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EngagINg the COmmunity to Reduce Preterm birth via Adherence to an Individualized Prematurity Prevention Plan (INCORPorATe IP3): intervention development and future pilot study design

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Abstract

Objective: Non-Flispanic Black birthing individuals are at increased risk of preterm birth compared to other racial and ethnic groups. In our clinical setting, we offer a tailored package of recommendations to reduce the risk of preterm birth known as an individualized prematurity prevention plan (IP3). Patient-centered, community engaged interventions that address patient-perceived barriers to preterm birth prevention are urgently needed.

Materials and methods: We engaged a group of stakeholders to develop a mutli-level (patient-centered and community-involved) intervention that will increase adherence to an individualized prematurity prevention plan (IP3) by addressing barriers identified during our prior qualitative studies.

Results: The intervention includes trained doulas from a community-led, Black owned doula group. The doulas will moderate group prenatal social support sessions. In between the group sessions, participants will be encouraged to continue interacting with one another and the doulas

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using a private Facebook™ group page. We will pilot test the intervention in a cohort of pregnant, self-identified non-Flispanic Black patients with a history of prior preterm birth.

Conclusion: We present a novel, patient-centered, community engaged intervention to reduce preterm birth in high-risk non-Flispanic Black birthing individuals. If the intervention is feasible based on the pilot study findings, we anticipate conducting an appropriately powered study to determine whether the intervention achieves our goal of reducing preterm birth.

Keywords

Disparity; preterm birth; intervention; doula; group prenatal care

Introduction

In 2020, the preterm birth (PTB) rate rose for the fourth consecutive year [1]. More than 3900 infants die annually in the US due to PTB, defined as delivery prior to 37 weeks gestation [2,3]. Infants who survive PTB are at increased risk for life-long medical morbidity, including physical and developmental delays. The collective impact of PTB leads to more than 26 million dollars in healthcare spending annually [4]. There are dramatic and persistent race disparities in PTB across the US, and non-Hispanic Blacks (NHBs) are 49% more likely to experience PTB than other racial and ethnic groups [5]. In North Carolina, 10.7% of all births are preterm compared to 13.7% of non-Hispanic Black births.

The risk of PTB is twice as high for a pregnant person with a history of prior PTB [6]. History of a prior PTB is one of the most important factors used to risk-stratify patients and often dictates the care plan for future pregnancies. It is standard obstetrical practice to evaluate a patient's history of PTB and present patients with evidence-based recommendations to reduce their risk. These recommendations may include behavior modifications, such as tobacco cessation, close clinical surveillance with serial cervix length ultrasounds, or medical therapies, such as low dose aspirin for preeclampsia prevention. In our clinical setting, we refer to this tailored package of recommendations as an individualized prematurity prevention plan (IP3). Implementation of IP3 plans is often labor-intensive and may require daily medication adherence, painful weekly injections, intrusive vaginal ultrasounds, or a surgical procedure. Despite these challenges, adherence to an IP3 may reduce the risk of recurrent PTB [7].

In addition to an increased risk of PTB, NHBs are also at increased risk for non-adherence to the guideline consistent care outlined in thelP3 [8,9]. For example, although the data are mixed, supplemental progesterone has been shown to reduce the risk of recurrent PTB by up to 33% and is supported the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal Fetal Medicine (SMFM) [7]. NHBs eligible for supplemental progesterone tend to start therapy later and discontinue earlier [9,10]. In our clinical setting, NHB eligible with prior preterm birth were at increased risk of presenting beyond the window to initiate supplemental progesterone [11].

To uncover barriers that impede uptake of and adherence to PTB prevention, we conducted several qualitative studies with pregnant or recently delivered NHBs with prior PTB [12,13].

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NHBs highlighted stress and lack of community support as key barriers to adherence. Several NHBs also commented that they had never met another person who had delivered preterm and identified isolation from the community as a barrier to PTB preventions. Given the obstacles to adherence, increasing PTB rate, and persistent disparity, interventions designed to support NHBs and promote adherence to their IP3 plans are imperative.

