh Medical Center (UPMC). Patients at UPMC were able to download the MHP app after receiving a prescription for the app, as indicated by an EHR variable. Those who were prescribed the app and downloaded it were in the *MHP cohort*. Those who were prescribed the app and did not download it were in the *usual care cohort*. Prescriptions were offered to pregnant people by their care team at an early prenatal visit at UPMC.

EHR data is available for both cohorts of patients. It is the source of all measures, unless otherwise noted.

A linear effects model will be used to evaluate effectiveness by estimating the average treatment effect for the primary endpoint, preventing preterm birth risk.

For each dependent measure, these models will control for primary predictors, as identified in the research literature, that are available in the EHR.

A dose-response model will be used to estimate the effects of continuous measures of non-adherence (as opposed to dichotomous non-adherence, such as not initiating app use). Multiple measures of adherence will be analyzed, including measures of daily use, weekly use, time to initiation, and time from discontinuation to birth.

1.1. Principal research objectives

1.1.1. Primary objective

To compare gestational weeks at birth, for the MyHealthy Pregnancy (MHP) cohort, defined as pregnant people who downloaded the MyHealthyPregnancy app, thereby onboarding into the study, compared to the usual care cohort, defined as pregnant people, who were invited to download the app, but did not do so. Analyses control for predictors of preterm birth.

1.1.2. Secondary objectives

1. To compare *preterm birth*, defined as delivery before 37 gestational weeks, for the MHP and usual care cohorts. Analyses control for predictors of preterm birth.
2. To compare *depression* rates for the MHP and usual care cohorts, using the clinical diagnosis of depression. Analyses control for predictors of depression.
3. To compare *anxiety* rates across MHP and usual care cohorts, using ICD10 codes. Analyses control for predictors of anxiety.
4. To compare rates of *referrals to behavioral health specialists* for the MHP and usual care cohorts. Analyses control for predictors of behavioral health referrals.
5. To compare rates of *referrals to social workers* for the MHP and usual care cohorts. Analyses control for predictors of social work referrals.
6. To compare rates of *preeclampsia* for the MHP and usual care cohorts. Analyses control for predictors of preeclampsia.
7. To compare *sufficient gestational weight gain*[1] for the MHP and usual care cohorts. Analyses control for predictors of gestational weight gain.
8. To compare the number of *prenatal appointments attended* for the MHP and usual care cohorts. Analyses control for predictors of prenatal appointment attendance.
9. To compare the proportion of *required prenatal appointments attended* in the MHP and usual care cohorts. Analyses control for predictors of prenatal appointment attendance.

1.1.3. Exploratory objectives

Exploratory outcomes are ones that might be affected by the app, but lack a known mechanism of action or are of less interest than the primary and secondary outcomes. These outcomes will be reported as supplemental material to the study.

Appendix A contains the full list of each type of measure.

1.2. Study design including blinding

Given the nature of the observational study, patients and providers were not blinded to the treatment condition (MHP, usual care).

The primary statistician will remain blinded to the treatment and usual care cohorts with the exception of using 20% of the unblinded data to evaluate confounders of the outcomes, build a model for propensity score matching, and evaluate confounders of MHP app usage.

1.3. Method of allocation of groups

Participants seeking prenatal care at the UPMC were offered a prescription to download the MyHealthyPregnancy app during an early prenatal visit. Participants were prescribed the app by

[1] Gestational weight gain will be evaluated based on 2009 Institute of Medicine guidelines (11). Recommended gestational weight gain depends on pregravid BMI and if it is a singleton or multiple pregnancy.

their obstetrician or the EHR system and had the option of downloading the app and consenting to trial participation. We have no direct knowledge of how obstetricians decided whether to offer the prescription or if there was encouragement to download the app in addition to the automated EHR prescription. Participants who downloaded the app will be categorized as the MyHealthyPregnancy (MHP) cohort. Participants who did not download the app will be categorized as the usual care cohort.

1.4. Data collection

1.4.1. Eligibility Screening

Participants were included in the study if they were offered a prescription for MyHealthyPregnancy, were at least 18 years of age, pregnant, received care at UPMC, and delivered at a UPMC hospital.

