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2008

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Ayman El-Mohandes
CUNY School of Public Health

Michele Kiely
CUNY School of Public Health

Jill G. Joseph
Children's National Medical Center

Siva Subramanian
Georgetown University

Allan A. Johnson
Howard University

See next page for additional authors

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Authors

Ayman El-Mohandes, Michele Kiely, Jill G. Joseph, Siva Subramanian, Allan A. Johnson, Susn M. Blake, Marie G. Gantz, and M. Nabil El-Khorazaty



Published in final edited form as:

Obstet Gynecol. 2008 September ; 112(3): 611–620.

An Integrated Intervention in Pregnant African Americans Reduces Postpartum Risk: A Randomized Trial

Ayman A.E. El-Mohandes, MD, MPH¹, Michele Kiely, DrPH², Jill G. Joseph, MD, PhD³, Siva Subramanian, MD⁴, Allan A. Johnson, PhD, LN⁵, Susn M. Blake, PhD, LCP¹, Marie G. Gantz, PhD⁶, and M. Nabil El-Khorazaty, PhD⁶

¹George Washington University, Washington, DC

²National Institutes of Health, Bethesda, MD

³Children's National Medical Center, Washington, DC

⁴Georgetown University, Washington, DC

⁵Howard University, Washington, DC

⁶RTI International*, Rockville, MD

Abstract

Objective—To evaluate the efficacy of an integrated multiple risk intervention delivered mainly during pregnancy, in reducing such risks (smoking, environmental tobacco smoke exposure, depression and intimate partner violence) postpartum.

Design—Data from this randomized controlled trial were collected prenatally and on average 10 weeks postpartum in six prenatal care sites in the District of Columbia. African Americans were screened, recruited and randomly assigned to the behavioral intervention or usual care. Clinic-based, individually tailored counseling was delivered to intervention women. The outcome measures were number of risks reported postpartum and reduction of these risks between baseline and postpartum.

Results—The intervention was effective in significantly reducing the number of risks reported in the postpartum period. In Bivariate analyses, the intervention group was more successful in resolving all risks (47% compared with 35%, $p=0.007$), number needed to treat=9, 95% confidence interval [CI] 5-31) and in resolving some risks (63% compared with 54%, $p=0.009$), number needed to treat=11, 95% CI 7-43) as compared with the usual care group. In logistical regression analyses, women in the intervention group were more likely to resolve all risks (OR=1.86, 95% CI: 1.25-2.75) and in resolving at least one risk (OR=1.6, 95% CI: 1.15-2.22).

Conclusions—An integrated multiple risk factor intervention addressing psychosocial and behavioral risks delivered mainly during pregnancy can have beneficial effects in risk reduction postpartum.

Introduction and Background

Medical, behavioral, and psychosocial risks may influence the health of women and their infants starting at pre-conception through pregnancy, delivery, and postpartum period. Psychosocial and behavioral risk factors such as smoking, environmental tobacco smoke

Corresponding author: Ayman El-Mohandes, Department of Prevention and Community Health, School of Public Health and Health Services, George Washington University Medical Center, 2175 K Street, NW, Washington, DC 20037, US, 202-415-0416, FAX: 202-416-0433, sphaxe@gwumc.edu.

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

exposure (ETSE), depression and intimate partner violence (IPV) have been associated with adverse pregnancy outcomes and poor long term health.”¹⁻⁴ Interventions addressing such factors in pregnancy have been variably successful.^{5,6} Those with modest success addressed risk factors in isolation despite their frequent co-occurrence. More recent studies have adopted an integrated approach addressing multiple risks simultaneously.⁷ Such interventions, when tested in women in the childbearing age, may hold greater promise in reducing reproductive morbidities.⁶

The intensity of psychosocial and behavioral risk factors may vary during pregnancy and after delivery. For example, women who stop smoking early in pregnancy may be unable to maintain cessation following delivery.⁸ Depression may become intensified postpartum.^{9,10} IPV, a factor associated with poor pregnancy outcomes,^{11,12} may vary in frequency and intensity in pregnancy^{2,13} and after delivery.¹⁴ Similarly, attitudes toward avoidance of ETSE in pregnancy and postpartum may be influenced by parents' evaluation of risk, and perceived difficulty in maintaining a smoke free home environment.¹⁵ Interventions designed to reduce psychosocial and behavioral risk during pregnancy may have an impact beyond delivery.¹⁶ Evidence of such postpartum effects is demonstrated in some studies.^{17,18}

The purpose of this study is to evaluate the efficacy of a cognitive behavioral intervention delivered during pregnancy in reducing behavioral risks in the postpartum period. The risks addressed included depression, IPV, smoking and ETSE in a population of African American pregnant women.

