Improving the clinical encounter to enhance an Individualized Prematurity Prevention Plan (IP3)
The IMPaCT-IP3 Study

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Purpose of the Study

The study objective is to determine the feasibility and acceptability of a patient-centered, culturally-sensitive intervention addressing barriers to IP3 adherence identified by Non-Hispanic Black women. We hypothesize that the intervention is both feasible (ie. target enollment reached and 95% of all intervention components delivered) and acceptable (over 80% of participants give the intervention top rating in their exit interview).

Background & Significance

Preterm birth (PTB), delivery prior to 37 weeks gestation, is the leading cause of neonatal mortality and morbidity resulting in life-long medical complications such as blindness, chronic lung disease and intellectual disabilities. In 2019, the US PTB rate increased for the fourth consecutive year reaching 10 percent. Additionally, dramatic racial disparities persist such that the PTB rate is 49% higher in non- 1 Hispanic black (NHB) women. Preterm birth (PTB) stems from multiple etiologies including medically indicated PTB and spontaneous PTB. Patients with a history of preterm birth seen in the Duke Prematurity Prevention Program are provided an Individualized Prematurity Prevention Plan (IP3). The IP3 is a targeted care plan that incorporates components tailored to a patient's individual risk factors for preterm birth such as life-style modifications (i.e. weight gain, nutrition recommendation, stress management), supplemental progesterone, serial cervix length screening, cerclage or low dose aspirin.

Adherence is a key component of success of the IP3. Given both the increasing PTB rate and persistent racial disparities, it is imperative to develop patient-oriented, culturally-sensitive interventions that improve the clinical encounter and increase IP3 adherence in NHB women. The current intervention was developed by a group of stakeholders and is grounded in qualitative data from NHB women about barriers and facilitators to supplemental progesterone for preterm birth prevention. The current proposal will test the intervention via a pilot randomized controlled trial comparing our intervention to an active control.

Design & Procedures

Once consented, patients will complete an intake via a red-cap data base. The intake will include confirmation of basic demographics gleaned from the HER (e.g. age, self-described race, obstetrical history) and review of the participant's IP3. We will use redcap to randomize participants to the intervention or an active control.

The intervention arm includes:

1. A narrated powerpoint presentation describing the logistical details and medical rationale for components of the IP3. Participants will view the chapters of the presentation that are relevant to their specific IP3. There are a total of 4 possible chapters (lifestyle modifications, cervix length screening/cerclage, progesterone therapy, low dose aspirin). Each chapter of the presentation is ~ 10 – 15 min in length. Each chapter also includes a 4- 5 questions pre-test and the same questions are delivered as a post-test after the presentation.

2. Print materials including a letter explaining the importance of prenatal care for preterm birth prevention to employers. The letter will be given to the research participant and NOT directly to the employer. She will decided if and when the letter is provided. The letter, as with all aspects of the project, is optional for her to use. We will record which patients say they would like to use it and ask if patients actually used it and found it helpful during the exit interview.

3. Text messages sent week to encourage the patient to continue with their IP3 and provide basic pregnancy information

4. Formal letter of encouragement from provider at 28 weeks gestation

The active control arm includes:

1. A narrated powerpoint with general information about the Duke Prematurity Prevention Program

2. Text messages sent approximately weekly with general pregnancy information (e.g. Tylenol is most often safe in pregnancy)

For the subset of patients that have low dose aspirin or vaginal progesterone as part of their IP3 (whether they are in the control or the intervention arm), they will get an additional weekly text to gauge medication compliance.

Measures:

1. Demographic data – Via EHR review and intake interview we will collect basic demographic data (e.g. e.g. age, self-described race, obstetrical history) and review the participant's IP3

2. IP3 Knowledge: We will assess the participant's knowledge about the medical and logistical details of the components of their IP3. In the intervention group, knowledge will be assessed via a brief pre-test/post-test prior to each chapter of the narrated powerpoint. In the active control group knowledge will be assess via the same questions that correspond to the pretest of the chapters that correspond to their IP3, however the will be a single assessment rather than a pre and post-test.

3. Pregnancy-Specific Anxiety (PSA): The PSA is a validated 13-item tool used to assess anxiety specific to pregnancy this tool has been correlated with preterm birth outcome. We will administer the PSA at intake and 28 weeks.

4. Interpersonal Processes of Care (IPC): The IPC is an 18-question questionnaire that asks participants about their experience with receiving care within a specific clinic (in this case the Duke Perinatal Durham Clinic).

5. Maternal Social Support Scale (MSSS): The MSSS is a six-question scale that quantifies a pregnant women's social support as low, medium or adequate. We will administer the MSSS at intake, 28 weeks gestation and postpartum

6. IP3 Adherence Data: We will gather data on adherence to the IP3 based on both participant report and EHR chart review.

7. Delivery outcomes: We will gather delivery outcome data (e.g. gestational age at delivery, birth weight, NICU admission, length of hospital stay) based on based on patient report and EHR chart review

Selection of Subjects

We will recruit up to 60 pregnant women from the Duke Perinatal Clinics with the following inclusion criteria: self-described non-Hispanic Black race, history of prior preterm delivery (before 37 weeks gestation), current singleton gestation, with an IP3 documented. We will exclude women with anomalous fetuses, age below 18 or are non-English speaking.

The study staff will approach the subject and provide information regarding the study. If the patient is interested in participating, then study staff will obtain informed consent at that time. The patient can take as much time to decide about participation and the study team will come up with a plan with the patient to follow up on a decision to participate. Voluntariness will be emphasized. Patients will also be told that they were identified as being eligible because their medical chart indicated they have a history of a prior preterm birth.

For those patients who choose to 'opt out,' to prevent unwelcome emails, phone calls, or other contacts from those other than a patient's clinician, researchers/study teams must check the opt out status for each patient who may be eligible for their study and exclude those not wishing to be contacted.

Data Analysis & Statistical Considerations

The proposed study is a feasibility and acceptability pilot study. We will measure:

Feasibility by:
-target enollment reached
-95% of all intervention components delivered

Acceptability will be measured by an exit interview which includes:
-quantative assessment of the adherence to intervention components
-qualitative feedback about how the intervention should be changed
-participants overall rating of the intervention over 80% of participants give the intervention top rating in their exit interview.