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An integrated intervention to reduce intimate partner violence in pregnancy: a randomized trial

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1 **AN INTEGRATED INTERVENTION TO REDUCE INTIMATE PARTNER VIOLENCE**
2 **IN PREGNANCY: A RANDOMIZED TRIAL**

3
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16 Funding/Support: This study was supported by grants no. 3U18HD030445; 3U18HD030447;
17 5U18HD31206; 3U18HD03919; 5U18HD036104, *Eunice Kennedy Shriver* National Institute of
18 Child Health and Human Development and the National Center on Minority Health and Health
19 Disparities

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21 Short title: An RCT to Reduce Intimate Partner Violence
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28 *RTI International is a trade name of Research Triangle Institute.

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PRÉCIS

This randomized controlled trial of a cognitive/behavioral integrated intervention during pregnancy shows efficacy in reducing intimate partner violence victimization and improving pregnancy outcomes.

35 ABSTRACT

36

37 OBJECTIVE: We estimated the efficacy of a psycho-behavioral intervention in reducing
38 intimate partner violence (IPV) recurrence during pregnancy and postpartum, and in improving
39 birth outcomes in African-American women

40 METHODS: We conducted a randomized controlled trial in which 1,044 women were recruited.
41 Individually-tailored counseling sessions were adapted from evidence-based interventions for
42 IPV and other risks. Logistic regression was used to model IPV victimization recurrence, to
43 predict minor, severe, physical and sexual IPV.

44 RESULTS: Women randomized to the intervention were less likely to have recurrent episodes
45 of IPV victimization (OR=0.48, 95%CI=0.29-0.80). Women with minor IPV were significantly
46 less likely to experience further episodes during pregnancy (OR=0.48, 95%CI=0.26-0.86,
47 OR=0.53, 95%CI=0.28-0.99) and postpartum (OR=0.56, 95%CI=0.34-0.93). Numbers needed to
48 treat were 17, 12, and 22, respectively as compared to the usual care Women with severe IPV
49 showed significantly reduced episodes at postpartum (OR=0.39, 95%CI=0.18-0.82) and number
50 needed to treat is 27. Women who experienced physical IPV showed significant reduction at the
51 first follow-up (OR=0.49, 95%CI=0.27-0.91) and postpartum (OR=0.47, 95%CI=0.27-0.82) and
52 number needed to treat is 18 and 20, respectively. Intervention women had significantly fewer
53 very preterm infants ($p=0.03$) and an increased mean gestational age ($p=0.016$).

54 CONCLUSION: A relatively brief intervention during pregnancy had discernable effects on IPV
55 and pregnancy outcomes. Screening for IPV as well as other psychosocial and behavioral risks
56 and incorporating similar interventions in prenatal care is strongly recommended.

57

58 **Clinical Trial Registration: ClinicalTrials.gov, www.clinicaltrials.gov, NCT00381823**

59

60 **BACKGROUND**

61
62 Intimate partner violence (IPV) is defined as a pattern of assaultive and coercive behaviors, that
63 includes the threat or infliction of physical, sexual, or psychological abuse that is used by
64 perpetrators for the purpose of intimidation of and/or control over the victim.¹⁻³ There is no set
65 agreement regarding what signs, symptoms or illnesses are considered the standard ICD-9
66 constellation for a diagnosis of IPV.^{4,5}

67 The CDC reports that approximately 5.4 million episodes of IPV occur every year in the
68 United States in women eighteen years and older.⁶ The literature is inconsistent as to whether
69 minorities are at increased risk, with some studies reporting significant differences⁷⁻¹⁰ and others
70 finding no racial or ethnic differences.^{11,12} The most recent, largest and nationally
71 representative study found no differences of lifetime prevalence for IPV by race/ethnicity, while
72 the rate for the 12 months preceding the survey was almost twice as high among African-
73 Americans.¹³ Although some authors link IPV to socio-economically deprived communities, it is
74 by no means limited to the economically disadvantaged. Families with conflicting priorities and
75 stressors associated with limited psycho-social reserves may be at greatest risk.¹⁴ Factors
76 including housing conditions, poverty and street violence are associated with higher prevalence
77 of violence inside the home environment. Political disenfranchisement and cultural isolation may
78 also be mediators for IPV. Women living under such conditions are more likely to be victimized
79 as compared to women living in more stable and better organized communities.¹⁵⁻¹⁷

80 Exposure to IPV is associated with a range of negative psycho-behavioral risks as well as
81 health outcomes including increased risk of poor physical health, physical disability,
82 psychological distress, mental illness, and heightened substance use including alcohol and illicit
83 drugs.¹⁸ Sexual and physical IPV have been linked significantly with depression, suicidality, and
84 post traumatic stress disorder.¹⁹⁻²² Women who suffer from IPV are more likely to have

85 sexually transmitted diseases, vaginal bleeding or infection and urinary tract infections.²³ Abuse
86 during pregnancy has been shown to be associated with significantly higher rates of depression,
87 suicide attempts as well as use of tobacco, alcohol and illicit drugs.²⁴⁻³¹ IPV has been linked to
88 both pregnancy complications (e.g., inadequate weight gain, infections and bleeding) as well as
89 adverse pregnancy outcomes (low birth weight (LBW), preterm delivery (PTB) and neonatal
90 death).³²⁻³⁴ IPV amongst minority populations, already at higher risk for poor pregnancy
91 outcomes, may be a significant contributor to the health disparities observed in reproductive
92 outcomes amongst African-American women.