Participants and Methods

Recruitment occurred at six prenatal care (PNC) clinics between July 2001 and October 2003. Primary and secondary hypotheses were specified in advance. To ensure statistical power for testing the hypotheses that the integrated intervention would achieve statistically significant reductions in the targeted risk factors, sample size determination was essential. Assuming a 5% level of significance, 80% power, 20% drop-out rate, and 20% loss to follow-up, a sample size of 1,750 pregnant women was required in order to retain 1,050 at the end of the study (525 in each care group). This number allowed detection of 10-20% reductions in risk-specific factors in the intervention group (IG) as compared to the usual care (UCG). Details are published in El-Khorazaty et al.¹⁹

During 28 months of recruitment, 4,213 women were approached for Audio-Computer Assisted Survey Interview screening, and 2,913 women consented. Eligibility criteria included minority status, age ≥ 18 years, ≤ 28 weeks of pregnancy, DC resident, English speaking, and reporting any of the four designated risks (active smoking, ETSE, depression, and IPV). Smoking was defined as smoking in the six months prior to pregnancy or since learning they were pregnant. ETSE was defined as exposure to smokers at home, in the same room, or in a car. Depression was evaluated using the Beck Depression Inventory II.^{20,21} For IPV, women were asked if a current or previous partner, boyfriend, husband, or baby's father had pushed, shoved, slapped, kicked, or physically hurt them or forced them to have sexual intercourse in the last year, or if they were afraid of their current partner. Eligible women were invited to participate and those interested consented to study participation.

A baseline interview gathered sociodemographic data and information on the designated risks. Survey data items assessing smoking and ETSE were taken or adapted from the Smoke-Free Families screening and baseline questionnaires,²² the 1990 and 1998 National Health Interview Survey supplements,²³⁻²⁶ and ETSE intervention studies.²⁷ Additional items assessed stage of change for smoking cessation^{28,29} and processes of change.³⁰ Depression was identified using the Hopkins Symptom Checklist, a validated, widely used depression score based on a set of

twenty items.^{31,32} Respondents rated each item on a 5-point scale from 0=Not at all to 4=Extremely distressed by various symptoms within the past month (e.g., poor appetite, feeling lonely or blue, restless sleep, thoughts of death and dying). Responses were summed, divided by 20, and resulting scores classified into one of two groups; $\leq .75$ = remission or no depression and $> .75$ depression. Survey items for IPV included the Conflict Tactics Scale³³⁻³⁵, a validated scale to measure risk of intimate partner violence and safety behaviors items.³⁶⁻³⁸ The conflict tactics scale measured annual frequency of physical assault and sexual coercion (partner to self). A single item assessed whether any IPV on the Conflict Tactics Scale occurred during pregnancy (either partner to self or self to partner). Active smoking was defined as smoking a puff of a cigarette in the previous week, ETSE as having been in the same room or area where someone was smoking in the past week; depression as having a score >0.75 on Hopkins Symptom Checklist; and IPV was confirmed if a woman reported being subjected to any of the actions on the revised Conflict Tactics Scale at least once by her partner in the past year. After telephone interview, women were randomized to IG or UCG.

Interventions for active and passive smoking were based on the Social Cognitive Theory^{39, 40} and the Transtheoretical Model.⁴¹ The smoking interventions used a Cognitive-Behavioral Therapy orientation⁴²⁻⁴⁴ tailored to individuals' "stage" of readiness for change. Active smoking intervention included the "Smoking Cessation or Reduction in Pregnancy Treatment" materials,⁴⁵⁻⁴⁷ and incorporated some content from the "Pathways to Change" manual.⁴⁸ ETSE intervention paralleled the active smoking intervention. The primary objectives were to promote smoking cessation, ETSE avoidance and/or reduction depending on the participants' readiness.