Materials and methods

We convened a multi-disciplinary group of stakeholders, including clinicians, social workers, and community leaders to operationalize the qualitative findings into a deliverable pilot intervention. The intervention is multi-level, as it addresses several patient-perceived barriers to adherence (e.g. stress and lack of support) and community-involved, as it draws on expertise from community organizations to deliver the intervention. The core elements of the intervention are community doula care and social support through group meetings of pregnant NHBs with prior PTB. We plan to pilot test the intervention and gather quantitative and qualitative indicators of feasibility, acceptability, and preliminary efficacy. There are limited examples in the literature detailing operationalization of qualitative findings into a culturally relevant deliverable intervention for PTB prevention. Therefore, the current manuscript details the process we used to operationalize qualitative findings into an intervention and our planned outcome measures for the future pilot study. Our methodological considerations for evaluating an intervention delivered during pregnancy can be generalized to other studies. We plan to refine the intervention based on pilot study findings and ultimately conduct an appropriately powered, multi-center study to determine if the intervention achieves our goal of improved adherence to PTB prevention strategies, thus reducing the burden of PTB among NHBs.

Results

Our conceptual model

We used an intervention mapping process with a group of stakeholders including representatives from the Duke University High Risk Obstetrical clinic team and community-led organizations that focus on maternal and child health (Table 1). We first reviewed data from our previously conducted qualitative studies to identify barriers to PTB preventive care [12,13]. In these qualitative studies, non-Hispanic Blacks with prior PTB identified stress, inconsistent clinical instructions, and lack of social support as key barriers to PTB prevention adherence. Next, we conducted a literature review on interventions that may target these barriers. We found evidence that group prenatal care and doula support reduce PTB in low-risk women, likely via stress reduction and improved social support [14–18]. The stakeholders have expertise in both group prenatal care and doula care. We next identified the intended clinical impacts of the intervention (i.e. the mechanisms by which a reduction of barriers would lead to increased adherence to the IP3 plan) such as decreased psychosocial stress, increased social support, improved care experience, and increased knowledge of the IP3 plan.

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The intervention protocol

After we developed our conceptual model, the stakeholders reviewed published protocols for delivering doula and group prenatal care. Group prenatal care often replaces traditional one-on-one provider visits, for low risk pregnancy. There is also some literature on group prenatal care is in the setting of specific high-risk conditions such as diabetes and HIV, however there are limited data on high-risk pregnancy due to prior preterm birth [19,20]. In the setting of high-risk pregnancy, in which patients have complex IP3 plans tailored to their specific histories, we decided that individual maternal fetal medicine (MFM) prenatal care visits were still necessary. We modified existing group prenatal care delivery models as an adjunct rather than a replacement of traditional prenatal care visits. Two trained doulas will moderate the group sessions.

Doulas are trained birth support professionals with expertise in providing intensive informational and emotional support. Although doulas classically provide in-person support during pregnancy, labor and postpartum, due to COVID-19 restrictions, we planned to incorporate doula support during the group sessions. The goal of the doula-led group sessions will be to increase social support and decrease psychosocial stress. The stakeholders reviewed published curricula from previously described group prenatal care models to develop the curriculum for the group social support meetings. The curriculum is designed to address topics salient to the target population and leverage existing expertise among the community doulas. We plan for eight 2-h long meetings, each of which include a medical topic and a reflection topic (Table 2). The medical topics such as preterm birth risk factors and symptoms of labor are incorporated into the sessions to increase knowledge about the IP3 plans. The reflection topics are designed to (1) impart resilience skills to decrease psychosocial stress, (2) use the group dynamic to increase social support, and (3) enhance self-advocacy skills to improve the perceived care experience. Examples of reflection topics include describing their hopes and goals for pregnancy, relaxation techniques and self-advocacy skills. Although medical providers will not be present for the group session, the primary investigator (PI) is a board-certified maternal fetal medicine specialist and director of the Duke Prematurity Prevention Program. The PI will be available to the doulas and participants if there medical concerns requiring urgent attention.

We also reviewed literature detailing various models of doula care delivery, including evidence suggesting racial concordance is associated with an improved birth experience for NHB women [21]. Thus, we are implementing doula services in collaboration with a Black-owned and operated community doula organization. Several of the doulas have personally experienced PTB or have prior experience supporting patients with such history.