1.4.2. Measures

Collected measures include demographics, baseline disease information, the primary outcome measure, the secondary outcome measures, the exploratory outcome measures, and app use information.

The primary outcome measure was chosen because it is the clinical measure that the app is intended to affect. Secondary measure 1 was chosen because it is the most common way of assessing preterm birth risk in similar trials. The other secondary measures are common clinical or operational measures of outcomes that components of the app intend to affect.

1.5. Sample Size Justification

Due to the observational nature of the study and recruitment context, it was not possible to predetermine the sample size based on statistical power for estimating the primary and secondary outcomes. Instead, all participants who met the inclusion criteria between September 2019 and February 2022 were included. The final sample has 12,344 deliveries, divided between the MHP and usual care cohorts (with 7147 in one and 5197 in the other, with their identities currently blinded). This represents about 12,287 different participants (we only have information about the percent of multiple deliveries for participants who downloaded the app, 0.464%). Given the sample sizes in the two cohorts, there is 80% power to detect an effect size of 0.051 days. Assuming that the outcomes are normally distributed with a standard deviation of 10 days (1), the study has 80% power to detect a 0.51 day difference in gestational age at birth between the cohorts.

1.6. Overview of proposed analyses

EG will analyze the primary, secondary, and exploratory outcomes for the trial data. LH will generate data and run models as needed so that EG remains blinded to the identity of each cohort (see section 2.5).

The primary analyses will be multiple linear regression models estimating average treatment effects of the MHP app. Secondarily, dose-response models will be created for the primary and secondary outcomes in order to understand the moderating effects of app usage.

The primary and secondary outcomes for the study will come from electronic health record (EHR) data for trial participants. Given the source and the nature of care for women who deliver in the UPMC system, few outcome data are missing data. As such, imputation will not be used to account for missing outcome data. Instead, participants will be excluded from analyses, if their outcome data is missing for an outcome measure.

As a sensitivity analysis, propensity score matching will be used to create similar cohorts of participants, excluding participants whose propensity scores are outside the overlap in the covariate distributions for the covariates that predict downloading the MHP app (see section 3.1.5). We will calculate average treatment effects for these matched subsets of participants. Inverse probability of treatment weighting will be used as an additional sensitivity analysis to account for the potential lack of overlap in covariate distributions between the study cohorts.

2. Data analysis plan – data description

2.1. Recruitment and representativeness of recruited patients

A flow diagram will describe the flow of participants from prescription of the MHP app into the MHP and usual care cohorts. The final diagram will be similar to Figure 1 below.

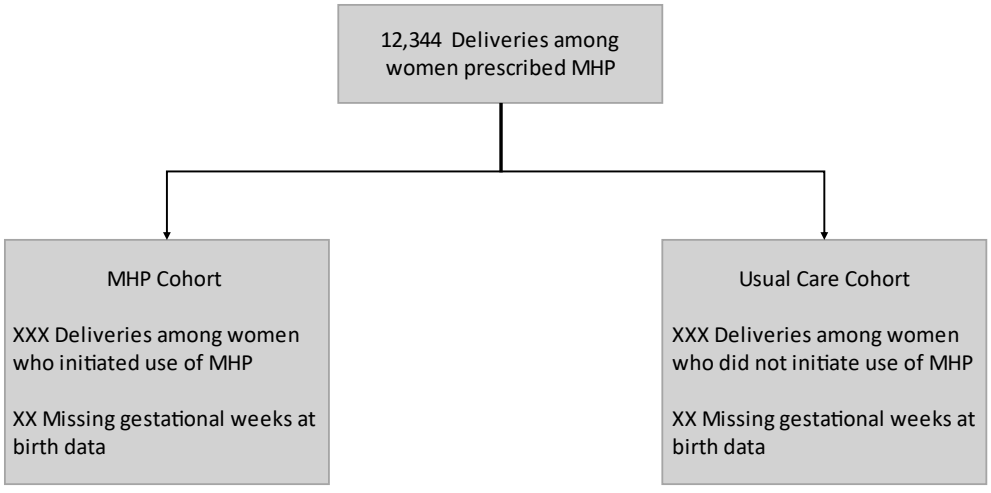

Figure 1. Flow of trial participants from app prescription to cohort inclusion

2.2. Baseline comparability of MHP versus usual care cohorts

Tables will be used to describe demographic and baseline measures for the MHP and usual care cohorts. Means and standard deviations will summarize continuous variables. Proportions and frequencies will summarize categorical variables. Based on STROBE guidelines, the statistical significance of differences between the cohorts will not be estimated, as this is not an appropriate method for identifying covariates that may have affected outcomes.