The cognitive behavioral therapy intervention for depression was adapted from a group intervention by Miranda and Munoz.⁴⁹ The IPV intervention was adapted from the Parker-McFarlane structured intervention,¹³ to individualized counseling sessions. Behavioral counseling for IPV was integrated from a brochure-based approach using Dutton's Empowerment theory⁵⁰ found to be effective in increasing safety behaviors and reducing IPV at 6 and 12 months postpartum.¹³ To be considered adequate, the intervention was intended to be delivered prenatally in a minimum of four sessions, with eight sessions considered complete. Up to two postpartum booster sessions were offered, reinforcing skills and goals and adapted to specific postpartum stressors.

The intervention delivered by Masters' degree trained counselors, lasted 36 ± 15 minutes per session prenatally and 38 ± 13 minutes postpartum. On average, participants attended 3.9 prenatal sessions and 0.8 postpartum sessions. Fifty-four percent of the IG attended at least 4 prenatal sessions, while 51% attended at least one postpartum. (For details on Project DC-HOPE, see El-Khorazaty et al.¹⁹). Eight women (6 IG and 2 UCG) were identified as suicidal (during intervention or data collection) and were referred immediately to mental health care and excluded from further participation. The anticipated additional cost to providing the intervention would be the hiring of a Master's level social or mental health professional and the space needed to deliver the service privately. Additional infrastructure costs are limited.

Women randomized to IG received behavioral counseling addressing the risk factors they reported. Two follow-up interviews were administered during the second trimester (22-26 weeks gestation) and third trimester (34-38 weeks gestation). A final interview was conducted at 10.3 weeks postpartum on average. During these interviews women were evaluated for smoking, depression, and ETSE using same the definitions as at baseline. IPV was defined as victimization during the time interval between two consecutive interviews. Interviewers were blinded to group assignment, while participants and the intervention team were not.

To preserve the randomization, participant data were analyzed according to their randomized group assignment, regardless of receipt of intervention, using an intent-to-treat approach. Of the 913 African American women with one or more risks at baseline, 723 participated in the postpartum telephone interview. In order to make an intent-to-treat analysis possible, multiple imputation (MI) methodology was implemented to estimate missing data for the remaining 190 (49 drop-outs, 111 lost to follow-up, and 30 deemed ineligible) using the sequential regression imputation method described by Raghunathan, et al.⁵¹ A linear, logistic, or polytomous regression model was used to impute continuous, binary, or categorical missing values. MI was performed to create five complete datasets, using IVEware imputation and variance estimation software.⁵²

Analyses were conducted for each of the five imputed datasets and the results were combined results using the MIANALYZE procedure in SAS⁵³ to obtain the multiple imputation inference. The final parameter estimates and the associated standard errors account for both within- and between-imputation variance. Basic descriptive statistics provided information regarding characteristics of participating women stratified by randomization assignment. Comparisons were conducted using General Linear Models for continuous variables and Generalized Linear Models for categorical variables. The GLM and GENMOD procedures in SAS were used. Frequencies presented in the tables are rounded to the nearest integer.

To quantify postpartum behavioral changes and to assess effects of the intervention, the distributions of risks in the two randomized groups at baseline and postpartum were compared. Within-person changes in number of risks over time was also evaluated. Each woman was characterized with respect to number of risks (1-4) at baseline. Each of the 913 participants was categorized postpartum in one of three ways: (1) Resolving all risks (RA); (2) Resolving some, but not all, risks (RS); and (3) Resolving no risks or increasing the number of risks (RN).

Intervention effectiveness was measured contrasting the proportion of women RA versus the proportion RN in the two groups. The proportions of participants resolving all or some risk were also compared between groups. To evaluate the impact of the intervention on risk status at postpartum, we used logistic regression analyses. Analyses were conducted using the LOGISTIC procedure in SAS version 9.1.⁵³ Control variables included age; education; marital status; employment status; enrollment in Medicaid and WIC; illicit drug and alcohol use at baseline; previous premature delivery, pregnancy loss, or live birth; time of PNC initiation; gestational age at baseline; smoking, ETSE, depression, and IPV at baseline.

All study related activities were approved by the Howard University IRB, the designated IRB of record for the clinical study sites, the RTI International IRB and the National Institute of Child Health and Human Development IRB.