93 The objective of this paper is to estimate the efficacy of a cognitive behavioral
94 intervention administered as part of a randomized controlled trial (RCT) during prenatal care
95 (PNC) in reducing IPV recurrence during pregnancy and improving birth outcomes (LBW and
96 PTB) in a population of African-American residents of Washington, DC.

97 **PARTICIPANTS AND METHODS**

98 The “NIH-DC Initiative to Reduce Infant Mortality in Minority Populations” is a collaboration
99 between Children’s National Medical Center, Georgetown University, George Washington
100 University Medical Center, Howard University, the *Eunice Kennedy Shriver* National Institute of
101 Child Health and Human Development, the National Center on Minority Health and Health
102 Disparities and RTI International. As part of this collaboration, we conducted a RCT to evaluate
103 the efficacy of an integrated behavioral intervention delivered during PNC in reducing cigarette
104 smoking, environmental tobacco smoke exposure (ETSE), depression and IPV during pregnancy
105 and in improving pregnancy outcome. This study was reviewed and approved by the
106 institutional review boards of all participating institutions.

107 Women were screened at six community based PNC sites serving mainly minority

108 women in the District of Columbia between July, 2001 and October, 2003. Women were
109 demographically eligible if they self-identified as being a minority, were ≥ 18 years old, ≤ 28
110 weeks pregnant, a DC resident and English speaking. Almost two-thirds (63.4%) were recruited
111 before 22 weeks gestation, 16.9% were recruited between 22 and 25 weeks gestation and 19.7%
112 were recruited between 26 and 28 weeks gestation. The women who were demographically
113 eligible were consented in a two-stage consent and enrollment process. After initial consent,
114 participants were screened for the four risk factors (cigarette smoking, ETSE, depression, and
115 IPV) using an audio-computer assisted self interview which also confirmed their demographic
116 eligibility. An average of 9 days after screening, a baseline interview took place where more
117 detailed information on socio-demographics, reproductive history and behavioral risks was
118 collected. Following this interview, women were consented to participate. Follow-up data
119 collection by telephone interviews occurred during the second and third trimesters of pregnancy
120 (22-26 and 34-38 weeks gestation, respectively) and 8-10 weeks postpartum. Intervention and
121 follow-up activities continued until July 2004. Details are published in El-Khorazaty et al.³⁵
122 A total of 2,913 women were screened and 1,398 met eligibility criteria (See Figure 1). Of these
123 85% (n=1,191) consented to participate in a baseline telephone interview before randomization;
124 1,070 (89.9%) were reached and participated. Eligible women were randomized to the
125 intervention group or usual care group. Of these women 1,044 were African-American and still
126 pregnant at the time of the baseline interview. Included in the analyses were 521 randomized to
127 the intervention and 523 randomized to usual care.

128 Women randomized to the intervention received an integrated cognitive behavioral
129 intervention and women randomized to usual care received their usual prenatal care, as
130 determined by the standard procedures at the PNC clinic. 336 women reported IPV

131 victimization in the past year during the baseline interview and this group could be further
132 categorized as having minor and/or severe IPV, physical and/or sexual IPV based on the Conflict
133 Tactics Scale (CTS).³⁶ A woman may experience multiple types of violence; thus these
134 categories are not mutually exclusive. Minor IPV was defined if the woman's partner slapped,
135 grabbed, pushed, or shoved her, threw something at her, twisted her arm or hair, and insisted,
136 without using force, on anal sex, intercourse, or sex without using a condom. Major IPV was
137 defined if the woman's partner kicked, bit, punched, beat up, hit, choked or slammed her, used
138 knife or gun, burned or scalded her on purpose, and used force or threats to have sex or anal sex.
139 Physical IPV was defined if the woman's partner threw something at her, pushed or shoved her,
140 used a knife or gun, hit, choked, slammed, grabbed, burned, or kicked her. Sexual assault was
141 defined if the woman's partner forced sex without using a condom, forced her to have sex,
142 threatened or insisted on having sex (oral, anal, or vaginal) against her will.

