2019

Predictors of Peripartum Care Attendance Among a Sample of African American Women at Increased Risk for Poor Prenatal Care Compliance

Anna B. Parlier-Ahmad

Virginia Commonwealth University

Predictors of Peripartum Care Attendance Among a Sample of African American Women at Increased Risk for Poor Prenatal Care Compliance

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science at Virginia Commonwealth University.

by
Anna Beth Parlier-Ahmad, B.S.
University of North Carolina Asheville, December 2012

Director: Dace S. Svikis, Ph.D.
Professor, Department of Psychology

Virginia Commonwealth University
Richmond, Virginia
December, 2019

Acknowledgements

I would like to thank my advisor and committee chair, Dr. Dace S. Svikis, for her mentorship and encouragement throughout this project. Her continued support and investment in my personal and professional growth has been instrumental in my graduate training thus far. I would also like to thank my other committee members, Drs. Lori Keyser-Marcus and Paul Perrin, in advance for their guidance and expertise. In addition, I would like to thank Diane Bishop for providing statistical consultation and guidance on this project. Finally, I would like to thank my family and friends for their continued support and encouragement.

Table of Contents

List of Tables

Abstract

PREDICTORS OF PERIPARTUM CARE ATTENDANCE AMONG A SAMPLE OF AFRICAN AMERICAN WOMEN AT INCREASED RISK FOR POOR PRENATAL CARE COMPLIANCE

By Anna Beth Parlier-Ahmad, B.S.
Director: Dace S. Svikis, Ph.D., Professor, Department of Psychology
Virginia Commonwealth University, 2019

Prenatal and postpartum care are important for reducing maternal and infant morbidity. Racial and ethnic disparities are prevalent in maternal peripartum health and infant birth outcomes as well as peripartum care access and utilization. They highlight the need to identify and better understand correlates of poor prenatal and postpartum care compliance. While risk factors for low adherence to peripartum care have been identified, no studies have looked specifically at predictors of prenatal and postpartum care attendance in an at-risk sample of African American pregnant women. Using existing data from an RCT targeting maternal and infant health disparities and comparing a patient navigation/behavioral incentive intervention to treatment as usual, the present study sought to identify predictors of prenatal and postpartum care attendance. Participants were African American women at risk for poor prenatal care compliance, who participated in the RCT and had a documented live birth (n=123). Using hierarchical linear and logistic regression, the study identified predictors of prenatal and postpartum care attendance, respectively. The study found high-risk pregnancy ($p < .001$) and fewer barriers to care ($p = .013$) significantly predicted better prenatal care attendance. Less than adequate prenatal care attendance significantly predicted postpartum visit nonattendance ($p < .001$).

In addition, given that study participants were limited to women who provided informed consent to RCT participation, the present study also examined representativeness of the clinical trial sample. Specifically, women who consented to the RCT (consenters; n=149) were compared

to those who did not (non-consenters; n=122) on a variety of demographic and psychosocial variables using chi-square for categorical variables and t-tests for continuous variables. Consenters and non-consenters differed only on education level, with consenters more likely to have at least a high school education than non-consenters. The present study provides benchmark data on sample representativeness and predictors of peripartum care in a clinical trial of strategies to improve prenatal care compliance. These findings could have important implications for healthcare system changes and treatment interventions among this population.

Predictors of Peripartum Care Attendance Among a Sample of African American Women at Increased Risk for Poor Prenatal Care Compliance

Within clinical research, randomized controlled trials (RCTs) are widely recognized as the "gold standard" for treatment efficacy research. However, rigorous inclusion criteria, narrow recruitment and retention strategies, and a lack of culturally sensitive research approaches often lead to relatively homogeneous samples limiting the generalizability of RCT findings. In particular, women and racial and ethnic minority group members are understudied, making it important to examine the extent to which findings obtained from predominantly White males generalize to such underrepresented subgroups.

Improvements have been spearheaded by NIH policy changes like the Revitalization Act (NIH, 2017). Despite these efforts, women and minorities continue to be underrepresented contributing to significant differences between RCT participants and patients in community-based settings (Chen, Lara, Dang, Paterniti, & Kelly, 2014; George, Duran, & Norris, 2014; Hall, 1999; Humphreys, Maisel, Blodgett, & Finney, 2013; Humphreys, Weingardt, & Harris, 2007; Mak, Law, Alvidrez, Perez-Stable, 2007).

The publication and adoption of the CONSORT guidelines has helped improve tracking and reporting of study enrollment and attrition rates as well as helped bring greater attention to how research participants and nonparticipants differ (Kelpin, 2016; Humphreys et al., 2013). Specifically, some studies have found research participants tend to have lower risk profiles compared to the population at large (Kennedy-Martin, Curtis, Faries, Robinson, & Johnston, 2015; Gesche, Renault, Norgaard, & Nilas, 2014).