Results

A total of 1,398 women met eligibility requirements (See Figure 1), of whom 85% (1,191) consented to participate in a baseline telephone interview before randomization; 1,070 (89.8%) completed the baseline interview. Of those, 157 were excluded from further analysis due to completion of pregnancy (n=4) before baseline interview or other than African American minority status (n=22). In addition, because of using different instruments (Audio-Computer Assisted Survey interview and baseline interview) were used to assess risks, 131 women who were screened-in to the study showed no risk at baseline interview and were excluded. Site- and risk-specific block randomization was conducted following the baseline interview. Of those African American pregnant women with risk reported at baseline, 452 were randomized to the IG and 461 to the UCG. (See Figure 1). 723 (79.2%) women were contacted postpartum, 350 were in the IG and 373 in the UCG (See Figure 1).

Characteristics of study participants are described in Tables 1 and 2. No significant differences were detected when comparing IG to UCG or all participants to those retained in the study in the postpartum period. (For more information on retention, see El-Khorazaty et al.¹⁹). At baseline, ETSE was most commonly reported risk (82.7%), followed by depression (50.7%) and IPV (36.8%) among those with at least one risk. The least common risk at baseline was active smoking, reported by 21.7%. Approximately 72.5% of participants reported one or two risks, while 27.5% of participants had three to four risks. Women exposed only to ETSE represented the highest percentage (28.2% of the 913), followed by women exposed to ETSE and depression (14.5%), those exposed to ETSE, depression and IPV (13.8%), women who were exposed to ETSE and IPV (7.7%), and those with depression only (7.0%) (data not shown). Women reporting all four risks represented 4.1% of the sample.

Significant reductions ($p<0.001$) between baseline and postpartum were observed for ETSE (82.7% to 54.8%), depression (50.7% to 27.3%), and IPV (36.8% to 9.9%). Consistent with postpartum relapse reported in previous studies, there was considerable recidivism in cigarette smoking at postpartum (21.7% to 26.5%, $p=0.021$). The number of risks reported at postpartum was lower than that at baseline. Overall, 28.5% of women with risk at baseline reported none at postpartum ($p<0.001$).

There were no significant differences in reporting of risks at baseline between the IG and UCG (Table 3). Comparing risk-specific change between baseline and the postpartum period in the two groups, the resurgence in smoking rates is significantly higher in the UCG ($p<0.001$), while the reduction in ETSE is significantly higher in the IG ($p=0.011$). No significant differences were seen in the change for depression and IPV between the two groups.

Table 4 presents number of risks at baseline and postpartum. While there were no significant differences at baseline, but at postpartum the IG and UCG differed significantly ($p=0.033$). Additional analyses comparing the two groups in the postpartum period revealed a significant difference in the distribution of risks. In the IG, 32.1% reported no risk compared to 24.9% of the UCG ($p=0.031$). For the IG, 8.6% reported three or more of the designated risks combined, compared to 12.3% of the UCG ($p=0.074$).

In Table 5, bivariate analyses compare risk resolution by care group. RA or RS for risks encountered at baseline are compared to RN. Comparison of the three categories of risk resolution in an unadjusted generalized linear model for the IG and UCG was significant ($p=0.005$). The IG shows a significantly higher percentage of RA or RS (63%) as compared to the UCG (54%). Resolution of RA versus RN and RS versus RN are compared separately, with significant differences between groups ($p=0.007$, $p=0.009$, respectively). The number needed to treat (NNT) (average number of mothers needed to receive the intervention for one additional woman to resolve risks over usual care mothers) is 14 women (95% CI: 7,139) to resolve some risks, 9 (95% CI: 5,31) to resolve all risks, and 11 (95% CI: 7,43) to resolve some or all risks.

Table 6 presents the results of multiple logistic regression models predicting risk resolution, either RA or RS. Participation in the IG was associated with RA vs. RN (OR=1.86, 95% CI: 1.25-2.75, NNT=7, 95% CI: 4, 19) and RA or RS vs. RN (OR=1.60, 95% CI: 1.15-2.22, NNT=9, 95% CI: 6, 29) in the postpartum period. Resolution of risk was associated in both models with depression, IPV, or ETSE documented in participants at baseline. In contrast, cigarette smoking at baseline reduced the odds of RA ($p<0.001$). Use of illicit drugs during pregnancy as reported at baseline reduced the odds of RA ($p=0.014$); alcohol use during pregnancy at baseline had a similar effect on reduction of RS ($p=0.018$). Employment during pregnancy was associated with increased odds ratio of RA ($p=0.020$).

