Care After Pregnancy Study (CAPS): Engaging Women in Postpartum Care

NCT04257552

STUDY 19040312

Study protocol and statistical analysis (10/31/2019)

STUDY PROTOCOL

We propose to conduct a three-arm randomized controlled trial (RCT) enrolling eligible women on the postpartum floors to either 1) attention control arm, 2) pre-scheduled postpartum visit arm, or 3) Healthy Beyond Pregnancy study arm. We designed the trial as a RCT given concern for confounding by factors known to be associated with compliance with the postpartum visit such as adherence with prenatal visits or labor and delivery complications as well as concern for unmeasured confounders, that might not be adequately addressed by alternative study designs.

Study Population: We will enroll women with a Pennsylvania Medicaid product who received prenatal care and delivered at Magee Womens Hospital (MWH) of the University of Pittsburgh Medical Center.

Exclusion criteria: We will exclude women who delivered prior to 24 weeks, women with an intrauterine fetal demise or neonatal death, and women without text-enabled phones. We will also exclude women who had a tubal ligation postpartum as they are unlikely to use additional birth control, our primary study outcome.

Recruitment:

Participants will be recruited over 8 months from the postpartum floors at MWH. A research coordinator will recruit all patients to maintain fidelity of the intervention and approach to the control arm. This is the approach we used in our successful pilot feasibility trial. Postpartum nurses will be informed about the study, however, in an effort to minimize contamination of our attention control arm providers involved in postpartum care will not receive education about the goals of our study. (We will not meet with providers ahead of time to emphasize that we are trying to increase attendance at the postpartum visit with our study as this could change usual care by those providers. Instead we inform providers that we are doing a study to engage women in postpartum care but not emphasize the goals of the study.)

Randomization Procedures: After confirmation of eligibility, women will be approached for informed consent. Consented participants will be randomly assigned to one of the study arms. Allocation will be in a 1:1:1 ratio. A permuted block design with random block sizes will be used to balance treatment assignments and to mask investigators from knowing the next assignment. No stratification variables will be used for randomization.

The randomization system will be available via a secure area of the project computer with access restricted to those clinical center personnel with permission to randomize patients. Trial investigators and staff will be certified to randomize women into the trial and trained to adhere to a strict randomization protocol. In particular, the clinical personnel must confirm the participant's eligibility status before an intervention assignment is provided. Sealed randomization envelopes will be provided to the clinical site as a backup in the event that the randomization system is not accessible. Trial personnel will open the next sequentially numbered randomization envelope and then record the information in the randomization log.

Study Arms

Attention Control Group:

If randomized to the attention control arm participants will receive discharge instruction from the

postpartum nurses per usual care. We will ask them to provide us with an SMS number. This will enable collection of self-reported breastfeeding duration (see section ascertainment of outcomes) as well as texts on general infant care. These texts are educational in nature and no data will be collected. They will receive a total of two texts on general infant care in the first month postpartum. This increased attention to the control arm mirrors the attention received by the Healthy Beyond Pregnancy arms and seeks to isolate the effect of the intervention from a general increased level of contact with providers. A usual care arm would only receive written discharge instructions from a postpartum nurse. We will also inform them that if they answer 80% of the breastfeeding questions at six months postpartum they will receive a $20 gift card.

Healthy Beyond Pregnancy:
If randomized to the Healthy Beyond Pregnancy arm the research coordinator will provide the participant with a tablet and stylus and direct them to the Healthy Beyond Pregnancy website. Women will complete the program in their postpartum rooms at Magee prior to discharge. All of the steps described below happen in the postpartum room and take roughly 10 minutes.

The first step in the Healthy Beyond Pregnancy web platform is an electronic survey that assesses a participant's self-identified postpartum concerns. Women are presented the following list of issues: (1) Postpartum Contraception (2) Breastfeeding Support (3) Postpartum Mood (4) Bowel and Bladder Function after Delivery (5) Sexual Activity after Delivery (6) Optimizing Inter-pregnancy Health (7) Follow up after Pregnancy Complications such as Gestational Diabetes or Hypertension (8) Follow up after Pregnancy Complicated by Hepatitis C (9) Vaccinations. The results of this survey will be collected. (Survey is uploaded.)

Women are then immediately presented with at least 3 educational videos that reflect their self-identified needs from the survey. We acknowledge that some issues must be addressed, regardless of the woman's self-identified needs. Specifically for women with a pregnancy complicated by gestational diabetes, preterm birth, or hypertension they will view videos about the implications of these pregnancy complications. If a participant indicates she is not interested in any of the postpartum domains on her survey, she will be shown the videos on contraception and breastfeeding.

The education videos were filmed with professional actors who reflect the age and racial make-up of our population. They were designed to increase all levels of awareness about important postpartum issues women face using language at an 8th grade level. Each video is less than 2 minutes. If women want to watch more than 3 videos, they have the option.

After completing the survey and watching their videos, the Healthy Beyond Pregnancy generates an individualized passport for postpartum care. This passport for care lists the women's self-identified postpartum needs as well as issues that should be prioritized based on her health history. As above this include information about follow up needed for women with gestational diabetes, preterm birth, or hypertensive disorders of pregnancy. The individualized passport for postpartum care will be printed out and given to the woman. It will not become part of her medical record. (We have uploaded the Mock-Up for the Passport to Health.)

