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Very Preterm Birth is Reduced in Women Receiving an Integrated Behavioral Intervention:  
A Randomized Controlled Trial

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\*RTI International is a trade name of Research Triangle Institute.

## **Abstract**

*Background* This study examines whether an integrated behavioral intervention with proven efficacy in reducing psycho-behavioral risks (smoking, environmental tobacco smoke exposure (ETSE), depression, and intimate partner violence (IPV)) in African-Americans is associated with improved pregnancy outcomes

*Methods* A randomized controlled trial targeting risks during pregnancy was conducted in the District of Columbia. African-American women were recruited if reporting at least one of the risks mentioned above. Randomization to intervention or usual care was site and risk specific. Sociodemographic, health risk and pregnancy outcome data were collected. Data on 819 women, and their singleton live born infants were analyzed using an intent-to-treat approach. Bivariate analyses preceded a reduced logistical model approach to elucidate the effect of the intervention on the reduction of prematurity and low birth weight.

*Results* The incidence of low birthweight LBW was 12% and very low birthweight VLBW was 1.6%. Multivariate logistic regression results showed that depression was associated with LBW (OR=1.71, 95%CI=1.12-2.62). IPV was associated with PTB and VPTB (OR 1.64, 95%CI=1.07-2.51, OR=2.94, 95%CI=1.40-6.16, respectively). The occurrence of VPTB was significantly reduced in the intervention compared to the usual care group (OR=0.42, 95%CI=0.19-0.93).

*Conclusions* Our study confirms the significant associations between multiple psycho-behavioral risks and poor pregnancy outcomes, including LBW and PTB. Our behavioral intervention with demonstrated efficacy in addressing multiple risk factors simultaneously reduced VPTB within an urban minority population.

**Keywords** African-American, birth weight, pregnancy, gestational age

## **Introduction**

Infant mortality continues to be an important indicator of health disparities in the United States. The relative contribution of preterm and low birth weight to infant mortality is high [1,2], especially in non-Hispanic blacks where it is more than double the rate reported in the overall U.S. population [3,4]. In general, infants at the lowest categories of weight and gestation are at highest risk for death and are the principal contributors to infant mortality [5-7]. Disparities in mortality between African-American and white infants could be partially explained by the higher rates of very low birth weight (<1500 grams) and very premature births ( $\leq$ 33 weeks) amongst African-Americans[8]. In 2005, the rates for very premature infants were 4.17% for non-Hispanic blacks versus 1.64% for non-Hispanic whites. Similarly for very low birth weight, the rates were 3.27% versus 1.21% [8].

While genetic and medical mediators may be associated with such disparities [9,10], there is growing evidence indicating the importance of maternal psycho-behavioral contributors to poor reproductive outcomes among African-Americans[11-13]. Despite such evidence there are few interventional models that have been tested for efficacy in reduction of these frequently co-occurring risks and their potential role in improving pregnancy outcomes. Our recent publications confirm the efficacy of cognitive behavioral interventions during pregnancy and postpartum [14,15] in urban African American women. The risk factors we chose to address (smoking, environmental tobacco smoke exposure (ETSE), depression and intimate partner violence (IPV)) have all been associated with poor pregnancy outcomes [16-19]. Mothers in the intervention group resolved some or all of these risks more frequently than those assigned to usual care[14].

Both the ACOG and AAP recognize the significance of these behavioral and mental health related issues and recommend screening for them during pregnancy [20,21]. Due to the association of such risks with underlying ecological factors, most notably poverty [22], unstable housing [23], transportation [24], the lack of cohesive social support systems [25] and stressful life events [26], it is unclear whether interventions targeting psycho-behavioral risks, identified during pregnancy, can have an impact. Furthermore, the interaction between psycho-behavioral risks and genetic predisposition [9,10] may interfere with potential intervention effects. There are only a few interventions that have demonstrated success in reducing the burden of such psycho-behavioral risks during pregnancy [13,27,28] and none have measured the effect on reproductive outcomes.

This paper addresses the effect of reducing these psycho-behavioral risks (smoking, ETSE, depression and IPV) on reduction of the rates of low and very low birth weight (LBW: <2,500 grams, VLBW: <1,500 grams) and preterm and very preterm births (PTB:<37 weeks gestation, VPTB:  $\leq$  33 weeks gestation). We demonstrated [14] that rates of psycho-behavioral risks are reduced in mothers randomized to a cognitive, behavioral intervention. In this study, we examine whether the intervention was also able to improve rates of LBW, VLBW, PTB, and VPTB within this population of African-American mothers.