Discussion

This study recruited minority women with psychosocial and behavioral risks seeking health care at urban PNC sites. These mothers brought other challenges to their pregnancies that could not or were not addressed by the intervention, including unmet economic needs, a low level of education, and associated behavioral challenges, including alcohol and drug use. Despite their poor reproductive profile (with high rates of miscarriage, stillbirth, and previous preterm delivery) and the low level of intendedness for the pregnancy, they sought PNC relatively early and used the prenatal health care delivery system at least 4 times in 85% of cases. Despite these constraints and the challenges of an overwhelmed health care system, we were able to demonstrate the efficacy of a cognitive behavioral intervention during the postpartum period.

The prenatal intervention as designed could be delivered during pregnancy at a minimum of four visits, well within a manageable range for this population. The mean time of 36 minutes for an individual intervention fits easily into the waiting periods between services provided. An important element for intervention feasibility was a judicious selection of interventions from a spectrum of risks that could be effectively addressed without being overwhelming to either patients or providers.

This intervention was successful in risk reduction without addressing associated alcohol and drug use. Both factors showed significant interference with the intervention effect, suggesting the importance of addressing them in future multiple risk factor interventions. Employment at the time of recruitment enhanced the intervention effect. This finding could be related to underlying characteristics of women who sought and secured employment, such as education, life skills, and self-efficacy, or a reflection of the employment status itself, including income, access to care, and overall level of organization and lifestyle.

We demonstrated the utility and feasibility of using an innovative, integrated approach. It is important to consider the fact that the intervention showed postpartum efficacy on a combination of risks that included smoking, a behavior with known recidivism. Postpartum effects of this intervention would very likely have been even higher if this risk factor were excluded. It is also possible that these effects could wane with time, causing the re-emergence of risks. Women in the IG may hypothetically retain coping and behavioral modification skills learned during the intervention, which could assist them in maintaining their behavioral gains for a longer period. We would recommend, in future studies, following these mothers for longer intervals to measure sustained effects.

A limitation of this study was the inability to deliver the minimum number of intervention sessions to 46% of the participants. Whether intervention delivery would be further compromised when tested for effectiveness under non-experimental conditions remains to be seen. The delivery of the postpartum booster sessions was limited to one to two sessions only, which may not have been adequate, especially in the case of depression. Successful cognitive behavioral therapy interventions addressing postpartum depression were much more intensive (up to 8 weekly home visits).⁵⁴ More modest interventions, including a single encounter with a mental health provider, did not show efficacy.⁵⁵ Our decision to exclude anxiety as a targeted risk factor may also have affected the efficacy of the intervention. There is growing evidence in the literature that anxiety and depression show significant overlap and are best addressed simultaneously.^{1,56} Future intervention design may include antidepressants. Including fathers could have improved efficacy, especially in smoking and ETSE. Including partners has also been shown to improve the chance of postnatal effects of interventions addressing postpartum distress and depression¹⁷. Finally these intervention effects may apply only to high risk minority pregnant women. It would be important to test this intervention in other racial or socio-demographic groups to show whether results can be generalized. Another significant

limitation is the high rate of loss-to-follow-up (20% of participants). Our effort to adjust through implementation of multiple imputation methodology can only partially compensate for attrition in a study designed to measure outcomes based on an intent-to-treat approach.

This study suggests that a multiple risk factor intervention that addresses both psychosocial and behavioral risks can be effective in reducing those risks when delivered during pregnancy and reinforced during the postpartum period. This intervention was delivered within the constraints of the existing PNC delivery system and confirms the willingness of high-risk, urban minority populations to participate in such interventions. The sustained postpartum effects were only tested on average 10 weeks postnatally. But even within that time period, the intervention appears to have benefited these mothers in terms of risk behaviors in the short run, and could ultimately influence the health and wellbeing of their infants long-term. Extending similar services within existing outreach programs (e.g., Healthy Families USA) may ensure better delivery of such interventions and require minimal additional infrastructural support.

Acknowledgments

This study was supported by grants no. 3U18HD030445; 3U18HD030447; 5U18HD31206; 3U18HD031919; 5U18HD036104, National Institute of Child Health and Human Development and the National Center on Minority Health and Health Disparities. Some of the findings were presented at the 2007 Pediatric Academic Societies' Annual Meetings.