2.3. Treatment Usage

At its current stage of development, the MHP app does not prescribe a set dosage, specifying how often patients should interact with it in order to have desired effects. As such, this study investigates app usage as a mediator of the outcome, rather than comparing users who did and did not meet a predetermined dosage.

We will assess the following aspects of usage: how soon after receiving the prescription participants initiated app use (in days); how soon they discontinued app use prior to delivery (in days since initiation); the percentage of days they used it overall (within the usage period); and the percentage of weeks they used it at least once (within the usage period). See Appendix A for details on these use metrics.

2.4. Loss to follow-up and other missing data

Given data-sharing constraints with UPMC, outcome data is available only for participants who delivered at UPMC hospitals. LH will report how many people downloaded the app and did not deliver at UPMC. This will allow us to estimate the percentage of participants lost due to delivering out of the system.

For included participants, there is a very little missing data for the primary measure (80/13752=0.06%). We will assume that such data is missing at random and exclude participants whose data is missing for a measure from analyses involving that measure. There is no missing data for the secondary measures. The same practice will be followed for the exploratory outcomes. No imputation will be done for any outcome measures.

Missing categorical values for baseline covariates (baseline disease information and demographics) will not be imputed, but treated as an additional category. Continuous variables missing less than 5% of the data will be imputed with the median value for that variable. Two continuous baseline covariates are missing more than 5% of data ADI_NATRANK (1330/13752=9.7%) and PREGRAVID_WEIGHT (1318/13752=9.6%). For these two variables, scatterplots and Little's test will be used to investigate if the data is missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR) on 20% of the unblinded data. If the data appears to be MCAR or MNAR, median imputation will be used. If the data is MAR, multiple imputation will be used. If multiple imputation is needed, LH will generate data for the missing values so that EG remains blinded. For all missing data, we will conduct

sensitivity analyses, repeating analyses of primary and secondary outcomes using imputed values two standard deviations above and below the median. See Appendix A for the full list of collected baseline covariates.

2.5. Development of outcome measurements

EG will view 20% of unblinded data to determine which potential confounders to include in the outcome models, in the addition to those identified in advance, based on previous research. Section 3.1.1 provides further details on how confounders will be selected. The unblinded data will be split evenly between the MHP and usual care cohorts in order for EG to remain blinded to the treatment and control cohorts when analyzing outcomes.

EG will also create a model of the confounders of app usage to use in dose-response models and a propensity score matching model for the groups.

To allow EG to remain blinded to the final data, while performing these analyses, LH will generate random values of adherence, drawn from the distribution for the MHP cohort, for the usual care cohort. LH will run the outcome models on the full set of data and will report the results to EG for interpretation. EG will finish data analysis before being unblinded to the labels of the MHP and usual care cohorts.

2.6. Descriptive statistics for outcome measurements

The primary and secondary outcome measurements will be described in the main text of the manuscript. The exploratory outcomes will be described in the supplemental material. For continuous variables, the mean and standard deviation will be reported for the MHP and usual care cohorts. For binary variables, frequency and proportion will be reported.

2.7. Exploratory metric

As an exploratory metric, we may calculate the patient cooperativity index (PCI) (2), which accounts for how frequently participants take "app holidays," extended breaks from using the app. The PCI is an odds ratio, where participants with a higher PCI are more likely to use the app one day after using it the previous day. In equation 2, p_{fs} is the probability that a participant uses the app the day after not using the app and p_{ss} is the probability that a participant uses the app the day after using the app. These probabilities will be calculated for participants who initiate use of the app, from that time until their last use.

(2)

$$PCI = \frac{p_{fs}/(1 - p_{fs})}{p_{ss}/(1 - p_{ss})}$$

3. Data analysis plan – inferential analysis

3.1. Main analyses of treatment differences

The main analysis compares the mean gestational weeks at birth between the MHP and usual care cohorts. An estimate of the average treatment effect, 95% confidence interval, and effect size will be reported. EG will remain blind to the 80% of outcome data not used to set the terms of the analysis (Section 2.5).