143 The intervention utilized in this RCT was delivered during routine PNC visits at the
144 clinics by interventionists (master's level social workers or psychologists), trained specifically to
145 deliver this intervention. The intervention was evidence-based and specific to each of the
146 designated psycho-behavioral risks.³⁷ At each intervention session the woman identified which
147 of the four risks she was experiencing. The intervention was delivered by the interventionist and
148 targeted to address all risks reported at each session, regardless of previously reported risks. The
149 intervention for IPV emphasized safety behaviors and was based on the structured intervention
150 developed by Parker and colleagues³⁸ and based on Dutton's³⁹ Empowerment Theory. This
151 intervention provided information about the types of abuse (e.g., emotional, physical and sexual)
152 and the cycle of violence (e.g., escalating, IPV, honeymoon period), a Danger Assessment
153 Component to assess risks, and preventive options women might consider (e.g., filing a

154 protection order) as well as the development of a safety plan (e.g., leaving important documents
155 and papers with others). In addition, a list of community resources with addresses and phone
156 numbers was provided. The intervention for smoking and ETSE were combined and based on
157 Smoking Cessation or Reduction in Program Treatment. This intervention was cognitive-
158 behavioral and based on a woman's stage of readiness for behavioral change.⁴⁰ The depression
159 intervention was developed by Miranda and Munoz⁴¹ based on cognitive behavioral theory and
160 focused on mood management, increasing pleasurable activities and increasing positive social
161 interactions.

162 The components of the intervention were designed for delivery in a minimum of four
163 sessions with eight prenatal sessions required for a complete intervention, based on the highest
164 number of sessions required for a specific risk. Fifty-one percent of the women randomized to
165 the intervention received four or more sessions, while one-quarter of the women attended no
166 intervention sessions. Individualized counseling sessions provided an integrated approach to
167 multiple risks responsive to a woman's specific risk combination. Two additional postpartum
168 booster sessions were provided to reinforce risk-specific intervention goals and support women
169 through the postpartum period. Intervention sessions were conducted privately in a room
170 proximate to or within the PNC clinics and occurred immediately before or after routine PNC.
171 Intervention activities addressing all of the individually identified risks at each session lasted for
172 an average of 35±15 minutes. Women in the intervention received \$10 for each intervention
173 session and additional \$15 and \$25 gift certificates for the first and second postpartum
174 intervention sessions, respectively.

175 During screening or follow-up, women reporting suicidal ideation were immediately
176 referred to the mental health consultation team. Women were evaluated and referred, as

177 necessary. Those found to be potentially suicidal (n=10) were excluded from the study.

178 The sample size was powered to test the reduction in psycho-behavioral risk, with the
179 theory that a reduction in risk would help improve pregnancy outcomes. Assuming a 5% level of
180 significance, 80% power would allow the detection of 10-20% reductions in risk-specific factors
181 among women in the intervention from a prevalence of 100% at recruitment. A sample of 1,050
182 women needed to be retained at the end of the follow-up period (525 women in each of the
183 intervention and usual care group). The anticipated number of women reporting IPV needed to
184 detect significance in reducing risk was 337 split between the two care groups). This sample size
185 was also sufficient to detect a 25% reduction in preterm birth and low birth weight combined in
186 the intervention as compared to that for the usual care group (estimated at 20%). Based on a
187 declining birth rate in D.C., the recruitment period was extended four months to reach the
188 required sample size.

189 Site- and risk-specific permuted block randomization to the intervention or usual care
190 was conducted. Both the investigators and the field workers were blinded to block size. A
191 computer generated randomization scheme was utilized to consider all the possible risk
192 combinations within each of the recruitment sites. When a woman completed the baseline
193 interview and was ready for randomization, the recruitment staff would call the data coordinating
194 center, where the subject's assignment was determined.

195 Validated instruments were used for each of the data collection time points. During
196 screening, IPV was identified by the Abuse Assessment Screen, a measure designed and
197 validated for use in pregnancy if a woman reported physical or sexual abuse by a partner in the
198 previous year.⁴² During the baseline and follow-up interviews, the frequency of physical assault

199 and sexual coercion (partner to self) was measured by the Conflict Tactics Scale.³⁶ A more
200 detailed description of instruments used for other risks is available in Katz et al.³⁷

201 Telephone interviewers and their supervisors were blinded to the participants'
202 randomization group. Research staff maintained confidentiality when communicating with
203 participants outside the clinic setting. Addresses were collected to facilitate tracing efforts, but
204 the women were informed that they would not receive mail from Project DC-HOPE. For women
205 experiencing IPV, staff did not want to raise women's risk for abuse by receiving mail from the
206 study that might be negatively regarded by an abusive partner, or would expose her pregnancy.
207 Women were also asked whether or not telephone messages from project staff could be left on
208 their telephone answering machines. If not, this was noted in her computerized record accessible
209 by all project teams. As financial incentives the women received \$5 for the screening, a 30-
210 minute telephone card for providing main study consent, and \$15 for each telephone interview.
211 At the time of recruitment medical records were abstracted and upon delivery data on infant and
212 pregnancy outcomes were recorded.

213 To preserve the randomization, participant data were analyzed according to their care
214 group assignment, regardless of receipt of intervention, using an intent-to-treat approach. All
215 statistical analyses were conducting using SAS version 9.1.3 (SAS Institute, Cary, NC).
216 Bivariate analyses were conducted to compare the baseline characteristics and pregnancy
217 outcomes of women assigned to the intervention versus usual care and to compare women who
218 reported a recurrence of IPV during pregnancy or postpartum versus those who did not. T-tests
219 compared groups based on continuous variables (using the TTEST procedure in SAS) and chi-
220 square tests compared the groups with respect to categorical variables (using SAS's FREQ
221 procedure). Logistic regression was used to model recurrence of IPV based on care group

222 assignment, controlling for relevant covariates (using the LOGISTIC procedure). Logistic
223 models were also created to predict minor, severe, physical and sexual IPV reported at each
224 interview. Adjusted odd ratios (AOR) were produced by models that included care group plus
225 other covariates.