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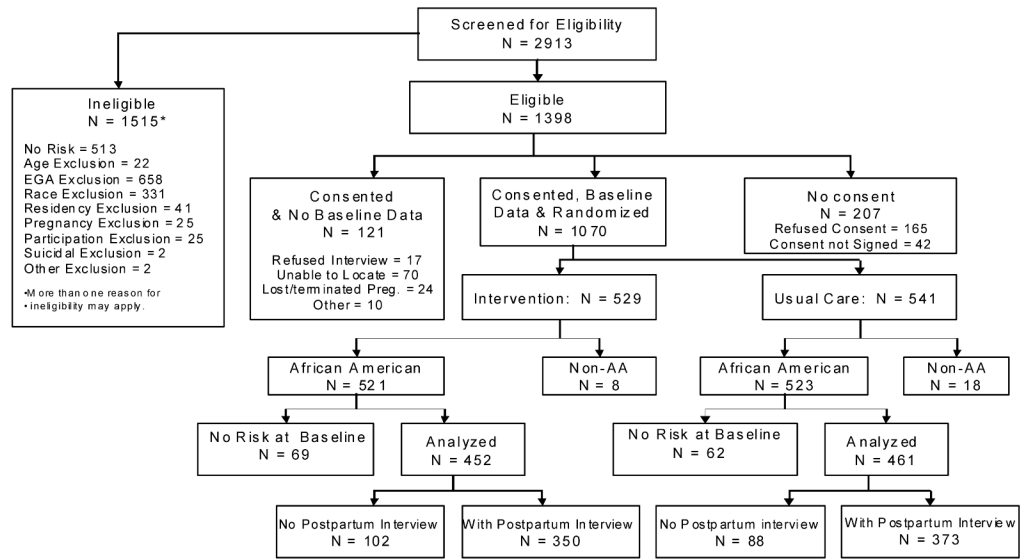


Figure 1. Screening, Eligibility, Recruitment, Randomization & Follow-up: Project DC-HOPE
 * 157 women were excluded from analysis either because they were non-AA (22), pregnancy loss (4), or because they had no risk at baseline (131).

Table 1
Participant characteristics self-reported at baseline

Characteristics	Category	Intervention (N=452)	Usual Care (N=461)	P-value
Maternal age	Mean ± SE	24.4 ± 0.3	24.8 ± 0.3	0.217
Education level	< High school	141 (31.3%)	143 (31.0%)	0.649
	HS graduate/GED	214 (47.3%)	210 (45.6%)	
	At least some college	97 (21.4%)	108 (23.4%)	
Currently working	Yes	157 (34.8%)	167 (36.2%)	0.648
Worked prior to pregnancy [^]	Yes	164 (55.8%)	174 (59.7%)	0.339
Relational status	Single/separated/ widowed/divorced	341 (75.5%)	353 (76.6%)	0.686
	Married or living with partner	111 (24.5%)	108 (23.4%)	
Household size	Mean ± SE	3.9 ± 0.1	4.0 ± 0.1	0.161
Medicaid	Yes	366 (80.9%)	355 (77.0%)	0.153
WIC	Yes	203 (44.9%)	195 (42.2%)	0.422
Alcohol use during pregnancy	Yes	103 (22.7%)	105 (22.8%)	0.969
Illicit drug use during pregnancy	Yes	66 (14.6%)	54 (11.7%)	0.201
Previous pregnancy	Yes	377 (83.4%)	397 (86.1%)	0.252
Gravidity	Mean ± SE	3.7 ± 0.1	3.8 ± 0.1	0.576
Previous live birth	Yes	306 (67.7%)	327 (70.9%)	0.290
Number of live births [†]	Mean ± SE	2.2 ± 0.1	2.2 ± 0.1	0.980
Previous miscarriage [*]	Yes	147 (38.9%)	155 (39.1%)	0.967
Previous stillbirth [*]	Yes	16 (4.2%)	23 (5.8%)	0.325

[^] among women not currently working

^{*} among women with a previous pregnancy.

[†] among women with a previous live birth.