The primary and secondary outcomes will be evaluated at the 5% significance level. No correction for chance will be used for the primary outcome, as there is only one test. For the 9 secondary outcomes, we will report both corrected and uncorrected p-values, using the Bonferroni correction to reduce risk of reporting a false positive result. As a sensitivity analysis, the Bonferroni corrected p-values for ten outcome values will be reported in the supplemental material of the report.

All tests will include all participants with data on the outcome measure involved.

3.1.1. Analysis of primary outcomes

The difference in gestational weeks at birth will be evaluated using a linear effects model accounting for confounders of preterm birth, as measured at baseline. We estimate that about 57 out of 12,344 deliveries are for a second pregnancy for participants included in the sample given that 0.464% of participants who downloaded the app had two deliveries in the sample. We have included these women in the sample because we cannot exclude similar women in the usual care cohort given limitations in our data. Likewise, we cannot account for random effects of multiple deliveries using a mixed effects model.

Baseline study variables will be included as confounders in the model if (a) the literature has identified the variable as a confounder of preterm birth risk and (b) they might plausibly have influenced participants' decision to download the app. If, for a variable, the evidence on condition (a) is inconclusive and condition (b) is possible, we will examine the data and include the variable if it passes a 10% change-in-estimates threshold for the outcome or for the likelihood of downloading the app. The change-in-estimate will be calculated by adding each study variable to the model from the literature individually. Only baseline variables will be evaluated as potential confounders, as they could not have been affected by use of the app.

We will report the results of two models for each outcome, one using only confounders identified in the literature and one adding confounders identified empirically (Appendix A). Including fewer confounders will reduce the likelihood that the average treatment effect applies only to an unrepresentative subset of the population. Including additional confounders will reduce the likelihood of statistical bias in estimating the average treatment effect.

The dataset contains many known confounders of preterm birth that could be included in the model including:

- Previous preterm birth (3)
- Race (3)
- Low body-mass index (3,4)
- Insurance type (5)
- Area deprivation index (6)
- Multiple gestations (3)
- Previous spontaneous abortions (7)
- Hypertension (3)
- Diabetes (3)
- Tobacco use (3)

There are also many known predictors of preterm birth that are not in the EHRs, hence not available for this study. They include educational attainment, marital status, interpregnancy interval, relatives who delivered preterm, and genetic predictors of preterm birth (3).

Some collected covariates are specific to this dataset. One is hospital location, which may capture differences in resources, practices, and patient populations. The second is the date of the first visit recorded in Epic, which may capture factors like access to care or social conditions (e.g., the pandemic). We will include hospital location as a variable in all models. We will not include date of first visit as it might be correlated with ones that affect the effectiveness of the app over time.

Residual plots will be used to evaluate the models for heteroskedasticity and the need for using robust standard errors, in order to allow for violations in the assumption that observations are independent and identically distributed (8).

Differences between the cohorts will be described using adjusted mean differences and p-values. Results will be considered significant at $p<0.05$.

3.1.2. Analysis of secondary outcomes

Analytical procedures for the secondary outcomes will follow those for the primary outcome. Each outcome will have its own appropriate confounders. As with the primary outcome, these confounders will be based on previous research and specified a priori. As needed, they will be supplemented by empirical analysis of the 20% subset, including baseline covariates specified in Appendix B, with a 10% change-in-estimate threshold for inclusion.

These confounders from the literature are available:

1. Preterm birth defined as delivery before 37 gestational weeks.
    a. Same confounders as the primary outcome
2. Clinical diagnoses of depression.
    a. History of anxiety and depression (9)
    b. Smoking (9)
    c. Past pregnancy complications or loss (9)
    Unavailable: Lack of partner or social support or having a problematic relationship, a history of abuse or child abuse, having had an unplanned or unwanted pregnancy, perceived stress, cognitive style (including "pessimism, anger and rumination; a tendency to be nervous, worried or shy; low self-esteem and low self-efficacy; and high levels of neuroticism or psychoticism") , and single marital status (9).
3. Anxiety rates (using ICD10 codes).
    a. History of anxiety and depression (9)
    b. Smoking (9)
    c. Past pregnancy complications or loss (9)
    Unavailable: Same as anxiety (9).
4. Referral to behavioral health
    a. No confounders identified
5. Referral to social work
    a. No confounders identified
6. Preeclampsia
    a. Prior pre-eclampsia (10)
    b. Chronic hypertension (10)
    c. Pre-gestational diabetes (10)
    d. BMI >30 (10)
    Unavailable: Antiphospholipid antibody syndrome (10).
7. Sufficient gestational weight gain
    a. Pre-pregnancy BMI (11)
    b. Age (11)
    Unavailable: Family violence; marital status; food insecurity; maternal pregravid metabolic status; hyperemesis gravidarium; anorexia; past bariatric surgery (11).
8. Number of prenatal appointments attended
    a. No confounders identified
9. Percent of required prenatal appointments attended
    a. No confounders identified

3.1.3. Analysis of exploratory outcomes

For the exploratory outcomes, we will report only descriptive statistics specified in section 2.6.

3.1.4. Dose-response analysis

A dose-response analysis will be used to test usage as a mediator of each outcome. Multiple measurements of usage were collected and are listed in Appendix A. Metrics specified in section 2.3 will be created by assessing whether the participant used any app activity on a given day. Logging into the app without activity will not count as app usage because this information was not collected for the full study period. Activity use is also more likely to be associated with engagement with the app than is login alone. Daily usage and weekly usage will be the dependent variables for the dose-response models. As an exploratory analysis, the PCI may be analyzed as a dependent variable. The dose-response relationship will be analyzed for the primary and secondary outcomes using a multiple linear effects model and the confounder adjustment method (12). The model for adherence will be created using 20% of the unblinded data. The dose-response effects for the primary outcome will be reported in the manuscript. The dose-response effect for the secondary outcomes will be reported in the supplemental material.

3.1.5. Additional statistical considerations

Method for handling confounding by indication

Because this trial is observational, there may be incomplete overlap in covariates between the MHP and usual care cohorts. To account for this possibility, inverse probability of treatment weighting will be used. Propensity score matching of comparable subgroups will also be used and reported as a sensitivity analysis (13).

Propensity score matching works by creating samples of participants who have the same likelihood of receiving treatment. Logistic regression will be used to generate propensity scores; nearest-neighbor matching without replacement will be used for matching. Baseline confounders will be included in the propensity score model, if they are related to the likelihood of receiving treatment and the outcome. Date of first visit will not be included in the model (for reasons given in Section 3.1.1). Participants without similar propensity scores, defined as greater than a caliper width, will be excluded from this sensitivity analysis. The average treatment effect will be calculated for the included subset of similar participants.

Austin recommends a "caliper width," defined as the difference between two propensity scores, as "equal to 0.2 of the standard deviation of the logit of the propensity score"(14). To balance the internal and external validity of this sensitivity analysis, this caliper width will be used, unless it excludes more than 20% of the sample. In that case, the caliper width will be increased until 80% of the participants are included. If this is adjustment is needed, the results using the smaller caliper width will be reported in the supplemental material. Following Austin (2011), standardized differences, QQ-plots, box plots, cumulative distribution functions, and empirical nonparametric density plots will be used to check the differences in baseline covariates between the treated and untreated samples (13).

Time-effects

For the primary models, we have chosen not to include the first appointment date as it could capture factors that affect the effectiveness of the app. During the study time frame, many outside factors could have affected the outcomes, especially due to the COVID-19 pandemic.

Because of this we will conduct a sensitivity analysis including a time effect, the date of the participant's first prenatal visit, in each model.

4. Software
   Data will be delivered to EG through a HIPAA-compliant password protected sharefile site. The data will be downloaded in a csv format and R will be used for data description and analysis.