## **Materials and Methods**

The “NIH-DC Initiative to Reduce Infant Mortality in Minority Populations” is a congressionally mandated research collaboration between four major academic institutions in Washington, DC (Children's National Medical Center, Georgetown University, George Washington University, and Howard University), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Center for Minority Health and Health Disparities,

and RTI International. As part of this collaboration, a randomized controlled trial was conducted to evaluate the benefits of an integrated behavioral cognitive intervention delivered during routine prenatal care (PNC) in reducing cigarette smoking, ETSE, depression, and IPV during pregnancy and improving pregnancy outcomes. These analyses used data collected from this trial.

Women presenting to six community-based clinical sites serving minority women (African-Americans and Hispanics) in the District of Columbia were screened for recruitment between July, 2001 and October, 2003. Women were deemed demographically eligible if self-identified as belonging to a minority group, being  $\geq 18$  years,  $<29$  weeks of pregnant, a DC resident and English speaking. Verbal pre-screening for other characteristics was discouraged by the study protocol in order to avoid bias. Demographically eligible women were invited and consented to participate in the screening. Participants were screened for the four risk factors using an audio-computer assisted self interview (A-CASI) which also confirmed their pregnancy status and demographic eligibility. See El-Khorazaty et al. for more details on recruitment and retention activities and results [29]. After initial screening confirmed eligibility, mothers were scheduled for a telephone interview. More information on sociodemographics, reproductive history and behavioral risks was collected during a baseline interview, conducted on average at 19 weeks of gestation, nine days after A-CASI screening. Follow-up data collection by telephone interview occurred during the second and third trimesters of pregnancy (22-26 and 34-38 weeks EGA, respectively). Intervention and follow-up activities continued until July 2004.

For purposes of recruitment, gestational age (GA) was based on women's reporting and verified by medical record abstraction. Upon delivery, infant's GA was abstracted from the medical records prioritized in the following order: ultrasound, exam and menstrual history.

Analysis for GA was based on the infants' GA assessment. Following the baseline interview, consent to participate was obtained and women were randomized to the clinical trial.

The sample size was determined to ensure adequate statistical power to test the hypotheses that our cognitive-behavioral intervention would result in reductions in the targeted risks. Assuming a 5% level of significance, 80% power would allow the detection of 10-20% reductions in risk-specific factors among women in the intervention group from a 100% prevalence at recruitment time, a sample of 1,050 women needed to be retained at the end of the follow-up period. This number was estimated to be sufficient to detect a 25% reduction in PTB and LBW combined in the intervention group as compared to that for the usual care (estimated at 20%). Based on a declining birth rate in D.C., the recruitment period was extended four months to reach the required sample size.

A total of 2,913 women were screened and 1,398 met eligibility criteria. There were 1,070 women, who were reached for baseline telephone interview and consented to participate in the randomized trial. This number exceeded the required sample size of 1,050 needed for 80% power and 5% level of significance. These demographically eligible pregnant women reporting one of the four risk factors were randomized to the intervention group (IG) or the usual care group (UCG) after completing the baseline interview. Of the 1,070 women, 1,044 were African-American and still pregnant at the time of the interview. Pregnancy outcomes data were available on 918, 88% of these participants. Mothers with a live birth represented 95% (n=870). Only mothers of a singleton live born with infant medical abstraction data available were included in these analyses (n=819, 94% of mothers with a live birth). This final number represented 89% of all women with a known pregnancy outcome. (See Figure 1.)

The intervention of this RCT was designed for delivery during PNC. The intervention

was evidence-based and specific to the designated psycho-behavioral risks [30]. The intervention for smoking and ETSE was based on Smoking Cessation or Reduction in Program Treatment (SCRIPT). This intervention is based on social cognitive theory [31] and tailored to a woman's stage of readiness for behavioral change [32]. The intervention for depression was based on a cognitive behavioral theory program developed by Miranda and Munoz [33] and proven successful with low income minority women seeking primary care services. The original group therapy model was adapted to an individual treatment format. The intervention focused on secondary prevention of symptoms of depression and emphasized strategies for mood management as well as establishing and maintaining positive social interactions. Sessions emphasized skill development towards revising negative cognitions. A structured intervention developed by Parker and colleagues [34] and based on Dutton's Empowerment Theory [35] which emphasized safety behaviors, was adopted for the IPV intervention. This brochure based intervention provided information about the types of abuse, the cycle of violence, a danger assessment component, in addition to the development of a safety plan. Individualized counseling sessions provided an integrated approach to multiple risks responsive to a woman's specific risk combination. Intervention sessions were conducted privately in a room proximate to the PNC clinics and occurred immediately before or after routine PNC, for an average of  $35\pm 15$  minutes. The intervention was designed to be delivered during PNC visits with eight discrete sessions. The intervention specialists were trained to apply the content of these sessions during one or more visits as needed. In order to avoid influencing the utilization patterns of PNC (an outcome compared between IG and UCG), no effort was made to facilitate or encourage participation in routine PNC in either group. Delivery of the intervention was dependent on the mother's decision to attend a scheduled PNC visit.