Table 2
Comparison of Enrolled and Retained Participants in the Postpartum Period

Characteristics	Category	All participants (N=913)	Women with Postpartum interview (N=723)	P-value
Sociodemographic Characteristics				
Maternal age	Mean (years) ± SE	24.6 ± 0.2	24.7 ± 0.2	0.752
Education level	< High school	284 (31.1%)	219 (30.3%)	0.715
	HS graduate/GED	424 (46.5%)	338 (46.8%)	
	At least some college	205 (22.4%)	166 (22.9%)	
Currently working	Yes	324 (35.5%)	262 (36.3%)	0.750
Worked prior to pregnancy [^]	Yes	338 (57.7%)	274 (59.8%)	0.508
Relational status	Single/separated/widowed/divorced	694 (76.0%)	539 (74.6%)	0.498
	Married or living with partner	219 (24.0%)	184 (25.4%)	
Household size	Mean ± SE	3.9 ± 0.1	3.9 ± 0.1	0.828
Medicaid (Baseline interview)	Yes	720 (78.9%)	570 (78.8%)	0.972
WIC (Baseline interview)	Yes	398 (43.5%)	314 (43.4%)	0.943
Other Exposures During Pregnancy				
Alcohol use during pregnancy (Baseline interview)	Yes	208 (22.7%)	167 (23.0%)	0.885
Illicit drug use during pregnancy (Baseline interview)	Yes	120 (13.1%)	96 (13.3%)	0.937
Reproductive History				
Gravidity (Baseline interview)	Mean ± SE	3.8 ± 0.1	3.7 ± 0.1	0.773
Number of live births [†]	Mean ± SE	2.2 ± 0.1	2.1 ± 0.1	0.548
Previous miscarriage (Baseline interview) [*]	Yes	302 (39.0%)	243 (39.1%)	0.968
Previous stillbirth (Baseline interview) [*]	Yes	39 (5.0%)	32 (5.2%)	0.923
Previous premature delivery (Baseline abstraction) [‡]	Yes	114 (18.1%)	91 (18.2%)	0.956
Pregnancy 'intended'	Yes	304 (33.3%)	233 (32.2%)	0.655
Pregnancy 'wanted'	Yes	693 (75.9%)	547 (75.6%)	0.878
Trimester of PNC initiation	1st Trimester	551 (60.3%)	441 (60.9%)	0.817
	2nd Trimester	344 (37.7%)	268 (37.1%)	
	3rd Trimester	18 (2.0%)	14 (2.0%)	
Number of PNC visits	1-3 visits	140 (15.4%)	105 (14.5%)	0.427
	4-8 visits	278 (30.4%)	211 (29.1%)	
	9+ visits	495 (54.2%)	407 (56.3%)	
Risk Status at Baseline				
Active smoking	Yes	198 (21.7%)	152 (21.0%)	0.745
ETSE	Yes	755 (82.7%)	599 (82.9%)	0.904
Depression	Yes	463 (50.7%)	367 (50.7%)	0.985
IPV	Yes	336 (36.8%)	274 (37.9%)	0.650

Characteristics	Category	All participants (N=913)	Women with Postpartum interview (N=723)	<i>P-value</i>
Number of risks	1	363 (39.8%)	288 (39.9%)	0.889
	2	299 (32.7%)	230 (31.9%)	
	3	213 (23.3%)	174 (24.1%)	
	4	38 (4.1%)	30 (4.1%)	

[^] among women not currently working

^{*} among women with a previous pregnancy.

[†] among women with a previous live birth.

Table 3
Individual Risk Factor Change in the Intervention and Usual Care Groups Comparing
Baseline to Postpartum (N=913) (Combined Five Imputed Datasets[#])

Characteristics	Intervention (N=452)	Usual Care (N=461)	<i>P</i> -value (IG vs. UCG)
Smoking at baseline interview	106 (23.4%)	92 (20.0%)	0.205
Smoking at postpartum interview	116 (25.6%)	126 (27.3%)	0.580
Change in percent [†]	2.2%	7.3%	<0.001
ETSE at baseline interview	372 (82.2%)	383 (83.1%)	0.712
ETSE at postpartum interview	233 (51.6%)	267 (57.9%)	0.055
Change in percent [†]	-30.6%	-25.2%	0.011
Depression at baseline interview	229 (50.6%)	234 (50.8%)	0.961
Depression at postpartum interview	115 (25.5%)	134 (29.0%)	0.303
Change in percent [†]	-25.1%	-21.8%	0.100
IPV at baseline interview	169 (37.4%)	167 (36.2%)	0.727
IPV at postpartum interview	39 (8.6%)	52 (11.3%)	0.216
Change in percent [†]	-28.8%	-24.9%	0.074

[#]Frequencies are averaged over the five imputations and rounded to the nearest integer.

[†]A positive percentage indicates increased risk from baseline to postpartum while a negative percentage indicates a decreased risk.