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Appendix A

Covariates and Outcomes

Variable Name in EHR	Description	Variable type
PATIENT_ID	ID for each patient not related to patient information	ID
MOM_AGE	Mother's age at time of delivery	Baseline covariate
FINANCIAL_CLASS	Payor at time of delivery from Medipac (insurance level, might be like coverage) (i.e. name like 'UPMC HEALTH NETWORK', 'MED PLUS', 'BEST HEALTH CARE', etc)	Baseline covariate
HOSP_ROLLUP_GROUPING1	Payor at time of delivery from Medipac (insurance type) (i.e. specifies type of UPMC insurance, examples include 'UPMC Commercial', 'Other MA Managed', 'Other Commercial', etc)	Baseline covariate
HOSP_ROLLUP_GROUPING2	Medicare, Medicaid, Self-pay, or Commercial Insurance	Baseline covariate
HPFLAG	Payor at time of delivery from Medipac (UPMC Health Plan Member flag, 1= has UPMC Health Plan, 0=Doesn't have it)	Baseline covariate
PT_ZIP	Patient zipcode	Baseline covariate
AD_ZIP_4	Patient zipcode, location extension (+4)	Baseline covariate
ADI_NATRANK	Area deprivation index, national ranking (0 most deprived, 100 least deprived)	Baseline covariate
RACE	Race, as reported through UPMC	Baseline covariate
MOM_HEIGHT	mother's height at time of delivery (cm)	Baseline covariate
OB_GRAVIDITY	Number of pregnancies (includes current pregnancy, so if it's their first pregnancy, this will be a 1)	Baseline covariate
OB_PARITY	Number of previous deliveries (will be 0 if it's their first pregnancy)	Baseline covariate
OB_FULL_TERM	Number of previous full term pregnancies	Baseline covariate
OB_PREMATURE	Number of previous premature deliveries (prior to 37 gestational weeks)	Baseline covariate
OB_ABORTIONS	Number of previous abortions, including theraputic/spontaneous abortions	Baseline covariate
OB_LIVING	Number of previous live deliveries	Baseline covariate
OB_SPONTANEOUS_AB	Number of previous miscarriage/spontaneous abortions	Baseline covariate
OB_THERAPEUTIC_AB	Number of previous theraputic abortions	Baseline covariate
PREGRAVID_WEIGHT	mother's pre-pregnancy weight (kg)	Baseline covariate
GESTAGE_ATVISIT_DAYS	This is the gestational age of the pregnancy at the time of prenatal visit. Calculated using the estimated delivery date ((280-(EPISODE.OB_WRK_EDD_DT-pat_enc.contact_date))).	Baseline covariate
PREGSTART_OBESE	Obese BMI at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_MORBIDOBESE	Morbidly obese BMI at first visit (binary variable)	Baseline covariate
PREGSTART_HTN	Chronic hypertension at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_CKD	Chronic kidney disease at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_DIAB	Type I or Type II diabetes at first prenatal visit (binary variable)	Baseline covariate

PREGSTART_ANXIETY	Diagnosed or active anxiety at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_DEPRESSION	Diagnosed or active depression at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_LIVER_DISEASE	Liver disease at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_TOBACCOUSE	Tobacco use history, recorded at first prenatal visit (options are "yes","never","quit","passive")	Baseline covariate
PREGSTART_O_PREEXISTINGHTN	Pre-existing hypertension in any of these forms or combinations, complicating pregnancy: essential hypertension, hypertensive heart disease, hypertensive chronic kidney disease, secondary hypertension, or unspecified hypertension. Diagnosed or listed as active problem at first prenatal visit. (binary variable); Definition came from EPIC codes	Baseline covariate
PREGSTART_O_PREGINDUCEDHTN_NOPROT	Gestational hypertension without significant proteinuria, could occur during any trimester, childbirth, or puerperium. Diagnosed or listed as active problem at first prenatal visit (binary variable);	Baseline covariate
PREGSTART_O_PREGINDUCED_PROTEDEMA_NOHTN	Gestational edema, gestational proteinuria, or gestational edema with proteinuria. Diagnosed or listed as active problem at first prenatal visit (binary variable);	Baseline covariate
PREGSTART_O_PREECLAMPSIA	Preeclampsia diagnosed or listed as active problem at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_O_SUPERIMPOSEDPREE	Preexisting hypertension with preeclampsia. Diagnosed or listed as active problem at first prenatal visit. (binary variable); Definition came from EPIC codes	Baseline covariate
PREGSTART_O_ECLAMPSIA	Eclampsia diagnosed or listed as active problem at first prenatal visit (binary variable)	Baseline covariate
PREGSTART_O_UNSPHTN	Unspecified maternal hypertension. Diagnosed or listed as active problem at first prenatal visit. (binary variable);	Baseline covariate
PREGSTART_O_ANYHTN	Pre-existing hypertension in any of these forms or combinations, complicating pregnancy: essential hypertension, hypertensive heart disease, hypertensive chronic kidney disease, secondary hypertension, or unspecified hypertension. Diagnosed or listed as active problem at first prenatal visit. (binary variable);	Baseline covariate
PREGSTART_O_CARDIOMYOPATHY	Disease of the circulatory system affecting any stage of pregnancy. Diagnosed or listed as active problem at first prenatal visit. (binary variable); Definition came from EPIC codes	Baseline covariate
PREGSTART_O_GDM	Gestational diabetes mellitus. Diagnosed or listed as active problem at first prenatal visit. (binary variable)	Baseline covariate
PREGSTART_MEDREPORTED	Medications reported at first prenatal visit (binary variable)	Baseline covariate
PREVIOUS_GDM	Previous GDM in a prior pregnancy, not including this current pregnancy (gestational diabetes) (binary variable)	Baseline covariate
PREVIOUS_OBANYHTN	Previous gestational hypertension in a prior pregnancy, not including this current pregnancy (binary variable)	Baseline covariate