Site- and risk-specific block randomization to IG or UCG was conducted. Investigators and field workers were blinded to the block size. A computer generated randomization scheme considered all possible risk combinations within each of the recruitment sites. Recruitment staff at each site called in the details of the risk profile for a new recruit, and the assignment was generated centrally by the data coordinating center.

Validated instruments were used for the A-CASI screening, and the baseline and follow-up telephone assessments of women with respect to risk factors. Telephone interviewers and their supervisors were blinded to the participants' randomization group. At the time of recruitment and upon delivery, maternal and infant medical records were abstracted and infant and pregnancy outcomes were recorded.

To preserve the randomization, participant data were analyzed according to their care group assignment, regardless of whether they received any intervention sessions, using an intent-to-treat approach. Statistical analyses were conducted using SAS version 9.1.3 (SAS Institute Inc., Cary, NC). Bivariate analyses compared women with and without adverse pregnancy outcomes (LBW, VLBW, PTB, and VPTB) with respect to sociodemographic characteristics and psycho-behavioral risks. Similar analyses compared baseline characteristics and outcomes among women assigned to IG vs. UCG. Chi-square tests and t-tests were used for these analyses. Bivariate analyses using exact chi-square tests compared reduction in the number of risk factors at baseline and the last follow up interview prior to delivery for women assigned to IC vs. UCG.

To evaluate the impact of sociodemographic and psycho-behavioral risks on adverse pregnancy outcomes, we used logistic regression to model LBW, VLBW, PTB, and VPTB. Unadjusted analyses were conducted to assess the impact of care group assignment on the four outcomes. Absolute risk reduction, percent reduction in risk and number needed to treat were

calculated. Adjusted logistic regression models controlled for variables including maternal age, care group, depression, IPV and illicit drug use during pregnancy. Variables were selected for inclusion in the logistic regression models if they reached significance in the bivariate analyses, and predictors significant at  $p < 0.05$  were retained in the final models.

## **Results**

For the total sample ( $n=1,044$ ), sociodemographic, psycho-behavioral and reproductive characterization at baseline showed that there were no significant differences between women randomized to the IG ( $n=521$ ) or UCG ( $n=523$ ), except for the number of PNC visits. In addition, there were no significant differences between women with a known infant outcome and those missing this information.

For women included in the analyses presented here ( $n=819$ ), 403 were in the IG and 416 were in the UCG. Sociodemographic, psycho-behavioral and reproductive characterization at baseline are presented in Table 1 and showed no statistically significant differences between women in the two groups. On average participants in the IG received  $4.4 \pm 2.7$  prenatal intervention sessions. 38.5% received 0-3 visits, and 61.5% received 4 visits or more. The mean time of an intervention visit was 35 minutes. Of the 819 women analyzed in this study 13.6% reported no risks during the baseline interview despite their acknowledgment of risk during the A-CASI screening. Almost two-thirds (62.6%) of participants reported 1-2 risks at baseline and 23.8% reported 3-4 risks. There were no differences between the IG and UCG in the distribution of risks ( $p=0.969$ ).

For these 819 women, when comparing risk resolution between the IG and UCG, the smoking quit rate in the IG was 24.3% vs. 20.3% in the UCG ( $p=0.593$ ). ETSE avoidance in the

IG was 33.3% vs. 27.7% in the UCG ( $p=0.165$ ) within the population of women who had reported ETSE at baseline. The recurrence of IPV in the IG was 7.9% vs. 21.6% in the UCG for women who reported IPV in the year preceding pregnancy as reported at the baseline interview ( $p=0.004$ ). For women who were classified as depressed at baseline using the Hopkins scale 32.7% in the IG had resolved their symptoms and 32.5% had resolved their symptoms in the UCG ( $p=0.977$ ).

Since this intervention was designed to address multiple risks simultaneously, an additional analysis was conducted to examine the interventional effect on multiple risks reported by mothers in both groups. Comparisons between IG and UCG showed a significantly greater reduction in risks in the IG compared to UCG. Table 2 reviews the effect of the intervention classified by the number of risks reported at baseline as compared to the number reported during the follow-up interview prior to delivery. There was a group of women who reported no risks at baseline in spite of acknowledging risk(s) at screening. These women may have acknowledged risks during the course of their pregnancy. Among women reporting no risks at baseline, more women in the UCG than the IG reported risks during the last follow-up interview conducted during their pregnancy ( $p=0.04$ ). Women randomized to the IG reported a significant reduction in their risks if they belonged to the group of women reporting 1-2 risks at baseline ( $p=0.021$ ). The intervention did not succeed in significantly reducing risks in women reporting 3-4 risks at baseline ( $p=0.383$ ). Within the group of women reporting 3-4 risks at baseline, only 74.7% of the intervention group vs. 65.9% in the usual care group reported reduction to 0-2 risks at follow-up. When comparing women with 3-4 risks at baseline who did not reduce their risks to 0-2 vs. those who did, they were less likely to be employed (22% vs. 40%,  $p=0.02$ ) and more likely to have used illicit drugs during pregnancy (39% vs. 18%,  $p=0.003$ ). The intervention did not