Historically, characteristics of individuals who consented to participate in an RCT and those who were eligible but declined to participate were limited to basic demographic variables

(e.g., gender, age; Park, Adams, & Lynch, 1998). Recently, a broader range of variables have been assessed, mostly through information obtained during the screening process to determine eligibility for the clinical trial. The few studies conducted have identified group differences in socioeconomic status, condition severity and/or level of impairment (e.g., Kelpin, Ondersma, Weaver, & Svikis, 2018; Kennedy-Martin et al., 2015; Lally et al., 2018).

Little is known about within group differences in underrepresented and minority groups for whom additional, potentially different, barriers may be associated with the decision not to participate in research. For example, it is well-established that women and racial minorities often face greater barriers to research participation including lack of childcare, lack of transportation, financial constraints, time constraints, and mistrust (Frew et al., 2014; George et al., 2014). Therefore, these groups warrant greater attention.

Using existing data from a CDC-funded RCT targeting health disparities in maternal and infant birth outcomes, the current study had a unique opportunity to compare psychosocial characteristics of pregnant, African American women at risk for poor prenatal care compliance who enrolled in an RCT investigating health care navigation and behavioral incentives to those who elected to decline study participation (Masho et al., 2011; Masho et al., 2013). The RCT compared an intervention that combined patient navigation and behavioral incentives to a usual care control group. Analyses found no intervention to control group differences in the primary outcome—prenatal care attendance—making sample representativeness of particular importance.

Racial and ethnic health disparities are prominent in maternal peripartum health and infant birth outcomes (ACOG, 2015; Partridge, Balayla, Holcroft, & Abenhaim, 2012) as well as peripartum care access and utilization (de Bocanegra, Braughton, Bradsberry, Howell, Logan, & Schwarz, 2017; Partridge et al., 2012; Rankin, Haider, Caskey, Chkraborty, Roesch, & Handler,

2016). It is well established that prenatal care and postpartum care are important determinants of maternal and infant health outcomes (ACOG, 2018; Partridge et al, 2012). Therefore, identifying predictors for prenatal and postpartum care nonattendance in African American women is a crucial step for improving attendance and reducing disparities.

Several risk factors associated with late initiation, very late initiation, and inadequate prenatal care have been identified among various samples of women in the United States. Multiple studies have found correlations between sociodemographic factors—such as younger age, single/never married, unemployment, public insurance, less than high school education, and low income—and poor prenatal care attendance (Osterman & Martin, 2018; Partridge et al., 2012). Reproductive history factors, such as parity and pregnancy intendedness can also play a role in prenatal care initiation and compliance (Baer et al., 2018; Orr, James, & Reiter, 2008). Other correlates of prenatal care nonattendance include mental health issues, substance use, and intimate partner violence (IPV), particularly surrounding the pregnancy period (Hensley, Sulo, Kozmic, & Parilla, 2018; Jamieson, 2018; Weir, Posner, Zhang, Willis, Baxter, & Clark, 2011).

In studies of the postpartum period, risk factors of postpartum care nonattendance have also been reported. Morgan and colleagues, for example, found younger age, less than high school education, unemployment, low income, and public or no insurance to be associated with poor postpartum care attendance. Women with substance use disorders are also less likely to attend postpartum visits than women without such disorders (Weir et al., 2018). In contrast, having a chronic health condition was correlated with higher odds of postpartum visit attendance (Bryant, Worjoloh, Caughey, & Washington, 2010). Mental health conditions have also been shown to be correlated with postpartum care attendance, but findings from studies of the relationship between mental health conditions and postpartum care attendance have been

inconsistent. Lastly, reproductive health, pregnancy specific factors, and birth outcomes have been shown to be correlates of postpartum care attendance (Chen, Hsia, Hou, Wilson, & Creinin, 2018; DiBari, Yu, Chao, & Lu, 2014; Masho et al., 2018; Weir et al., 2018).

While risk factors associated with late initiation, very late initiation, and inadequate prenatal care and postpartum care nonattendance have been identified, to our knowledge, there have not been other studies investigating predictors of prenatal and postpartum care attendance in African American women at risk for poor prenatal care compliance. The current study used data from the previously mentioned RCT targeting health disparities in maternal and infant birth outcomes to address this gap in the literature.

The specific aims of the current study were as follows:

Specific aim 1. Examine sample representativeness by comparing women who did and did not consent to RCT participation. Two hypotheses were tested:

1) Women who consent to the RCT will endorse fewer risk factor questionnaire items than those who do not consent to the research.
2) Women who enroll in the RCT will have lower scores on the risk factor questionnaire than women who decline study participation.

