

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

NCT: NCT04933812

IRB Document Date: 01/17/2023

Previous studies have shown preterm births (PTB) are high in non-Hispanic Black (NHB) women and women are more likely to have a PTB if they previously had one. Pregnant women with history of PTB at Duke Maternal Fetal Medicine receive IP3 plans to reduce the risk of recurrent PTB and these interventions are often stressful. The EnagagINg the Community to Reduce Preterm Birth via Adherence To an Individualized Prematuritiy Prevention Plan (INCORPorATe IP3) was developed to provide support for NHB women who had prior PTB. This intervention included information provided through Facebook group discussions with doulas and Zoom group meetings to review a variety of pregnancy-related topics.

Participants received questionnaires to complete at intake, between 20-28 weeks GA, and after 30 weeks GA in addition to group satisfaction surveys after each Zoom meeting. Results from the questionnaires and surveys will be reported as counts (percentages) for categorical variables and mean (SD), median (IQR), and range for continuous variables.

<b>Table 1. Participant Characteristics</b>	
Characteristic	
Age (mean, SD)	
Number of Prior Preterm Births (median, IQR)	
Insurance Status	
Public	
Private	
None	
Body mass index at prenatal care intake (mean, SD)	
Chronic hypertension	
Pre-gestational Diabetes	
Tobacco use at any time in pregnancy	
Preterm Birth Preventative Recommendations (i.e., IP3 plan)	
Lifestyle modifications (n, %)	
Cervix length/Cerclage (n, %)	
Progesterone (n, %)	
Low Dose Aspirin (n, %)	
All data are reported as n (%) unless detailed otherwise	

<b>Table 2. Feasibility and Acceptability Measures</b>	
Recruitment: #Eligible people approach/ # recruited	
Facebook Engagement: Number of participants who logged onto the Facebook page Number of participants who posted/reposted anything Facebook engagement metrics	
Group Social Support (GSS) Session Engagement: Median number of GSS visits attended [IQR] Number (%) of participants who attending 5 or more sessions	

**Table 3. Group Social Support Sessions**

Session #	Topics Covered	# Attended/# Enrolled at session timepoint	Post-meeting survey % very satisfied % somewhat satisfied %non satisfied	No-Show Survey Results
#1				
Date				
#2				
Date				
#3				
Date				
#4				
Date				
#5				
Date				
#6				
Date				

**Table 4. Other Feasibility and Acceptability Measures**

Recruitment: #eligible people approach/ # recruited	
Retention: # participants who completed all survey measures Avg # survey measures completed/participant	
Facebook Engagement: Number of participants who logged onto the Facebook page Number of participants who posted/reposted anything Facebook engagement metrics	
Healthcare Utilization	

<b>Table 5. Adherence and Pregnancy Outcomes</b>	
<b>Preterm Birth Preventative Recommendation Adherence (adhered/recommended, percent)</b>	
<b>Lifestyle Modifications</b>	
IOM weight gain guidelines	
Tobacco cessation	
<b>Supplemental Progesterone</b>	
17-P	
Vaginal progesterone	
<b>Cerclage/Serial Cervix Length</b>	
Cerclage	
Serial cervix lengths	
<b>Low Dose Aspirin</b>	
<b>Pregnancy Outcomes (n, %)</b>	
<b>Preterm Birth/Gestational Age Outcomes:</b>	
Preterm delivery <37 weeks	
Gestational age at delivery in weeks, mean (SD)	
Length of gestation in current pregnancy compared to earliest preterm birth, mean (SD)	
<b>Maternal Outcomes:</b>	
Preeclampsia/gestational hypertension	
Number of antepartum triage evaluations, median (IQR)	
Antepartum hospital admission	
Length of delivery admission in days, median (IQR)	
<b>Neonatal Outcomes:</b>	
Birth weight in grams, mean (SD)	
Neonatal Intensive care unit admission	

<b>Table 6. Secondary Quantitative Measure (mean, SD)</b>	<b>Intake N= 32</b>	<b>Protocol Completion N=</b>	<b>Change</b>
<b>Interpersonal Process of Care (IPC-18) at protocol completion</b>			
Description: Validated 18-question instrument that measures patient care experience during clinical visits in four domains. Scores for each domain range from 1 to 5 on a Likert scale			
<b>Communication Domain</b>			
Lack of clarity (higher scores are negative, denote increased lack of clarity from clinicians)			
Elicits concern (higher scores are positive, denotes the clinician elicited concerns more often)			
Explain results (higher scores are positive, denotes the clinician explained results more often)			
<b>Decision Making Domain</b>			
Decision Making (higher scores are positive, denoting more collaborative decision making between the clinician and patient)			
<b>Interpersonal Style Domain</b>			
Emotional support (higher scores are positive, denoting more emotional support from the clinician)			
Discrimination due to race/ethnicity (higher scores are negative, denote increased discrimination from clinicians)			
Disrespectful to office staff (higher scores are negative, denote increased disrespectful behavior from clinicians towards office staff)			
<b>Maternal Social Support Scale (MSSS)</b>			
Description: Six question questionnaire answered from 1 to 5 on a Likert scale, higher scores are positive and denote increased support			
MSS at intake			
MSS at protocol completion			
<b>Pregnancy Specific Anxiety (PSA) at 28 weeks</b>			
Description: Frequency of four emotions rated from 1 to 5 on a Likert scale, higher scores are negative and denote increased anxiety			
PSA at intake			
PSA at 3 <sup>rd</sup> trimester			