address illicit drug use, which could have interfered with the efficacy of the intervention on reducing other associated risks. Within this group of women, active smoking was reported at baseline in 78% of those who did not resolve risk versus 35% in those that did ( $p=0.001$ ). The intervention did address active smoking, but was not successful in significantly modifying this behavior [14].

Women were classified based on four adverse pregnancy outcomes: LBW, VLBW, PTB, and VPTB. Table 3 compares the sociodemographic and psycho-behavioral characteristics of mothers delivering infants weighing  $< 2,500$  grams versus  $\geq 2,500$  grams, and mothers delivering infants weighing  $< 1,500$  grams versus  $\geq 1,500$  grams. Illicit drug use, depression and IPV were significantly more frequent in mothers delivering LBW infants. There were no significant differences between mothers delivering infants below 1,500 grams and those delivering infants  $\geq 1,500$  grams. Table 4 presents similar comparisons of mothers delivering infants  $< 37$  weeks gestation versus  $\geq 37$  weeks and those delivering infants  $< 34$  weeks gestation versus  $\geq 34$  weeks. In both comparisons the rates for depression and IPV are significantly higher for mothers delivering infants at a lower GA. An older maternal age is associated with higher rates of PTB.

Table 5 reviews the rates for LBW, VLBW, PTB, and VPTB by intervention group. The table also shows the absolute risk reduction (usual care rate – intervention rate) in these pregnancy outcomes and the number needed to treat (receive the intervention) to prevent one new case of the designated outcomes. The rates for the four outcomes are all higher in the UCG but the difference only reaches significance for VTPB, with 2.2% (9/402) in the IG versus 5.0% (21/416) in the UCG (OR=0.43, 95% CI=0.20-0.95). On average, 36 mothers needed to receive the intervention to prevent one VPTB. For VLBW, the rate is more than double in the UCG (2.2%=9/415) vs. that in IG (1.0%=4/402), but does not reach significance (OR=0.45,

95%CI=0.14-1.48). In addition, 83 mothers, on average, needed to receive the intervention to prevent one VLBW.

In the logistic regression model for LBW (Table 6), depression at baseline was associated with a significantly increased likelihood of delivering an infant <2,500 grams (OR=1.71, 95%CI=1.12–2.62). The logistic regression models for PTB and VPTB are presented in Table 6. IPV documented at baseline is associated with PTB and VPTB (OR=1.64, 95%CI=1.07–2.51, OR=2.94, 95%CI=1.40–6.16, respectively). An older maternal age is associated with an increased rate of PTB (OR=1.06, 95%CI=1.02–1.09). Assignment to the integrated intervention addressing the four psycho-behavioral risk factors was significantly associated with a reduction in VPTB rates (OR=0.42, 95%CI=0.19–0.93).

## **Conclusion**

This study confirms findings of previous investigators showing an association between psycho-behavioral risk and poor pregnancy outcomes, including LBW and PTB. Our results emphasize the importance of testing interventions targeting multiple risks simultaneously due to their co-occurrence and potential inter-dependency [30]. We have also demonstrated the efficacy of this integrated intervention within an urban minority population exposed to many of the ecological challenges mentioned earlier. The prevalence of such risk factors within this population was strikingly high. Amongst pregnant African-American District of Columbia residents, 18+ years, at <29 weeks of gestation who were eligible for recruitment to the study, the prevalence of the targeted risk factors was 17.6% for IPV, 24.2% for depression, 10.4% for smoking and 38.8% for ETSE. (Note that this statement refers to risks, not women. Almost two-thirds (60.2%) of mothers with risk exhibited more than one risk factor concomitantly.) The population from

which our sample was drawn continues to suffer from significantly high rates of poor reproductive outcomes. The disparities in LBW and PTB between blacks and whites ranged between 2.0 to 2.4 for the years 2002-2004. The disparities for VLBW and VPTB ranged from 3.9 to 4.2 during the same time period. African-Americans in the District had an infant mortality rate of 17.0/1000 live births in 2005, two times the rate reported for whites [36].

