PRogram In Support of Moms: An Innovative Stepped-Care Approach for Obstetrics and Gynecology Clinics (PRISM)

NCT02760004

Document Date:5/9/23

Analysis plan

Our general approach to statistical analysis followed commonly accepted procedures. All analyses were conducted using SAS 9.4. As a first step in analysis, descriptive statistics and measures of association including measures of central tendency and measures of dispersion were used to summarize all variables. This analysis included graphical analysis of distributional characteristics of all variables. Bivariate associations between explanatory variables of interest were assessed by student t-tests, Wilcoxon rank-sum, and Chi-square tests for continuous, ordinal, and categorical values, respectively.

Data analysis Hypothesis 1. *Depressed perinatal patients receiving care from clinics enrolled in PRISM will experience more improvement in depression symptoms than patients receiving care from the enhanced usual care clinics (2 point difference-of-difference in EPDS)*To answer the specific hypothesis included in this difference-in-differences analysis aim we used unadjusted repeated measures linear regression models with the EPDS score as the dependent variable and the group (PRISM/MCPAP for Moms) and two time periods as the independent variables along with the interaction term of group by time period. The estimates of the difference in time points between groups was reported along with 95% confidence intervals (CI), p-values and the sample size (n).

Data analysis Hypothesis 2. *Depressed perinatal patients receiving care from clinics enrolled in PRISM will have improved treatment initiation and sustainment (as measured by attendance and one initial mental health assessment or treatment visit and an average ≥1 mental health visit every 1 months until remission of symptoms or study assessment) as compared to women receiving care from clinics enrolled in enhanced usual care.* Our primary outcome in this hypothesis was treatment initiation and sustainment, which was operationalized as receipt of prescription by an obstetrician, attendance in mental health visit(s), and adherence to medication, all of which were represented as dichotomous variables. Specifically, we used logistic regression to calculate odds ratios, corresponding confidence intervals and p-values to determine the impact of treatment group (PRISM/MCPAP) on treatment initiation and sustainment. These models were run both unadjusted and accounting for clustering of practices within treatment groups using Mixed Model analysis with clinic as a random effect.

Sub-hypothesis. *Depressed women receiving care from the enhanced usual care clinics will experience a small amount of improvement in depression and treatment participation at 12 months postpartum as compared to during pregnancy or immediately postpartum.* We anticipated that the enhanced usual care clinic will also experience improvement in both depression and treatment participation. As such we repeated the analyses outlined in H1 and H2 specifically within each of the treatment arms. In this instance, however, instead of considering a treatment by time interaction we only evaluated the time effect.

Additional analyses. A number of additional analyses are planned that will examine changes in patient level measures, as well as heterogeneity of the treatment effect, and will enable us to better understand how the intervention works and whether it works better for certain subset populations. We will examine the impact of gestational age or length postpartum on EPDS score. Additionally, we will test for both moderation and mediation. Specifically, we expect to conduct subgroup analysis by race/ethnicity, SES, psychiatric co-morbidity, and practice type. To identify potential mediators we will use the classic method of mediation analysis as outlined by Baron and Kenny.[126] Mediation analysis seeks to understand the mechanisms through which the intervention has its effect. Therefore, measure of treatment fidelity and implementation are potential key mediators. To formally test for mediation we will use a technique developed by Karlson, Holm, and Breen,[127-129] which decomposes the association of an independent variable with a given outcome into a direct and indirect (mediated) component in the context of a generalized linear model. This type of analysis will directly inform the dissemination plan by clueing us into which components of this multi-faceted intervention are responsible for substantial portions of observed effectiveness.