226 **RESULTS**

227 Table 1 presents the sociodemographic characteristics and psycho-behavioral risks at baseline
228 between women randomized to the intervention (n=521) or usual care (n=523). There were no
229 significant differences between these two groups. During the baseline interview, 336 women
230 (32.2%) reported IPV in the previous year. Of these women 169 were in the intervention and
231 167 were in the usual care group (See Figure 1). In this subgroup, there were no significant
232 differences between the women in the two randomization groups (See Table 1). Mothers were of
233 24.5 years mean age. On average participants initiated PNC at 13 weeks of gestation. Seventy-
234 six percent were single, 68% had at least a high school education and 79% were enrolled in
235 Medicaid. In this population, 22% of the mothers admitted to active smoking during pregnancy,
236 78% self-identified as being at risk for ETSE and 62% were depressed as measured by the
237 Hopkins Scale. In addition, 32% admitted to using alcohol and 17% admitted to illicit drug use
238 during pregnancy.

239 Of those women reporting IPV at baseline, 306 women (91.1%) completed at least one of
240 the follow-up or postpartum interviews. No significant differences were found between those
241 with follow-up data (n=306) and those without (n=30), nor were women randomized to the
242 intervention (n=150) significantly different from those randomized to the usual care (n=156).

243 Women reporting continued IPV during pregnancy or postpartum (n=94) were
244 significantly different from those who reported no further episodes of IPV (n=212) beyond

245 baseline with respect to care group ($p=0.006$), gestational age at baseline ($p=0.035$), alcohol use
246 during pregnancy ($p=0.014$) and depression at baseline ($p=0.009$).

247 Controlling for these four variables in the logistic regression, only care group, alcohol use
248 and depression were significant in the reduced model. Logistic regression results for continued
249 IPV at all interviews during pregnancy and postpartum ($n=94$) showed that women in the
250 intervention were less likely to have recurrent episodes of IPV (AOR=0.48, 95% CI=0.29-0.80).
251 Alcohol use during pregnancy measured at baseline and depression were associated with the
252 chance of recurrent episodes of IPV (AOR=1.85, 95% CI=1.09-3.12; AOR=1.90, 95% CI=1.11-
253 3.25, respectively). Women in the intervention were less likely to be victimized by their partners
254 at the first or second follow-up interviews (second or third trimester) (see Table 2). Although the
255 trend remains, the difference does not reach significance in the postpartum period.

256 Table 3 presents adjusted odds ratios and numbers needed to treat for the impact of the
257 intervention on minor IPV, severe IPV, physical IPV and sexual IPV at baseline and each of the
258 follow-up interviews. It should be noted that reported IPV at baseline refers to the one year
259 preceding the interview while at each of the three subsequent interviews, the reference period
260 was since the previous interview, on average 9-10 weeks during pregnancy and 14 weeks
261 between the second follow-up and the postpartum interview. At baseline no significant
262 differences between groups were observed for any of these four categories. Women with minor
263 IPV and randomized to the intervention were significantly less likely to experience further
264 episodes at all of the follow-up points. Women categorized with severe IPV in the intervention,
265 showed a significantly reduced incidence of episodes at postpartum, compared to the usual care
266 group. Women experiencing physical IPV were significantly less likely to experience episodes
267 at first follow-up or at postpartum interviews, compared to the usual care group. For women

268 experiencing sexual IPV, the intervention did not significantly reduce their incidence of episodes
269 at any follow-up visit during pregnancy or postpartum.

270 For women experiencing IPV victimization throughout pregnancy and postpartum, Table
271 4 presents a comparison of intervention and usual care women with respect to various adverse
272 pregnancy outcomes. The results indicate that rates of low birthweight (<2,500 grams) (LBW)
273 were not different in the two groups (intervention=12.8% versus usual care=18.5%, $p=0.204$),
274 while very low birthweight (<1,500 grams) (VLBW) rates were lower among intervention
275 women (intervention=0.8% versus usual care=4.6%, $p=0.052$). In addition, rates of preterm
276 births (37 weeks gestation) (PTB) were not statistically different in the two groups (13.0% versus
277 19.7%, $p=0.135$). However, the two groups of women were significantly different with respect
278 to very PTB (<33 weeks gestation) (VPTB) (1.5% versus 6.6%, $p=0.030$). Also, for the mean
279 gestational age at delivery, the two groups were significantly different (38.2 weeks versus 36.9
280 weeks, $p=0.016$).