The plausibility of some causal association between psycho-behavioral risk(s) and poor pregnancy outcomes, either directly or indirectly, is high and yet no intervention so far has shown the efficacy of such risk reduction on improving infant mortality rates. Recent findings in the literature confirm the significant contribution of higher rates of preterm birth to the black white disparity in infant mortality [37]. This contribution is especially pertinent to extremely premature and VLBW groups [38]. Our results show promise in impacting infant mortality rates through reduction of birth rates within the highest risk categories (VLBW and extremely premature). Prenatal health care providers may be reluctant to screen for psychobehavioral risk due to the lack of evidence to support the value of intervention. Our results underscore the importance of psycho-social and behavioral therapy resource availability as an integral component of comprehensive prenatal care. Funding and reimbursement for such services should become a health policy priority.

Limitations included that this study was not powered to test efficacy of the intervention with respect to pregnancy outcomes, but rather resolution of psycho-behavioral risks. Another limitation was the inability to reach 9.7% of women in the intervention group (n=39). Whether intervention delivery would be further compromised when tested for effectiveness under non-experimental conditions remains to be seen. This would be unlikely since the intervention was not intended nor did it interfere with the mother's choice to attend a particular routine PNC visit.

Our results on reduction of risk were based on mothers' self-report and therefore represent a limitation in the accuracy of measuring outcomes. Whether including fathers could have improved intervention efficacy is unknown, especially when studying biological outcomes. The intervention effect(s) we found may apply only to high risk minority pregnant women. It would be difficult to speculate whether the unique distribution of risk factors within this population influenced the results positively or negatively. Conclusions on effectiveness can only be reached after applying the intervention to the general population.

The results of our study show that the intervention, after controlling for confounding variables, reduced VPTB rates, i.e., increased gestational ages at delivery significantly and showed a trend toward reduction in VLBW rates, in spite of the fact that the study was not powered for these outcomes. Post-hoc calculations show the need for 1,878 enrollees to reach significant differences in the VLBW category. It would be important to test this intervention in other racial or sociodemographic groups or in a similar, but larger population to show whether results can be generalized. Our results also validate the association between psycho-behavioral risk and LBW, PTB and VPTB. In bivariate analysis, depression and IPV are statistically associated with a higher incidence in the three birth outcomes. When entered into a logistic regression model with other predictors, depression retains a statistical association with LBW, while IPV is only significantly associated with PTB and VPTB. A recent study with a similar population used a home visiting model for high risk pregnant women focusing on social support, health education and access to services, significantly lowered the women's risk of delivering a LBW infant [39]. An earlier paper showed that in comparison with usual care women in the intervention group more frequently resolved some or all of their risks than did women in the usual care group (odds ratio=1.61; 95% confidence interval=1.08-2.39; $p=0.02$ )[14]. The notable

finding in this study is that this randomized integrated cognitive behavioral intervention can also show improvement in pregnancy outcome.

It is also worthy of note that the behavioral intervention had a stronger impact on reducing the more preterm and lower birth weight rates. One could speculate that the targeted psychosocial and behavioral risks are either more directly involved in the triggering of labor in the earlier gestational period or could be mediating other health behaviors or responses associated with earlier preterm labor. Nonetheless, the efficacy of targeting the risks we chose appears to improve pregnancy outcomes directly or indirectly in an urban minority population. The significant reduction of VPTB implies increases in gestational ages and birth weight in infants born to women receiving cognitive behavioral interventions during pregnancy, promises to impact on infant mortality reduction, but larger studies will be required to confirm such an impact.