Specific aim 2. Identify sociodemographic, pregnancy specific, IPV, mental health, substance use, and social support variables predictive of prenatal care attendance within a sample of pregnant, African American women at risk for poor prenatal care compliance. The following hypothesis was tested:

1) When controlling for sociodemographic risk factors in the initial block and pregnancy risk level and reported barriers to prenatal care in the second block, the following factors will significantly improve the prediction for ratio attended to expected prenatal

care visits in the second block: Pregnancy intendedness, IPV, mental health, substance use, and social support.

Specific aim 3. Identify sociodemographic, adequacy of prenatal care, mental health, substance use, and birth outcome variables associated with postpartum care attendance within a sample of pregnant, African American women at risk for poor prenatal care compliance. The following hypothesis was tested:

1) When controlling for sociodemographic risk factors in the initial block and adequacy of prenatal care in the second block, the following factors will significantly improve the prediction for the number of postpartum care visits attended in the third block: Mental health, substance use, and maternal and infant birth outcomes.

Review of Literature

Representativeness and Generalizability of Clinical Trials

Randomized clinical trials (RCTs). RCTs are widely regarded as the "gold standard" for treatment efficacy research. Rigorous inclusion criteria for RCT enrollment, however, often lead to homogeneous samples of individuals that no longer represent the broader, more heterogeneous population from which they were drawn. Strict eligibility criteria, limited recruitment and retention strategies, and a lack of culturally sensitive research approaches limit sample heterogeneity and thereby generalizability of study findings (George et al., 2014; Humphreys et al., 2013). In particular, females and racial and ethnic minority group members are understudied, making it important to examine the extent to which findings obtained from predominantly white males generalize to such underrepresented subgroups.

Federal legislation. Over the last three decades, the National Institutes of Health (NIH) has begun to address limits in generalizability and representativeness of RCT findings. In the

early 1990s, the NIH passed the Revitalization Act requiring racial and ethnic minorities and women be included in clinical research unless inclusion was deemed inappropriate due to health, the purpose of research, or other circumstances approved by NIH (NIH, 2017). The Office of Research on Women's Health (ORWH) was established to help address the lack of inclusion of women in research and address gaps in scientific knowledge about women's health across the lifespan (Blehar et al., 2013). Even with legislation to help develop more inclusive research samples, racial and ethnic minorities and women remain underrepresented contributing to significant differences between RCT participants and patients cared for in community-based settings (Chen et al., 2014; Hall, 1999; Humphreys et al., 2007; Mak et al., 2007).

Reporting guidelines. In the mid-1990s, an international group of clinical researchers, statisticians, epidemiologists, and biomedical editors published the Consolidated Standards of Reporting Trials (CONSORT) statement. The statement provides guidance for researchers on essential information to report so consumers of research can make informed judgments regarding the internal and external validity of study findings (Begg et al., 1996). The CONSORT statement recommends the use of a flow diagram to provide information about the original size of the sample, the number excluded from the study, attrition rates, the number of participants in each study arm and whether the authors conducted an intention-to-treat analysis. The CONSORT guidelines have contributed to significant improvement in quality of reporting in clinical research.

Prior to the development of the CONSORT statement, individual differences among those who participated in clinical research and those who did not received little attention. The CONSORT flow diagram has helped increase awareness, and greater attention is now being paid to how research participants differ from those who do not participate (Kelpin, 2016; Humphreys

et al., 2013). Studies have found, for example, that research participants often have lower risk profiles compared to "real-world" populations, mostly due to strict eligibility criteria (Kennedy-Martin et al., 2015; Gesche et al., 2014).

Although CONSORT guidelines have provided improved tracking of participants and encouraged transparency from the research community on enrollment and attrition, the majority of studies provide little information about individuals who meet RCT eligibility criteria but then decline further study participation (Egger, Juni, & Bartlett, 2001). Historically, available information was limited to demographic variables such as gender and race (Park et al., 1998). More recently, RCTs in medical settings have used anonymous screeners to determine eligibility for an RCT, thereby providing an opportunity to compare, within a sample of RCT eligible individuals, characteristics of those who consent to the clinical trial and those who decline further participation (e.g., Kelpin et al., 2018; Lally et al., 2018; Unger, Gralow, Albain, Ramsey, and Hershman, 2017).

Published findings have yielded varied results. Kelpin and colleagues (2018), for example, in a sample of primary care patients who met criteria for heavy/problem alcohol and/or drug use, found those giving informed consent to an RCT were more likely to report a variety of psychosocial and mental health problems, often of greater severity, than those who declined participation. In a cancer clinical trial, eligible patients with lower income (<$50,000 annual income) and education were less likely to participate in research than those with higher income and education levels (Unger et al., 2017). In a study of a lifestyle intervention for patients with severe mental illness, Lally and colleagues (2018) found that individuals giving informed consent had lower illness severity and less functional impairment than those not enrolled in the RCT.