The intervention delivery strategy

We focused on developing a strategy to deliver an intervention without in-person gatherings due to the COVID-19 pandemic. Based on the expertise from the community partners in the stakeholder group, we will use Facebook™ as the primary platform to facilitate group interaction. We developed a private Facebook™ group that includes the community doulas and participants. Participants will be encouraged to interact with one another and ask questions using the forum function on the group page. We have developed a set of discussion

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prompts to inspire communication on the page and continued community building prior to the planned virtual group meetings.

Future pilot study

Target population, recruitment, and enrollment

We will pilot test the intervention in a cohort of pregnant NHBs because the intervention was developed based on qualitative findings from people who self-identify as NHB. Additionally, there are notable disparities in preterm birth rates, and NHB are 49% more likely than patients of other all races and ethnicities to experience PTB. Our target participants are currently pregnant, self-identify as NHB, and have a history of prior preterm delivery. The prior preterm delivery could be due to idiopathic preterm labor, preterm pre-labor rupture of membranes, or preeclampsia. We will exclude pregnancy beyond 20weeks because many preterm birth preventions are initiated by that gestational age. We will also exclude multiple gestation given the lack of evidence-based preterm birth preventions in the setting of multiple gestation. These clinical characteristics are readily available upon review of the electronic medical record (EMR). Our perinatal research staff have training and experience gleaning pregnancy data from the EMR.

We will identify potential participants meeting the eligibility criteria by reviewing EMR at a large medical system located in the southeast. Participants meeting the inclusion and exclusion criteria will be approached for enrollment remotely via telephone. Individuals who agree to participate will be provided a link to an on-line Redcap™ database to complete the informed consent. We plan to recruit 30 NHBs to participate. Based on recruitment for prior studies, we anticipate recruiting five participatnts meeting the inclusion criteria every month, and the intervention delivery will be initiated between 16 and 20 weeks of pregnancy and continue until 2 months postpartum (8 months total) (Figure 1).

Data collection

At initial enrollment, we will collect basic demographics and obstetrical and medical history based on chart review. We will collect baseline assessments of psychosocial stress, social support, perceived care experience, and knowledge about the IP3. We will re-assess at the mid-intervention (after the fourth group meeting) and after the intervention protocol is completed (Figure 1).

Psychosocial stress will be measured using the Pregnancy-Specific Anxiety (PSA) scale. The PSA is a validated instrument that asks pregnant persons to rate how often they have felt specific emotions within the past week on a Likert scale from 1 (never) to 5 (always) [22]. Although a measure of anxiety, we chose this instrument to evaluate psychosocial stress because the questions within the instrument focus on many of the emotions highlighted in the qualitative studies. Social support will be measured using the Maternal Social Support Scale (MSSS), a questionnaire designed as a simple screening tool for perceived social support in pregnancy [23]. We will use the Interpersonal Processes of Care (IPC) survey to assess each patient’s perceived care experience. The IPC is a validated instrument designed

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to evaluate patient perceptions of interactions with medical providers across diverse racial and ethnic groups [24].

The IP3 knowledge questionnaire includes four to five questions about each potential component of the IP3 (Supplementary Appendix). The questions were developed and pilot tested as part of a previous intervention. Each participant is asked only questions about their unique IP3; for example, a participant with an IP3 plan that recommends low dose aspirin and serial cervix lengths will only be asked questions about those therapies. There are four potential IP3 components; therefore, the complete IP3 knowledge questionnaire can include up to 16 questions.

Feasibility outcomes

The primary objective of the pilot study will be to determine if the INCORPorATe IP3 is feasible, prior to a larger trial focused on determining efficacy. Feasibility will be evaluated using the RE-AIM framework [25], which assesses the reach, effectiveness, adoption, implementation, and maintenance of an intervention (Table 3). *Reach* focuses on whether an intervention program reaches the target population. During the pilot study, we will measure *reach* by evaluating recruitment and retention metrics. Based on prior studies recruiting a similar patient population, our benchmarks are 30% of eligible participants successfully enrolled and 80% retention [12,13]. *Effectiveness* will be measured by patient satisfaction and adherence to the prescribed IP3. We will measure patient satisfaction based on a brief questionnaire that will be distributed following each group meeting (Supplementary Appendix file A). Adherence to the IP3 will be determined based on EMR review (serial cervix lengths and cerclage) and a modified simple medication adherence questionnaire (17-hydroxyprogesterone caproate and low dose aspirin, Supplementary Appendix file B). *Adoption,* focused on the use and uptake of the intervention, will be assessed via qualitative exit interviews with the participants and doulas. The exit interview discussion guide allows the women to evaluate how the intervention impacted their experience with pregnancy care. We will adapt the Facebook™ group discussion prompt and group meeting curriculum based on participant and doula feedback, and we will iteratively adapt the intervention during the pilot to maximize future adoption. Any changes to the intervention will be carefully documented. Participant feedback on the Facebook™ group will also be derived from engagement metrics that are collected by Facebook™. Each month, we will formally assess engagement. If low engagement is noted (defined as less than 25% of participants actively engaging based on Facebook™ metrics), we will survey participants about their feedback on the content to modify the content. If high engagement (25% or above) is noted, no further feedback will be solicited, and we will allow the content to continue to develop organically.