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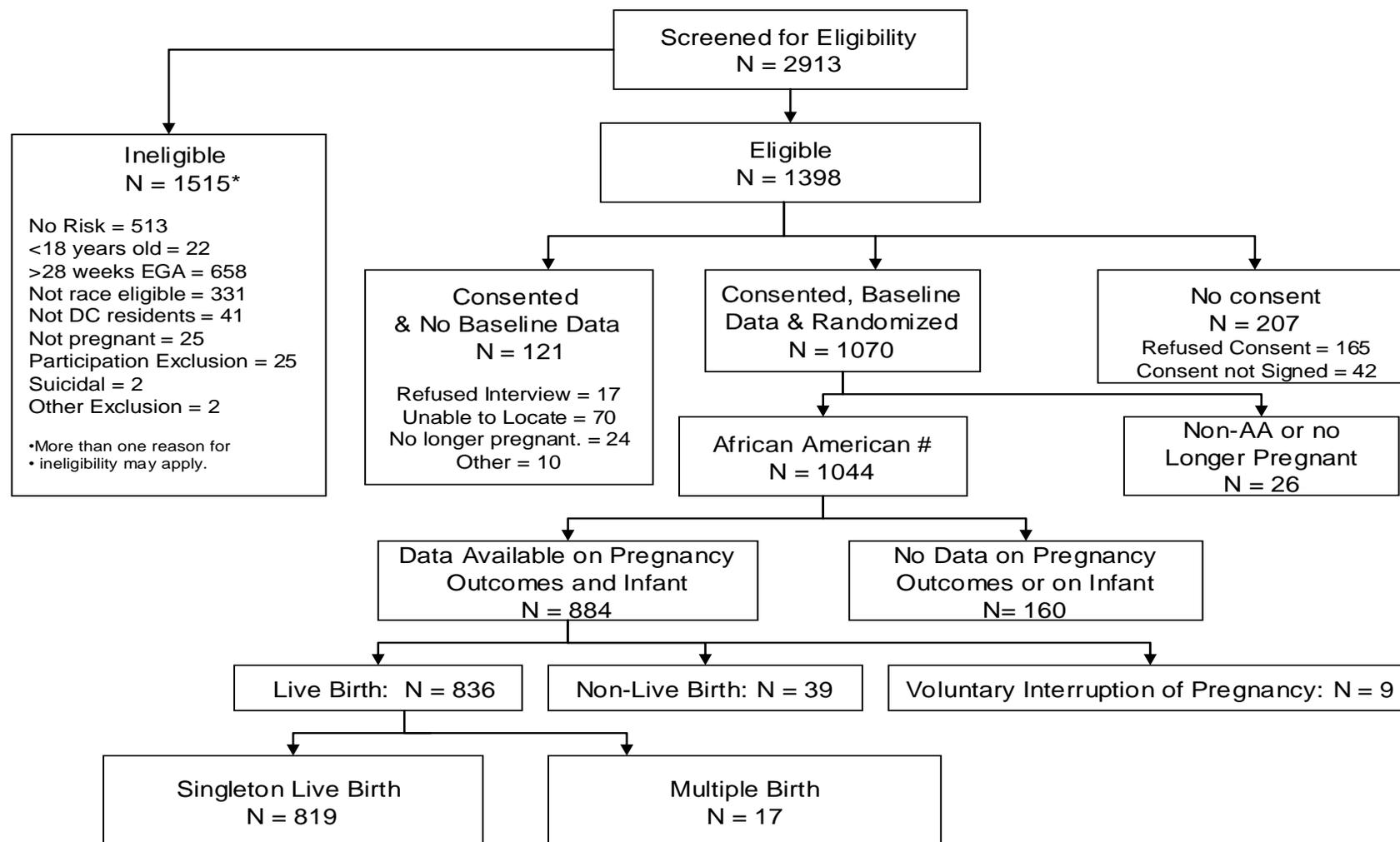
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**Figure 1. Profile of Project DC-HOPE Randomized Controlled Trial**



# Only African American (AA) women who were still pregnant at the time of the baseline interview are included in the analysis.

Table 1. Characteristics of the Study Population at Baseline (N=819)

Characteristic	Category	Intervention (n=403)	Usual Care (n=416)	P-value	Total (N=819)
Number of prenatal intervention visits	None	39 (9.7%)	---	---	---
	1-3	116 (28.8%)	---		
	4-7	191 (47.4%)	---		
	8+	57(14.1%)	---		
Maternal age	18-22	189 (47.0%)	165 (39.8%)	0.109	354 (43.3%)
	23-27	118 (29.4%)	136 (32.8%)		254 (31.1%)
	28 +	95 (23.6%)	114 (27.5%)		209 (25.6%)
Gestational age (weeks)	Mean ± SD	19.5 ± 6.6	18.8 ± 6.7	0.121	19.1 ± 6.7
Gestational age at PNC initiation (weeks)	Mean ± SD	13.1 ± 6.2	13.2 ± 6.4	0.906	13.1 ± 6.3
Education Level	< High school	114 (28.3%)	119 (28.6%)	0.699	233 (28.4%)
	High school graduate/GED	202 (50.1%)	198 (47.6%)		400 (48.8%)
	At least some college	87 (21.6%)	99 (23.8%)		186 (22.7%)
Employment status	Working now	139 (34.5%)	156 (37.6%)	0.351	295 (36.1%)
	Not working now, worked previous to pregnancy	149 (37.0%)	158 (38.1%)		307 (37.5%)
	Not working now, did not work previous to pregnancy	114 (28.3%)	98 (23.6%)		212 (25.9%)
Relationship status	Single/separated/widowed/divorced	306 (75.9%)	309 (74.3%)	0.585	615 (75.1%)
	Married or living with partner	97 (24.1%)	107 (25.7%)		204 (24.9%)
Trimester of PNC initiation	1 <sup>st</sup> Trimester	238 (60.9%)	237 (57.8%)	0.408	475 (59.3%)
	2 <sup>nd</sup> Trimester	143 (36.6%)	166 (40.5%)		309 (59.3%)
	3 <sup>rd</sup> Trimester	10 (2.6%)	7 (1.7%)		17 (2.1%)
Number of PNC visits	Mean ± SD	9.3±3.4	8.8±3.3	0.053	9.0±3.4
Household size	Mean ± SD	3.8±1.8	4.0±1.9	0.101	3.9±1.8
Total household income	<\$2,000 per month	204 (73.1%)	211 (69.6%)	0.354	415 (71.3%)
Medicaid	Yes	321 (80.0%)	321 (77.3%)	0.346	642 (78.7%)
WIC	Yes	181 (44.9%)	187 (45.0%)	0.991	368 (44.9%)
Food stamps/supplemental food program	Yes	230 (57.2%)	243 (58.4%)	0.728	473 (57.8%)
Public assistance/TANF	Yes	158 (39.3%)	176 (42.4%)	0.367	334 (40.9%)
Alcohol use during pregnancy	Yes	86 (21.4%)	90 (21.6%)	0.933	176 (21.5%)
Illicit drug use during pregnancy	Yes	56 (13.9%)	45 (10.8%)	0.180	101 (12.3%)
Pregnancy 'wanted'	Yes	309 (76.9%)	313 (75.6%)	0.672	622 (76.2%)
Previous pregnancy	Yes	330 (81.9%)	358 (86.1%)	0.103	688 (84.0%)
Previous live birth	Yes	266 (66.0%)	292 (70.2%)	0.199	558 (68.1%)
Number of live births (women with previous live birth)	Mean ± SD	2.1±1.4	2.1±1.4	0.591	2.1±1.4