281 **DISCUSSION**

282 This study evaluates efficacy of a psycho-behavioral intervention during prenatal and postpartum
283 care on the reduction of IPV recurrence and improved pregnancy outcomes in African-American
284 mothers reporting IPV victimization. We were able to recruit 336 women acknowledging IPV
285 victimization within the past year during the baseline interview and who were willing to
286 participate in the intervention. In addition, 91% of these women continued to participate in this
287 randomized trial during pregnancy and/or postpartum. This finding emphasizes the relative ease
288 of recruitment of high risk African-American women to IPV reduction programs in the PNC
289 setting. The recruitment staff were trained to be culturally sensitive and the screening tool was
290 both simple and administered confidentially. These women are also willing to maintain

291 participation in a program that provided cognitive behavioral strategies relevant to psycho-
292 behavioral problems they experienced during pregnancy.

293 The integrated intervention provided women with suggestions to deal with depression
294 and tobacco exposure in addition to strategies aimed at reducing risk of IPV. Alternative
295 explanations for our findings were considered. For other services for which we queried the
296 women, there were no differences between women experiencing IPV and those not. We also
297 considered whether women's previous reproductive history might explain why the intervention
298 group had significantly better outcomes. None of the factors (previous preterm delivery,
299 previous miscarriage, previous stillbirth, number of previous voluntary interruptions of
300 pregnancy) that might predict poor reproductive outcomes were different between the two care
301 groups. Finally we considered whether medical conditions that might influence pregnancy
302 outcomes (preconception and gestational diabetes, chronic and gestational hypertension, or
303 sexually transmitted infections) were significantly different between the two care groups. None
304 of these medical conditions were significantly different between the two care groups.

305 The American College of Obstetricians and Gynecologists identifies the response to
306 domestic violence against women as a priority and recommends screening within primary care
307 settings.⁴³ They also recommend the Patient Health Questionnaire as a screening instrument for
308 IPV, depression and anxiety. This questionnaire recognizes the co-occurrence of these psycho-
309 social risks as well as screening for substance exposure known to occur more frequently in
310 victims of IPV.^{24-27, 31} The findings of our study confirm the importance of emphasizing a more
311 global approach towards risk assessment and service provision to this population of high risk
312 African-American mothers.

313 IPV has been associated with poor pregnancy outcomes in the literature.^{28, 30, 32-34, 44-47}

314 Our study is the first we are aware of that found reductions in adverse pregnancy outcomes
315 despite previous evidence for associations between IPV during pregnancy and LBW.^{28, 30, 32-34}
316 The intervention model targeting multiple risk factors in African-American women suffering
317 from IPV victimization shows promising results that could be translated toward reduction of
318 infant mortality within that population. The current literature agrees that very preterm infants
319 contribute more than 90% of the overall infant mortality statistic.⁴⁸ The effect of the intervention
320 impacted multiple pregnancy outcomes, especially the highest level of neonatal risk, VLBW and
321 VPTB. The significant reduction of VLBW and VPTB in our intervention group may have
322 important implications on reduction of disparities in poor pregnancy outcomes and infant
323 mortality among African-Americans.

324 Whether or not our analyses were adjusted for alcohol use and depression, the
325 intervention universally reduced minor IPV during pregnancy and postpartum. It is important to
326 recognize that the classification of minor IPV on the Conflict Tactics Scale includes acts of
327 assault such as slapping, grabbing, pushing and shoving as well as twisting of the arm or hair.
328 While such actions may be considered minor on the CTS they are significant acts of aggression
329 and violence. The intervention was unable to impact more severe acts described as using a knife
330 or gun, choking, burning, scalding or kicking. The lack of effect on sexual IPV could be
331 attributed to the reluctance or discomfort of the study participants to divulge or discuss these
332 topics. The intervention team was instructed to show sensitivity to the level of comfort of the
333 study participants in this domain. The intervention as designed and implemented only reduced
334 the recurrence of minor and physical IPV, but could have reduced other associated risks.

335 The impact of IPV on pregnancy outcome is complicated by its co-occurrence with
336 depression and alcohol use.^{47,49-51} The behavioral intervention for depression could have

337 significantly contributed to our success. Among the women reporting IPV at baseline, 62 percent
338 reported being depressed and 32 percent reported alcohol use during pregnancy. Addressing IPV
339 and depression together may have helped women implement suggested strategies to assess risks,
340 consider preventive options and develop a safety plan. We also detected a significant
341 association between IPV and illicit drug use (16.7%) and active smoking (22%), both known to
342 be risks for PTB and LBW.^{52,53} In reduced logistical models, alcohol use during pregnancy and
343 depression measured at baseline continued to exert a significant influence on perpetuating IPV
344 during pregnancy and postpartum. This describes a cycle where co-occurring risk factors are
345 immutably entangled.

346 A limitation of the study was that it was not powered to test the efficacy of the
347 intervention with respect to adverse pregnancy outcomes, but rather resolution of the psycho-
348 behavioral risks. Women were only modestly invested in participating in the intervention.
349 Despite the fact that we were able to deliver the minimum number of intervention sessions to
350 59% of participants with IPV, women randomized to the intervention were successful in risk
351 reduction. These rates of participation may be a reflection of difficult life circumstances among
352 poor urban women. These mothers encountered other behavioral challenges during pregnancy,
353 such as alcohol and drug use, that were not addressed by the intervention. Had we addressed
354 these, we might have been even more successful. The intervention effect(s) we found may apply
355 only to high risk minority pregnant women. It would be important to test this intervention in
356 other racial or sociodemographic groups to confirm generalizability. Larger studies testing the
357 effectiveness of implementing such interventions in community based clinics providing PNC
358 could have important health policy implications.