The coordinator will stay in the room to assist the participant with the website and ensure that the participant completes the program. After the participant schedules her postpartum visit, she

will receive a print out that includes the date and time of her appointment, a copy of her commitment statement as well as a reminder of the $40 incentive she will receive if she fulfills her commitment and attends her postpartum visit, and her individualized passport to postpartum care. The commitment contract simply states that the patient is committing to coming to her postpartum visit and she will electronically sign it. We will also inform her that if she answers 80% of the breastfeeding questions at six months postpartum she will receive an additional $20 gift card. (The commitment contract can be viewed on the attached mock-ups in the supplementary file.)

Note the study team is working with outpatient clinic to identify available appointment times for women to schedule. The HBP program securely emails the schedulers in the outpatient clinic to communicate which visits have been scheduled in real time.

Once completing the program, women can go back into the program and watch other videos either while in the hospital or at home. They cannot re-take the survey or change the date of their visit. We are not tracking which videos women go back into watch.

Usual Care with Pre-scheduled Postpartum Visit:
If randomized the usual care with pre-scheduled visit arm, participant will schedule their postpartum visit with the study coordinator. They will then receive discharge information per usual care. We will also collect her SMS number and inform her that if answers 80% of the breastfeeding questions by text message at six months postpartum she will receive an additional $20 gift card.

To be clear, all arms will receive interactive text messages to collect breastfeeding data. These texts will go out a 1 week, 4 week, 12 weeks and 6 months postpartum. (This breast feeding form is attached below.) We will also collect basic demographic and medical history on all patients after enrollment.

Primary outcome: The primary outcome of this trial is the use of an effective contraceptive method at 3 and 6 months.

Definition of effective contraception use after delivery: We will determine the proportion of women who utilize a non-barrier birth control method of their choice at 3 months postpartum. Barrier methods have a pregnancy rate of at least 10 pregnancies per 100 women per year and are classified as least effective by the Center for Disease Control. All other methods are classified as effective or highly effective(98). We will also determine the proportion of women who utilize a non-barrier birth control method at 6 months postpartum.

Definition of breastfeeding duration and other breastfeeding outcomes: We will determine the proportion of women who are providing any infant feeds with breast mild at 3 and 6 months. We will also determine the proportion of mothers exclusively breastfeeding at all time points-- 1 week, 4 weeks, 12 weeks (3 months), and 6 months. Finally, we will estimate the total duration of breastfeeding.

STATISTICAL ANALYSIS

Analyses for all study outcomes will be conducted according to the intention-to-treat principle.

For dichotomous outcomes (e.g. use of effective contraception at 6 months), chi-square statistics will be used to compare event rates by assigned treatment group for uptake of effective contraception (yes/no) with an alpha-level=0.05. Proportions, the relative risk, and the absolute risk difference will be estimated, and 95% confidence intervals will be calculated. Multivariable logistic regression analysis will be used to adjust for observed group imbalances and factors known to be associated with the outcome (see potential confounders above) as a sensitivity analysis. Multivariate models will also be used to elucidate the roles of demographic factors including race and relevant clinical factors as predictors. There will be some missing data for the trial outcomes. Parallel analyses will be performed on imputed datasets as a sensitivity analysis. Multiple imputation of the missing outcome data will be conducted under alternative scenarios assuming that the data are missing at random conditional on specified participant characteristics and that they are missing not at random.

For event history type outcomes (e.g. total duration of feeding human milk or duration of effective contraception use) time from delivery will be analyzed using interval-censored survival analysis methods using a two-sided test with alpha=0.0167(103). The estimated event rates at 3 and 6 months, the difference between assigned treatment groups, and the corresponding confidence intervals will be presented.

For outcomes with repeated measures (breast/chest feeding at multiple time points) generalized linear mixed-effects modeling with linear contrasts will be used to examine the effect of treatment assignment on the longitudinally assessed outcome over time, with treatment group assignment as a between-subject factor, time as a within-subject factor, and an interaction between treatment group and time. Given the level of measurement and distribution of the dependent variable, an appropriate error structure and link function will be selected. For example, since provision of human milk is assessed as a binary variable, a binomial error structure will be assumed and a logit link will be applied. Random effects for participants will also be included. Fixed and/or time-dependent covariates may be included secondarily to adjust for group imbalances and variables related to the dependent variables based on the literature or data screening results. Standard fit criteria (e.g., AIC and BIC) will be used to identify the best-fitting repeated measures covariance structure. F-tests will test the main and interaction effects included in the model. Individual regression parameters will be estimated with confidence intervals. For each model, residual analyses will be conducted to identify sources of model misspecification, outliers, and influential observations. Sensitivity analyses will be performed to discern the impact of influential cases on modeling results. Linear contrasts will be specified in the repeated measures models to test whether Healthy Beyond Pregnancy demonstrates greater improvements in breast/chest feeding outcomes compared to attention control or pre-scheduled visit arm at each time point.