<b>Characteristic</b>	<b>Category</b>	<b>Intervention (n=403)</b>	<b>Usual Care (n=416)</b>	<b>P-value</b>	<b>Total (N=819)</b>
Previous stillbirth or miscarriage (women with previous pregnancy)	Yes	136 (41.2%)	143 (39.9%)	0.735	279 (40.6%)
Active smoking	Yes	77 (19.1%)	70 (16.8%)	0.395	147 (17.9%)
ETSE	Yes	284 (71.7%)	300 (73.5%)	0.564	584 (72.6%)
Depression	Yes	175 (43.4%)	184 (44.2%)	0.816	359 (43.8%)
IPV	Yes	132 (32.8%)	131 (31.5%)	0.699	263 (32.1%)

PNC: prenatal care, WIC: Women, infant, and children, ETSE: environmental tobacco smoke exposure, IPV: intimate partner violence.

Table 2. Distribution of the Study Population by Number of risks at Baseline and Risk Status at Last Follow-up Preceding Delivery by Care Group\*

Number of Risks	Intervention	Usual Care	Exact Pearson chi-square <i>p</i> -value
<b>A. Number of Risks at Baseline</b>			
0	13.9%	13.2%	0.968
1-2	62.3%	63.0%	
3-4	23.8%	23.8%	
<b>B. Risk Resolution/Increase at Last Follow-up Preceding Delivery</b>			
<b>1. <u>For Women with 0 Risk at Baseline:</u></b>	n=54	n=50	0.040
No change in number of risks	61.1%	40.0%	
Increase by 1-2 risks	38.9%	58.0%	
Increase by 3-4 risks	0.0%	2.0%	
<b>2. <u>For Women with 1-2 Risks at Baseline:</u></b>	n=221	n=239	0.021
Resolution of all risks	29.0%	18.4%	
No change in number of risks	67.0%	75.3%	
Increase to 3-4 risks	4.1%	6.3%	
<b>3. <u>For Women with 3-4 Risks at Baseline:</u></b>	N=87	n=85	0.383
Resolution of all risks	8.0%	4.7%	
Reduced risks to 1-2	66.7%	61.2%	
No change in number of risks	25.3%	34.19%	

\* among women with at least one follow-up interview preceding delivery (intervention=362 and usual care=374).

Table 3. Demographic and Risk Characteristics at Baseline by Low Birth Weight or Very Low Birth Weight