359 There is evidence that this intervention for pregnant African-American women reduced

360 IPV victimization during pregnancy and improved pregnancy outcome. If generalizable, our
361 results should encourage health care providers and third party payers to go beyond screening for
362 psycho-social and behavioral risks to providing services during PNC to address such risks. The
363 potential cost savings associated with reduction of births within the highest risk category may be
364 substantial.

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

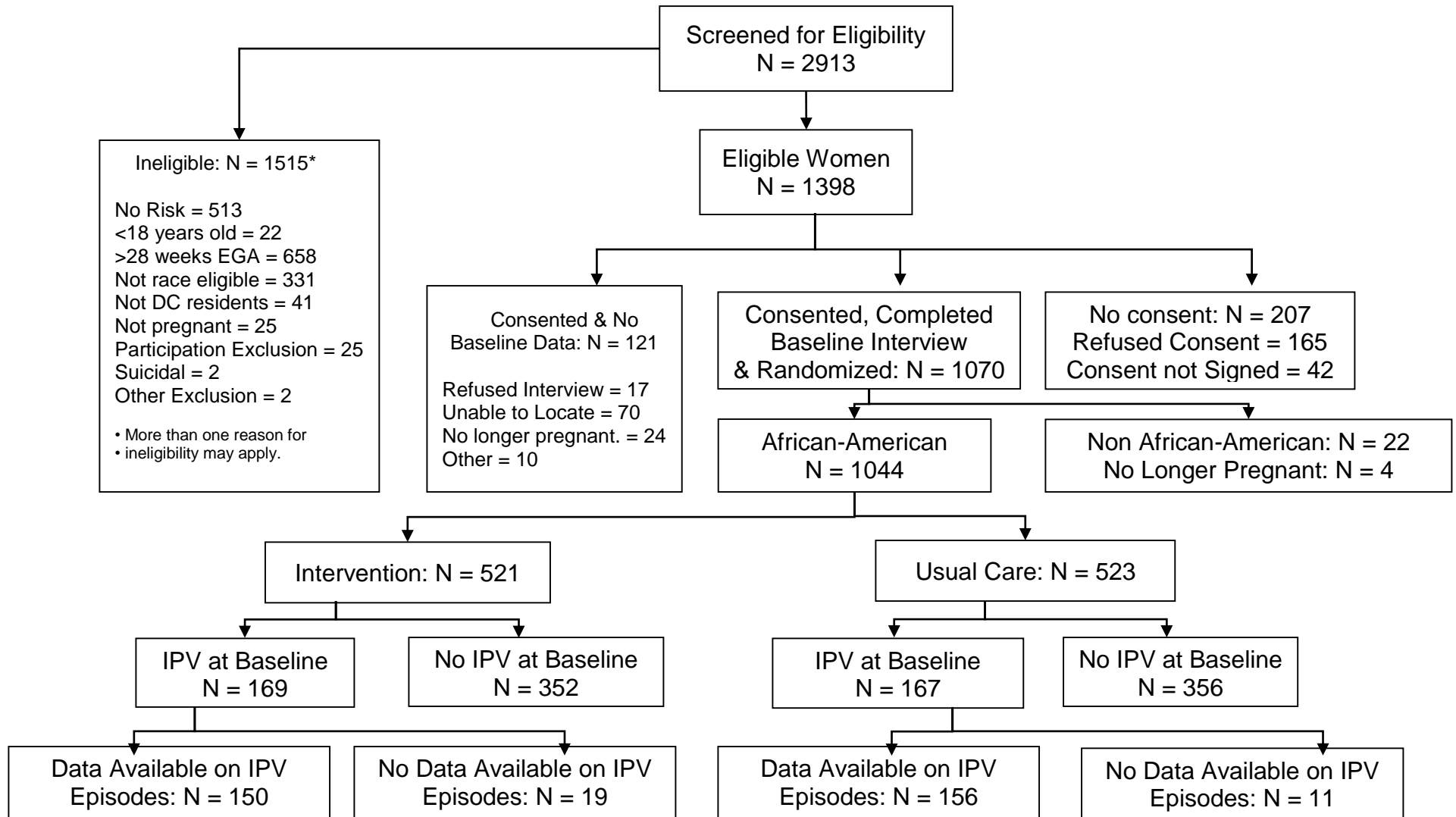


Table 1. Characteristics of All Participants and those Acknowledging Intimate Partner Violence (IPV) Victimization at Baseline