Table 4
Comparison of Risk Factors in the Intervention and Usual Care Groups at Baseline and Postpartum Interviews for Women with At Least One Risk (Combined Five Imputed Datasets[#])

Characteristic	Category	Intervention (N=452)	Usual Care (N=461)	<i>P</i> -value ^{##} (IG vs. UCG)
Number of risks at baseline (smoking, ETSE, depression, IPV)	1	173 (38.3%)	190 (41.2%)	0.526
	2	154 (34.1%)	144 (31.3%)	
	3	105 (23.2%)	108 (23.5%)	
	4	20 (4.4%)	18 (3.9%)	
Number of risks at postpartum (smoking, ETSE, depression, IPV)	0	145 (32.1%)	115 (24.9%)	0.033
	1	158 (34.9%)	178 (38.7%)	
	2	110 (24.4%)	111 (24.1%)	
	3	31 (6.8%)	49 (10.6%)	
	4	8 (1.8%)	8 (1.7%)	

[#]Frequencies are averaged over the five imputations and rounded to the nearest integer.

^{##}Using Generalized Linear Modeling.

Table 5
Risk Resolution between Baseline and Postpartum Interviews by Care Group (Combined Five Imputed Datasets)

Resolution	Category	Intervention (N=452)	Usual Care (N=461)	P-value# (IG vs. UCG)	Odds Ratio (95% CI)	Absolute Risk Difference	Number Needed to Treat (95% CI)
A. Distribution of Risk Resolution							
Risks resolved	None (or increased): RN	166 (36.6%)	212 (46.1%)	0.005			
	Resolved Some: RS	141 (31.3%)	134 (29.0%)		1.34 (0.97, 1.86)	0.06	14 (7, 139)
	Resolved All: RA	145 (32.1%)	115 (24.9%)		1.62 (1.15, 2.29)	0.10	9 (5, 31)
B. Comparison of Risk Resolution							
Resolved all risks vs. none (RA vs. RN)	Yes	145 (46.7%)	115 (35.1%)	0.007	1.62 (1.15, 2.29)	0.12	9 (5, 31)
	No	166 (53.3%)	212 (64.9%)				
Resolved some or all risks vs. none (RA or RS vs. RN)	Yes	287 (63.4%)	248 (53.9%)	0.009	1.48 (1.10, 1.98)	0.10	11 (7, 43)
	No	166 (36.6%)	212 (46.1%)				

Note: Column totals do not add up because of rounding of the five imputations to the nearest integer.

Using Generalized Linear Modeling.

Table 6
Results of Multiple Logistic Regression Models[#] Predicting Various Risk Resolution Categories at Postpartum Interview

Parameters	Category	P-value	Odds Ratio	95% CI for OR
A. Women resolved all risks vs. women resolved no risks at postpartum (RA vs. RN) (N=638)				
Intercept		<.001	0.22	(0.12, 0.41)
Care group	IG vs. UCG	0.002	1.86	(1.25, 2.75)
Current employment	Y vs. N	0.020	1.53	(1.07, 2.19)
Illicit drugs (baseline interview)	Y vs. N	0.014	0.39	(0.19, 0.82)
Active smoking at baseline	Y vs. N	<.001	0.32	(0.18, 0.59)
ETSE at baseline	Y vs. N	0.020	1.74	(1.09, 2.77)
Depression at baseline	Y vs. N	0.028	1.55	(1.05, 2.30)
IPV at baseline	Y vs. N	<.001	2.61	(1.66, 4.11)

B. Women resolved at least one risk vs. women resolved no risks at postpartum (RA or RS vs. RN) (N=913)				
Intercept		<.001	0.15	(0.09, 0.25)
Care group	IG vs. UCG	0.005	1.60	(1.15, 2.22)
Alcohol use (baseline interview)	Y vs. N	0.018	0.58	(0.38, 0.91)
ETSE at baseline	Y vs. N	<.001	3.46	(2.25, 5.33)
Depression at baseline	Y vs. N	<.001	3.62	(2.59, 5.06)
IPV at baseline	Y vs. N	<.001	4.82	(3.31, 7.02)

[#] Covariates screened for significance include maternal age; education; marital status; employment status; enrollment in Medicaid and WIC; illicit drug and alcohol use at baseline; previous premature delivery, pregnancy loss, or live birth; early initiation of prenatal care (PNC); gestational age at baseline; smoking, ETSE, depression and IPV at the time of the Baseline interview.