Characteristic	LBW (n=97)	Not LBW (n=720)	VLBW (n=13)	Not VLBW (n=804)
Birth weight (mean $\pm$ SD)	2057 $\pm$ 418	3303 $\pm$ 440	1239 $\pm$ 279	3186 $\pm$ 545
Maternal age (mean $\pm$ SD)	25.4 $\pm$ 6.2	24.5 $\pm$ 5.3	26.8 $\pm$ 5.5	24.6 $\pm$ 5.5
Education $\geq$ High school	74%	71%	62%	72%
Married/living with partner	28%	25%	31%	25%
Medicaid recipient	79%	79%	77%	79%
PNC initiation (weeks) (mean $\pm$ SD)	13.0 $\pm$ 6.7	13.2 $\pm$ 6.2	13.0 $\pm$ 5.7	13.1 $\pm$ 6.3
Number of PNC visits (mean $\pm$ SD)	7.5 $\pm$ 3.3	9.3 $\pm$ 3.3	5.3 $\pm$ 2.0	9.1 $\pm$ 3.4
Alcohol use during pregnancy	24%	21%	23%	22%
Illicit drug use during pregnancy	20%*	11%	15%	12%
Active smoking	24%	17%	15%	18%
ETSE	72%	73%	54%	73%
Depression	56%**	42%	69%	44%
IPV	41%***	31%	54%	32%

\*  $p=0.021$ , \*\*  $p=0.013$ , \*\*\*  $p=0.039$

LBW: low birth weight, VLBW: very low birth weight, PTB: preterm births, VPTB: very preterm birth, PNC: prenatal care, ETSE: environmental tobacco smoke exposure, IPV: intimate partner violence.

Table 4. Demographic and Risk Characteristics at Baseline by Preterm or Very Preterm Birth

Characteristic	PTB (n=102)	Not PTB (n=716)	VPTB (n=30)	Not VPTB (n=788)
Maternal Age (mean $\pm$ SD)	26.1 $\pm$ 6.6*	24.4 $\pm$ 5.3	25.8 $\pm$ 6.2	24.5 $\pm$ 5.4
Education $\geq$ High School	74%	71%	73%	72%
Married/Living with Partner	23%	25%	27%	25%
Medicaid Recipient	81%	78%	80%	79%
PNC Initiation (weeks) (mean $\pm$ SD)	12.5 $\pm$ 6.2	13.2 $\pm$ 6.3	11.3 $\pm$ 6.1	13.2 $\pm$ 6.3
Number of PNC visits (mean $\pm$ SD)	7.6 $\pm$ 3.1	9.2 $\pm$ 3.4	6.1 $\pm$ 2.7	9.1 $\pm$ 3.4
Alcohol use during pregnancy	24%	21%	20%	22%
Illicit drug use during pregnancy	13%	12%	10%	12%
Active Smoking	23%	17%	20%	18%
ETSE	70%	73%	66%	73%
Depression	53%**	43%	63%†	43%
IPV	42%***	31%	57%‡	31%

\*  $p=0.010$  \*\*  $p=0.046$ , \*\*\*  $p=0.021$ , †  $p=0.028$ , ‡  $p=0.003$

PTB: preterm births, VPTB: very preterm birth, PNC: prenatal care, ETSE: environmental tobacco smoke exposure, IPV: intimate partner violence.

Table 5. Effect of the Intervention on Improving Pregnancy Outcomes

Pregnancy Outcome	Intervention (n =403)	Usual Care (n =416)	Unadjusted OR (95% Confidence Interval)	Absolute Risk Reduction (% Reduction in Risk)	Number Needed to Treat*
LBW	10.9% (n=44)	12.8% (n=53)	0.84 (0.55 - 1.29)	1.9% (15%)	53
VLBW	1.0% (n=4)	2.2% (n=9)	0.45 (0.14 – 1.48)	1.2% (55%)	83
PTB	11.9% (n=48)	13.0% (n=54)	0.91 (0.60 – 1.38)	1.1% (8%)	91
VPTB	2.2% (n=9)	5.0% (n=21)	0.43 (0.20 – 0.95)	2.8% (56%)	36

LBW: low birth weight, VLBW: very low birth weight, PTB: preterm births, VPTB: very preterm birth, OR: Odds Ratio.

\* Both odds ratio and number needed to treat are measures of the effect size to assess clinical significance.

Table 6. Logistic Regression Analysis for Low Birth Weight, Preterm Birth and Very Preterm Birth

Characteristic	Adjusted Odds Ratio*	95% Confidence Interval
Low Birth Weight Model (N=817)		
Depression at baseline	1.71	1.12 – 2.62
Preterm Birth (N=818)		
Maternal age	1.06	1.02 – 1.09
IPV at baseline	1.64	1.07 – 2.51
Very Preterm Birth (N=818)		
Behavioral intervention	0.42	0.19 – 0.93
IPV at baseline	2.94	1.40 – 6.16

Variables were selected for inclusion in the final logistic regression models if they reached significance in the bivariate analyses, and predictors significant at  $p < 0.05$  were retained in the final models. For low birth weight, preterm birth, and very preterm birth models, the significant variables in the bivariate analyses included: behavioral intervention, maternal age, depression, IPV, and illicit drug use during pregnancy.

\* Odds ratio is the preferred measure of effect size to assess clinical significance in logistic regression.