Characteristic	Value	All Participants		Women with IPV at Baseline	
		Intervention (N=521)	Usual Care (N=523)	Intervention (N=169)	Usual Care (N=167)
Maternal age	Mean ± SD	24.4±5.5	24.8±5.3	24.5±5.8	24.5±5.4
Gestational age at enrollment (weeks)	Mean ± SD	19.3±6.9	18.6±6.8	19.2±6.8	18.5±6.9
Education level	< High school	159 (30.5%)	157 (30.0%)	54 (32.0%)	53 (31.7%)
	HS graduate/GED	245 (47.0%)	241 (46.1%)	77(45.6%)	67 (40.1%)
	At least some college	117 (22.5%)	125 (23.9%)	38 (22.5%)	47 (28.1%)
Employment status	Working now	185 (35.5%)	196 (37.5%)	58 (34.3%)	67 (40.4%)
	Not working now, worked previous to pregnancy	185 (35.5%)	193 (36.9%)	67 (39.6%)	59 (35.5%)
	Not working now, did not work previous to pregnancy	150 (28.8%)	130 (24.9%)	44 (26.0%)	40 (24.1%)
Relationship status	Single/separated/widowed/divorced	396 (76.0%)	401 (76.7%)	132 (78.1%)	122 (73.1%)
	Married or living with partner	125 (24.0%)	122 (23.3%)	37 (21.9%)	45 (27.0%)
Emotional support from partner	Mean ± SD	36.9±20.6	37.3±20.5	32.8±20.9	32.7±19.7
Emotional support from others	Mean ± SD	39.4±15.1	40.8±14.7	37.7±14.9	39.3±14.9
Emotional support from partner prior to delivery	Mean ± SD	34.3±21.6	33.9±21.8	31.0±21.9	29.6±21.6
Emotional support from others prior to delivery	Mean ± SD	41.8±12.7	41.7±13.4	40.5±13.7	39.9±14.7
Trimester of PNC initiation	1 st Trimester	305 (61.6%)	300 (58.9%)	94 (58.8%)	98 (60.9%)
	2 nd Trimester	179 (36.2%)	201 (39.5%)	60 (37.5%)	60 (37.3%)
	3 rd Trimester	11 (2.2%)	8 (1.6%)	6 (3.8%)	3 (1.9%)
Medicaid	Yes	411 (78.9%)	402 (76.8%)	134 (79.8%)	129 (77.7%)
WIC	Yes	226 (43.4%)	228 (43.6%)	74 (43.8%)	76 (45.5%)
Supplemental food program	Yes	369 (71.1%)	382 (73.0%)	168 (99.4%)	162 (97.0%)
Public assistance/TANF	Yes	213 (41.0%)	223 (42.7%)	73 (43.2%)	69 (41.3%)
Alcohol use in this pregnancy	Yes	111 (21.3%)	112 (21.4%)	58 (34.3%)	49 (29.3%)
Illicit drug use in this pregnancy	Yes	67 (12.9%)	56 (10.7%)	26 (15.4%)	30 (18.0%)
Marijuana use	Yes	62 (11.9%)	52 (9.9%)	23 (13.6%)	28 (16.8%)
Cocaine use	Yes	6 (1.2%)	7 (1.3%)	5 (3.0%)	3 (1.8%)
Pregnancy 'wanted'	Yes	403 (77.4%)	395 (75.5%)	127 (76.1%)	117 (71.3%)
Previous pregnancy	Yes	425 (81.6%)	443 (84.7%)	141 (83.4%)	144 (86.2%)
Previous live birth	Yes	173 (33.2%)	163 (31.2%)	112 (69.5%)	116 (69.5%)

Characteristic	Value	All Participants		Women with IPV at Baseline	
		Intervention (N=521)	Usual Care (N=523)	Intervention (N=169)	Usual Care (N=167)
Number of live births (women with previous pregnancy)	Mean ± SD	2.1±1.5	2.2±1.4	1.9±1.7	1.7±1.5
Previous preterm delivery	Yes	72 (14.2%)	66 (12.7%)	30 (22.2%)	23 (16.4%)
Previous stillbirth, miscarriage and loss (women with previous pregnancy)	Yes	181 (42.6%)	192 (43.3%)	59 (42.1%)	68 (47.2%)
Gestational diabetes	Yes	25 (5.8%)	32 (7.0%)	8 (5.6%)	11 (7.5%)
Preconception diabetes	Yes	19 (3.7%)	18 (3.4%)	7 (4.2%)	4 (2.4%)
Gestational hypertension	Yes	14 (3.3%)	20 (4.4%)	3 (2.1%)	6 (4.1%)
Chronic hypertension	Yes	31 (6.0%)	29 (5.5%)	13 (7.8%)	5 (3.0%)
Active smoking at baseline	Yes	106 (20.3%)	92 (17.6%)	38 (22.5%)	36 (21.6%)
ETSE at baseline	Yes	365 (71.4%)	377 (73.3%)	128 (77.1%)	130 (78.8%)
Depression at baseline	Yes	229 (44.0%)	234 (44.7%)	101 (59.8%)	106 (63.5%)
IPV at baseline	Yes	169 (32.4%)	167 (31.9%)	---	---
Active smoking prior to delivery	Yes	70 (16.6%)	65 (15.2%)	24 (17.8%)	26 (19.6%)
ETSE prior to delivery	Yes	247 (58.7%)	277 (65.2%)	82 (61.2%)	89 (66.9%)
Depression prior to delivery	Yes	152 (35.9%)	170 (39.8%)	71 (52.6%)	71 (53.4%)
Active smoking at postpartum	Yes	89 (21.9%)	106 (25.0%)	31 (22.8%)	44 (31.9%)
ETSE at postpartum	Yes	196 (48.5%)	233 (55.9%)	63 (46.7%)	85 (63.0%)
Depression at postpartum	Yes	90 (22.2%)	118 (27.8%)	39 (28.9%)	51 (37.0%)

