Official Title: EngagINg the COmmunity to Reduce Preterm Birth Via Adherence To an Individualized Prematurity Prevention Plan (INCORPorATe IP3)

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EngagINg the COmmunity to Reduce Preterm Birth via Adherence To an Individualized Prematurity Prevention Plan (INCORPorATe IP3): A feasibility study protocol

Introduction:

Non-Hispanic black women are 49% more likely to experience a preterm birth (PTB), delivery before 37 weeks. PTB is associated with increased risk of poor short and long-term neonatal outcomes. PTB can occur in multiple clinical scenarios including spontaneous PTB (e.g. preterm labor, preterm pre-labor rupture of membranes) and medically induced preterm labor (e.g. preeclampsia). Women with a history of PTB are at 1.5 – 2 fold increased risk for future PTB. There are medical therapies than can reduce the risk of recurrent PTB specific to the presumed etiology of the prior PTB. Thus, women with a history of a prior PTB who receive care with Duke Maternal Fetal Medicine (MFM) receive and Individualized Prematurity Prevention Plan (IP3) to reduce their risk of recurrent PTB. The IP3 plans are often labor intensive with requirements ranging from daily medications, weekly clinic visits, painful injections or invasive ultrasounds.

Given the increased rate so of PTB among NHB women and some suggestion of decreased adherence in this population[1], we previously conducted qualitative studies with NHB women to uncover patient perceived barriers to IP3 adherence[2,3]. These studies revealed that NHB women with prior preterm birth felt that stress and lack of support were key barriers to preterm birth prevention adherence. Stress and limited support made women feel isolated from their peers and community. Based on these data we worked with a stakeholder group to develop a patient-centered, community-involved intervention that will increased adherence to an individualized prematurity prevention plan using community-level social supports. The resulting invention titled, EngagINg the COmmunity to Reduce Preterm Birth via Adherence To an Individualized Prematurity Prevention Plan (INCORPorATe IP3) includes community doula led group social support.

The primary objective of this protocol is to determine if INCORPorATe IP3 is feasible prior to a larger trial focused on determining efficacy. Feasibility will be measured using the RE-AIM framework[4]: *Reach or Participation (Primary Outcome):* (a) percent of eligible participants who are successfully recruited and attend at least one group session; *Effectiveness:* retention rate in the intervention; *Implementation:* fidelity to the intervention protocol; *Maintenance:* intervention sustainability based on continued engagement from the participants.

Methods:

Recruitment:

We plan to pilot our intervention with three groups of 5 – 20 women (total up to 60 women). We plan to enroll women who are currently pregnant up to 20 weeks of gestation, who self-identify as non-Hispanic black with a history of prior preterm delivery (before 37 weeks gestation) due to idiopathic preterm labor, preterm pre-labor rupture of membranes, cervical insufficiency or preeclampsia. Further we will include women who are receiving care with the Duke Perinatal Clinics and plan to deliver within

the Duke Health System. We will exclude non-English speaking women, multiple gestation and women with current or prior pregnancy with major fetal anomaly. We will identify participants meeting the eligibility criteria via review of potential participant's electronic medical record. Eligible participants will be approached for enrollment.

Intervention Delivery:

Given limitations of in-person gatherings in light of the COVID 19 pandemic, we developed the intervention to be delivered via virtual platforms. The study protocol will be an adjunct rather than a replacement of traditional prenatal care with Duke Perinatal. The core components of the intervention will be interaction with community doulas and other NHB with prior PTB via facebook group page and group meetings.

After being consented, participants will be given a link to join the private Facebook group. Prior to gaining entry into the private page, participants will be presented with a set of guidelines for appropriate Facebook page usage and must electronically acknowledge receipt and understanding of these guidelines. The Facebook group will include a chat function where group members can respond to questions posed by the doulas and other group members. Participants will be encouraged to interact with one another and ask questions using the chat function on the group page. We also developed a set of discussion prompts to inspire communication and continued community building in between group meetings.