Implementation will be evaluated based on fidelity to the intervention protocols. *Maintenance* will be evaluated based on health care utilization, including triage and unscheduled clinic visits. Savings from reductions in unscheduled evaluations may render the intervention cost-neutral or potentially cost-saving.

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Group social support meetings

We will survey 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 postmeeting surveys will be brief (approximately 10 questions) and focused on participant satisfaction with the length of the meeting and the meeting content, and participants will be asked about desired topics for future meetings. The study team will compile the survey feedback such that the feedback will remain anonymous.

We will solicit feedback from the doulas delivering the intervention about the group meetings via planned debriefs following the first, second, fourth, sixth, and eighth sessions. The study investigators and doulas will troubleshoot problems, review the aggregated surveys, and modify the curriculum for future group meetings.

Summative feedback

To gather summative feedback about the intervention from participants, we will send a brief survey and conduct up to hour-long qualitative in-depth individual interviews (IDIs). Participants will be asked about their interactions with other participants, the doulas, and the impact of the intervention of their pregnancy experience. We will also solicit feedback on ways to optimize the intervention. A trained qualitative interviewer who is not part of the research study team will conduct the exit IDIs. All participants will be interviewed at the conclusion of the study protocol. At the end of their participation in the study, the doulas will be asked to give feedback about their experiences providing remote doula support, leading the group sessions, interactions with participants and asked for suggestions to optimize the intervention.

Conclusion

Each month, more than 33,000 babies in the US are born preterm, which increases the risk for life-long medical comorbidities. The NHB community bears a disproportionate burden of preterm birth and its potentially devastating impacts. If the INCORPorATe IP3 intervention is feasible based on the pilot study findings, we anticipate conducting an appropriately powered study to determine whether the intervention achieves our goal of reducing preterm birth in NHBs. While the INCORPorATe intervention will be delivered during pregnancy, we also plan to perform future studies in partnership with our multi-disciplinary stakeholder group that will focus on reducing preterm birth among NHB patients across the life-course including preconception and postpartum.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data availability statement

N/A, no datasets associated with the current manuscript.

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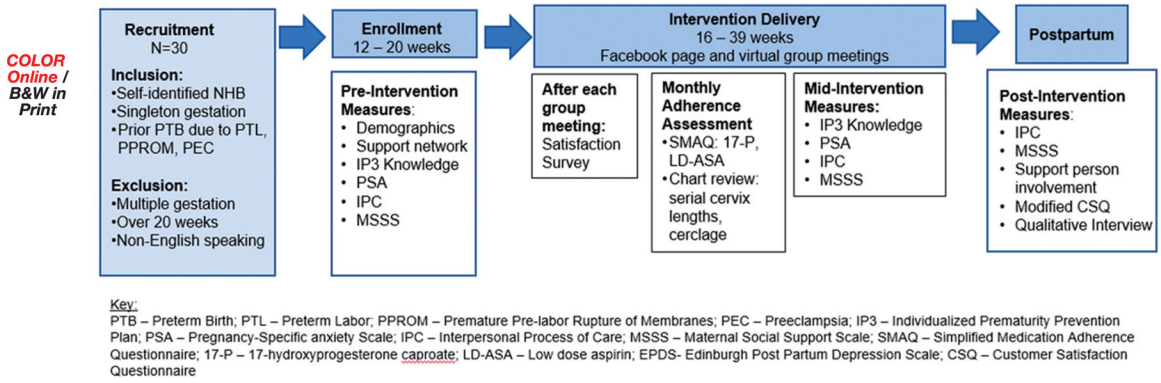

Figure 1.
INCORPorATe IP3 intervention and outcome measures.