Notes: (1) PNC: prenatal care; WIC: Supplemental Nutrition Program for Women, Infant and Children; TANF: Temporary Assistance for Needy Families; ETSE: Environmental Tobacco Smoke Exposure; IPV: Intimate Partner Violence

(2) All characteristics are measured at baseline except when noted otherwise.

Table 2. Comparison of Intervention and Usual Care Groups by Continued IPV

Characteristic	Intervention	Usual Care	<i>p</i> -value
IPV Victim at FU1	14/92 (15.2%)	32/105 (30.5%)	0.012
IPV Victim at FU2	10/110 (9.1%)	20/110 (18.2%)	0.050
IPV Victim at PP	17/134 (12.7%)	29/137 (21.2%)	0.063
IPV Victim at All FU1, FU2 and PP	35/150 (23.3%)	59/156 (37.8%)	0.006

Note: IPV: Intimate Partner Violence; U1: First Follow-up (22-26 weeks gestation) interview;
 FU2: Second Follow-up (34-38 weeks gestation) interview; PP: Postpartum interview

Table 3. Adjusted Odds Ratios* for the Impact of the Intervention on Various Categories of Intimate Partner Violence Victimization during Pregnancy and Postpartum

Intervention vs. Usual Care	Minor IPV	Severe IPV	Physical IPV	Sexual IPV
BL:				
N (%)	327 (31.4%)	185 (17.7%)	295 (28.3%)	153 (14.7%)
AOR (95% CI)	1.07 (0.81 – 1.40)	0.97 (0.70 – 1.35)	1.07 (0.81 – 1.42)	1.03 (0.72 – 1.47)
Absolute Risk Difference**	0.014	0.004	0.014	0.004
Number Needed to Treat (95% CI)***	---	---	---	---
FU1:				
N (%)	56 (9.5%)	24 (4.1%)	52 (8.8%)	22 (3.7%)
AOR (95% CI)	0.48 (0.26 – 0.86)	0.53 (0.22 – 1.27)	0.49 (0.27 – 0.91)	0.39 (0.15 – 1.03)
Absolute Risk Difference**	0.061	0.024	0.054	0.031
Number Needed to Treat (95% CI)***	17 (11 – 67)	---	18 (12 – 108)	---
FU2:				
N (%)	49 (6.8%)	16 (2.2%)	34 (4.7%)	23 (3.2%)
AOR (95% CI)	0.53 (0.28 – 0.99)	0.85 (0.31 – 2.33)	0.56 (0.27 – 1.17)	0.55 (0.23 – 1.32)
Absolute Risk Difference**	0.083	0.004	0.026	0.018
Number Needed to Treat (95% CI)***	12 (5 – 642)	---	---	---
PP:				
N (%)	72 (8.7%)	36 (4.4%)	62 (7.5%)	27 (3.3%)
AOR (95% CI)	0.56 (0.34 – 0.93)	0.39 (0.18 – 0.82)	0.47 (0.27 – 0.82)	0.99 (0.46 – 2.16)
Absolute Risk Difference**	0.045	0.037	0.050	0.001
Number Needed to Treat (95% CI)***	22 (14 – 146)	27 (20 – 96)	20 (14 – 61)	---

Notes: IPV: Intimate Partner Violence; BL: Baseline; FU1: First Follow-up (22-26 weeks gestation); FU2: Second Follow-up (34-38 weeks gestation); PP: Postpartum; AOR: Adjusted Odds Ratio; CI: Confidence Interval.

* Adjusted for alcohol use during pregnancy and depression at baseline.

** Absolute difference between intervention and usual care groups.

*** Number needed to treat is calculated for significant adjusted odds ratios and significant risk differences.

Table 4. Pregnancy Outcomes among Women Experiencing Intimate Partner Violence throughout Pregnancy and Postpartum by Care Group

Characteristic	Intervention (n=150)	Usual Care (n=156)	<i>p</i> -value
LBW	17 (12.8%)	24 (18.5%)	0.204
VLBW	1 (0.8%)	6 (4.6%)	0.052
Birth Weight (grams): Mean \pm SD	3139 \pm 593	3098 \pm 717	0.618
PTB	18 (13.0%)	27 (19.7%)	0.135
VPTB	2 (1.5%)	9 (6.6%)	0.030
Gestational Age at Delivery (weeks) : Mean \pm SD	38.2 \pm 3.3	36.9 \pm 5.9	0.016

Note: LBW: Low Birth Weight; VLBW: Very Low Birth Weight; PTB: Preterm Birth; VPTB: Very Preterm Birth; SD: Standard Deviation