PREVIOUS_PREECLAMPSIA	Previous preeclampsia in a prior pregnancy (binary variable)	Baseline covariate
AUTOIMMDX_PT20WKS	Previous gestational autoimmune disease prior to 20 weeks (in prior pregnancy) (binary variable)	Baseline covariate
PRIOR_SBBTW16AND34	Prior stillborn between 16 and 34 weeks in a prior pregnancy (binary variable)	Baseline covariate
PRIOR_LBBTW31AND36	Prior premature live birth between 31 and 36 weeks in a prior pregnancy (binary variable)	Baseline covariate
PRIOR_SBAFTER34	Prior stillborn after 34 weeks in a prior pregnancy (binary variable)	Baseline covariate
PRIOR_VPTBBTW222AND30	Prior very premature birth between 22 and 30 weeks in a prior pregnancy (binary variable)	Baseline covariate
PRIOR_STILLBORN	Prior stillborn (time period not specified) in a prior pregnancy (binary variable)	Baseline covariate
PRIOR_PPROM	Prior preterm premature rupture of membranes in a prior pregnancy (binary variable)	Baseline covariate
PRIOR_PPROMBEFORE37	Prior preterm premature rupture of membranes before 37 weeks in a prior pregnancy (binary variable)	Baseline covariate
HOSPITAL	which hospital they delivered at	Baseline covariate
SINGLETONS	1=singleton birth, 0=twins, triplets, etc (binary variable)	Baseline covariate
PREG_CONTACT_DATE	First visit in Epic while pregnant	Baseline covariate
EST_GEST_AGE_DAYS	gestational age at the time of birth	Primary outcome
MOM_DELIVERY_WT	weight of mother at time of delivery (kg)	Secondary outcome
PREGANY_DEPRESSION	Diagnosis of depression or active depression at some point during pregnancy (would also be 1 if PREGSTART_DEPRESSION is 1) (binary variable)	Secondary outcome
PREGANY_ANXIETY	Diagnosis of anxiety or active anxiety at some point during pregnancy (would also be 1 if PREGSTART_ANXIETY is 1) (binary variable)	Secondary outcome
PREGANY_PREE	Preeclampsia diagnosed or listed as active problem at any visit while pregnant (binary variable)	Secondary outcome
PNV_COUNT	Number of prenatal appointments attended	Secondary outcome
PNV_TOTSCHED	Number of prenatal appointments scheduled (blank if the same as PNV_COUNT i.e. they didn't cancel any appointments)	Secondary outcome
PREGANY_BEHAVIORALREF	Behavioral health referral at some point during pregnancy (binary variable)	Secondary outcome
PREGANY_SWREF	Social work referral at some point during pregnancy (binary variable)	Secondary outcome
BABY_DISPOSITION	baby's disposition after birth (home health agency, home/self care, children's hospital, cease to breathe, etc)	Exploratory outcome
STILLBORN	whether this baby was stillborn (binary variable)	Exploratory outcome
C_SECTION	Had c-section (binary variable)	Exploratory outcome
BIRTH_WEIGHT	baby's birth weight in grams	Exploratory outcome
NICU_DELIVERYADMISSION	whether the baby was brought to the NICU (binary variable)	Exploratory outcome
ASSUMED_INDUCTION	If a delivery was by c-section prior to 259 days gestation, but there is no documentation of induction then we assume	Exploratory outcome