We also plan for eight two-hour long meetings each of which include a pregnancy-related topic and a reflection topic (table 2). The curriculum for the group meetings was designed to address topics salient to the target population while leveraging existing expertise among the community doulas. Group meetings will occur via private zoom meeting link.

Evaluation and Adaptation:

We will solicit feedback from both participants and the doulas throughout the pilot intervention delivery. We will make adaptations to intervention based on the feedback.

Facebook Group

We will solicit feedback from the participants and the community doulas throughout the pilot intervention with the plan to adapt the intervention based on their feedback. Participant feedback on the Facebook group will be derived from engagement metrics that are collected by Facebook. We will assess engagement formally on a monthly basis.

Group Social Support Meetings

We will survey the participants about their satisfaction following each of the eight group meetings. Surveys will be distributed via text messages (Twilio) or email based on the participants preferences. The post-meeting surveys will be brief (approximately 8 questions, see appendix 1) and

focused on participant satisfaction with the length of the meeting and the meeting content. We will also solicit desired topics for future meetings. The study team will compile the survey feedback such that the feedback will remain anonymous.

Outcome Measures:

We will collect basic demographic and pregnancy information based on chart review. Baseline demographics will include age, medical comorbidities, and pregnancy history. During the intervention, we will monitor intervention engagement based on Facebook page engagement, attendance to group meetings and completion of surveys/measures. We will also collect measures of IP3 knowledge, perceived social support, pregnancy specific anxiety and maternal social support using validated scales at three timepoints: intake, after meeting #4, and after the final meeting (#8).

- **IP3 knowledge questionnaire** includes approximately four questions aimed to evaluate a participants knowledge about the details of their IP3 plan. Participants will only receive questions that pertain to their specific IP3. They will be given the answers immediately following the assessment
- **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.
- **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).
- **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.
- IP3 Adherence Data: We will gather data on adherence to the IP3 based on both participant report and EHR chart review.

We will review the medical record to determine adherence to the IP3 plan and record delivery outcomes (e.g. gestational age at delivery, delivery route, length of hospital stay, etc.)

Selection of Subjects List inclusion/exclusion criteria and how subjects will be identified:

We will recruit 60 pregnant women from the Duke Perinatal Clinics with the following inclusion criteria: self describe race NHB, history of prior singleton preterm delivery (before 37 weeks gestation, current singleton gestation, with IP3 plan. 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 spontaneous 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.

Subject Recruitment and Compensation Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

We will screen clinic schedules and approach women meeting the eligibility criteria during a clinic visit. Consenting participants will be compensated $20 at intake and $20 after completion of the exit interview.

There will be three meetings in total.
$20 for each participant for coming to the meeting and then a raffle of $200 (which one person will win). This will happen at all three meetings.

Then there is another 'spot prize' of $200 which will be raffled for all those that attended the interview – again 1 winner.

Appendix 1. Sample Post-Meeting Participant Feedback Questions:

1. How satisfied were you about today's group session? -Very satisfied -Somewhat satisfied -Not satisfied

2. Thinking about the amount of time you spent in the group today, do you feel that:

-You would have preferred more time with the group

-You would have preferred less time with the group

-The amount of time with the group was just right

3. How comfortable were you with the group today? -Very comfortable -Somewhat comfortable -Not comfortable

4. How well did the zoom platform function for the group today? – Very well –Ok – Poorly

5. Which topics were most helpful: (radio button and free text)

6. Which topics were least helpful: (radio button and free text)

7. Are there any specific topics you'd like to cover in our next session? Free response

8. Anything you'd like different? Free response:

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2. Wheeler SM, Massengale KEC, Adewumi K, et al. Pregnancy vs. paycheck: a qualitative study of patient's experience with employment during pregnancy at high risk for preterm birth. BMC Pregnancy Childbirth 2020;20:565.
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4. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999;89:1322-7.