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Table 1.

Intervention Design Stakeholders.

Stakeholder	Experience/perspective
Duke University High Risk Obstetrical Team	
Duke Prematurity Prevention Program	Clinical program with Duke High Risk OB clinic designed to reduce preterm birth by providing multidisciplinary care to patients with high risk for preterm birth
Duke Perinatal Clinical Social Work	Licensed clinical social workers who provide resources for patients
Community-led organization partners	
Mobilizing African American Mothers through Empowerment (MAAME)	Black-owned local volunteer organization of Doulas
Durham Volunteer Doulas	Provides free doulas throughout the local community and partners with the health department to provide group prenatal care
Diaper Bank of North Carolina	Increases access to diapers and other hygiene products throughout the local community and state
North Carolina Pregnancy Care Managers	State-funded program that provides care coordination and home visits for pregnant Medicaid patients

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Table 2.

INCORPorATE group prenatal social support curriculum.

Session	Facebook post topic	Medical topic(s)	Reflection topic(s)
#1. 16–20 weeks	Share your preterm birth story.	Individualized Prematurity Prevention Plan: Discuss components of IP3/ rationale	• Rapport building and group “rules” • Hopes for this pregnancy • How IP3 fits in with hopes/goals
#2. 20–24 weeks	What does support look like to you?	Changing Baby – Changing You • Definition of pre-viable, periviable, preterm, term and full term • Risk factors for PTB	• Anxieties/concerns about pregnancy • Relaxation techniques • Community resources
#3. 24–28 weeks	Who’s in your village?	TEAMING UP Together • SUPPORT PERSON MEETING	• Tools to support the participant during pregnancy, delivery and after
#4. 28–32 weeks	Tell us about a time that you felt powerful.	Preterm Labor – warning signs/symptoms • Review signs/sx of PTL/PTB, Share prior stories of PTL/PTL	• Self-Advocacy Skills • Discrimination and disrespectful care
#5. 32–36 weeks	Envisioning your ideal birth.	The labor process • Induction • C-section • Postpartum healing	• Pain management techniques • Avoiding lacerations
#6. 36–37 weeks	Share breast or bottle feeding stories.	Pregnancy progression • Review 3rd tri labs • Fetal kick counts	Tips for trouble shooting breast feeding
#7. 37–39 weeks	What are your hopes/dreams for you and your family?	Late pregnancy warning signs • Signs and symptoms of preeclampsia • Signs and symptoms of labor	• Post pregnancy back to work • Safe pregnancy spacing • Birth control and sterilization options
#8. PP	Baby pictures and birth stories	Reunion – • Introduce babies • Share stories	Qualitative data collection on intervention

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Table 3.

Intervention Evaluation Framework.

RE-AIM dimension:	Indicator(s):	Planned data collection:
REACH: Is the intervention program reaching the target population?	Recruitment	• Number of potential participants meeting inclusion criteria • Number of potential participants approached for enrollment • Number of potential participants recruited
	Retention	• Engagement on Facebook™ page • Participant virtual meeting attendance • Survey/measurement completion
Effectiveness: Did the intervention program accomplish the proposed goals?	Patient Satisfaction	• Post meeting satisfaction survey following every virtual group meeting • Modified customer service questionnaire at the end of the protocol • Formal qualitative exit interview
	Preliminary Impact	Adherence to IP3 plan: • Low Dose Aspirin: SMAQ • 17-OHPC: SMAQ • Cerclage: chart review for operative note • Serial cervix lengths: chart review for ultrasound reports
Adoption: How did the adoption vary across the groups?	Fidelity	• Observer to attend each virtual group meeting and record topic discussed
Implementation How do we adapt to make sure the intervention fits and is feasible?	Adaptation	• Review of observer, participant and doula post-meeting surveys after each meeting • Curriculum adaptation based on surveys
Maintenance When will the intervention program become operational? How will it continue overtime?	Health care utilization	Compare intervention participants and other Duke Prematurity Prevention Patients: • Number of triage visits • Unscheduled provider add-on visits

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