	it was indicated and this column has a 1 (binary variable). Otherwise, it's 0. Definition came from Hy.	
INDICATED_ONSET	When a delivery form documents that a delivery was induced but not for PROM (binary variable). Definition came from Hy.	Exploratory outcome
CURRENT_PPROM	premature rupture of membranes; diagnosis of O42* during current delivery (binary variable).	Exploratory outcome
VISITNUMBER_F2F	Number of face-to-face visits when pregnant.	Exploratory outcome
PREGANY_PREGINDUCEDHTN_NOPROT	Gestational hypertension without significant proteinuria, could occur during any trimester, childbirth, or puerperium; Diagnosed or listed as active problem at any visit while pregnant. Definition came from EPIC codes	Exploratory outcome
PREGANY_SUPERIMPPREE	Superimposed Preeclampsia diagnosed or listed as active problem at any visit while pregnant (binary variable)	Exploratory outcome
PREGANY_ECLAMPSIA	Eclampsia diagnosed or listed as active problem at any visit while pregnant (binary variable)	Exploratory outcome
PREGANY_UNSPHTN	Unspecified hypertension diagnosed or listed as active problem at any visit while pregnant (binary variable)	Exploratory outcome
PREGANY_ANYHTN	Any hypertension diagnosed or listed as active problem at any visit while pregnant (binary variable)	Exploratory outcome
PREGANY_GDM	Gestational diabetes diagnosed or listed as active problem at any visit while pregnant (binary variable)	Exploratory outcome
CANCELEDVISIT_COUNT	Number of prenatal appointments canceled (blank if 0 appointments canceled)	Exploratory outcome
ANTEPARTUM_EDLD	Number of EDLD visits during pregnancy (EDLD = Emergency Department Labor and Delivery)	Exploratory outcome
ANTEPARTUM_EDTR	Number of ER visits during pregnancy	Exploratory outcome
ANTEPARTUM_ADMISSION	Number of ‘IP’ or ‘OP’ hospital visits between pregnancy start date in Epic and delivery	Exploratory outcome
ANTEPARTUM_LOS	Sum of all antepartum admission lengths of stays for each delivery.	Exploratory outcome
POSTPARTUM_EDTR	Number of postpartum visits to ER up to 42 days after pregnancy	Exploratory outcome
POSTPARTUM_ADMISSION	Number of ‘IP’ or ‘OP’ hospital visits between delivery date and 42 days postpartum.	Exploratory outcome
POSTPARTUM_LOS	Sum of all postpartum admission between delivery date and 42 days postpartum.	Exploratory outcome
POSTPARTUM_NICU	Provided flags for infant ICU admission within 42 days postpartum.	Exploratory outcome
PP_LOS	postpartum length of stay in hospital in days	Exploratory outcome

Usage metrics

Variable Name	Description
DailyCheckin	Dates of filling out the daily check-in (includes responses to questions on daily mood, number of hours slept, sleep quality, SDOH questions, aspirin adherence, etc)
ArticleReads	Dates of clicking on any article within the app (only after November 2020)
MentalHealthCheckin	Dates of filling out mental health check-in
RelationshipHealthCheckin	Dates of filling out relationship health check-in
SleepHealthCheckin	Dates of filling out sleep health check-in
HelpfulResource	Dates of looking at the helpful resource section (only after November 2020)
HelpfulResourceClick	Dates of clicking on a helpful resource from the helpful resources section (only after November 2020)
OpensApp	Dates of accessing the app at all (best after November 2020, but can also seem many things before November 2020)
Kick Counter	Dates of logging a kick-counting session in Kick Counter section of the app
Contraction Counter	Dates of logging contractions in the Contraction Counter section of the app
Journaling Section (just dates)	Dates of entering a journal into the journaling section of the app
Adding appointment reminders	Dates of adding in an appointment into the Prenatal Visits section of the app