Special Populations. Even though there is increasing information about who agrees to participate in medical research and who does not, less is known for members of racial and ethnic minority groups and women. To date, most studies comparing those who consent to clinical trials and those who do not have enrolled males and females as well as minority and non-minority group members. However, studies do not specifically compare within group characteristics associated with research participation. Therefore, less is known about characteristics associated with a decision to consent to RCT participation in such underrepresented groups, where additional barriers and other unique factors may be associated with a decision not to enroll in a clinical trial.

It is well-established that many women face greater barriers to RCT participation than men including lack of child care, time constraints, lack of transportation, and other access issues (Frew et al., 2014). Additionally, women who struggle with intimate partner violence, mental health issues, and substance use problems have to overcome even more barriers such as social stigma, fear of child protective services, and other legal consequences in order to seek healthcare, much less participate in research. Often, these barriers can escalate or be exacerbated during pregnancy.

Racial differences in the willingness to participate in medical research have been largely attributed to mistrust of researchers and health care providers. A long history of systematic abuse and mistreatment in medical research including the US Public Health Services Syphilis Study at Tuskegee (Tuskegee Study) among African Americans has resulted in fears of continued purposeful mistreatment and forced relinquishing of rights. The Tuskegee Study was a 40-year study that unethically withheld treatment from Black men with diagnosed syphilis in order to study the natural course of the untreated disease (CDC, 2015). Understandably, mistrust has been

associated with the perception that research will benefit only White people and not people of color (George et al., 2014). Other barriers among Black populations include lack of support from family members, limited time, financial constraints, and language barriers (George et al., 2014).

Maternal and Infant Health Disparities

In addition to racial and ethnic disparities in research representation, notable health disparities exist between Black, non-Latinx individuals and individuals of other racial and ethnic identities. These health disparities are particularly salient in maternal peripartum health and infant birth outcomes (ACOG, 2015). In 2007, Black, non-Latinx mothers experienced more preterm births than mothers from any other racial or ethnic group; approximately one in five babies were born preterm (CDC, 2011). Further, Black, non-Latinx women are more likely to experience fetal growth restriction than women of other races and ethnicities (Bryant et al., 2010). In 2015, Black, non-Latinx mothers were more likely to experience infertility, unintended pregnancy, preterm birth, fetal death, and maternal death than mothers from any other racial or ethnic group (ACOG, 2015). Racial and ethnic disparities in prenatal and postpartum health care access and services may be contributing to these disparities in maternal and infant outcomes (de Bocanegra et al., 2017; Partridge et al., 2012, Masho et al., 2011).

Prenatal Care

Disparities in adequacy of prenatal care. Historically, prenatal care has been an important determinant of maternal and infant health outcomes. In a recent study, Partridge and colleagues (2012) investigated the impact of prenatal care on birth outcomes using data from the National Center for Health Statistics between 1995 to 2002. Authors found that women with inadequate prenatal care were at greater risk for prematurity, stillbirth, both early and late

neonatal loss and infant death compared to women with adequate prenatal care (Partridge et al., 2012).

Unfortunately, racial and ethnic disparities are prominent in prenatal health care access and services. In 2016, approximately three in four women in the United States (US) received the recommended amount of prenatal care (Osterman & Martin, 2018). White, non-Latinx women were more likely to begin prenatal care during the first trimester of pregnancy and receive adequate prenatal care, while Black, non-Latinx women were more likely to receive late, inadequate, or no prenatal care (Osterman & Martin, 2018; Partridge et al., 2012).

Measuring adequacy of prenatal care. The American College of Obstetrics and Gynecology (ACOG) and the American Academy of Pediatrics (AAP), recommend that prenatal care begin during the first trimester of pregnancy, typically between 8 and 12 weeks of gestation (APP & ACOG, 2017). Frequency of subsequent follow-up visits varies somewhat. Ideally, a woman with an "uncomplicated" first pregnancy should be examined every 4 weeks for the first 28 weeks of gestation, every 2 weeks from 28 to 36 weeks of gestation, and weekly thereafter until delivery—for a total of 14 prenatal care visits (APP & ACOG, 2017). However, parous women with low risk pregnancies may be seen less frequently, and women with higher risk pregnancies (i.e., medical or obstetric problems) will likely require more frequent monitoring throughout pregnancy.

Prenatal care attendance is typically characterized in two ways—timing of prenatal care initiation and frequency of visits thereafter. However, in the field of obstetrics and gynecology, how these constructs are defined and measured varies. Many researchers consider initiation of prenatal care after the first trimester to be late initiation of prenatal care. Others define late initiation as starting in the third trimester. For the current review of the literature, *late initiation*

will be defined as initiating care after the first trimester, and *very late initiation* will be defined as care beginning in the third trimester.

The Adequacy of Prenatal Care Utilization (APNCU) Index takes into account both time of prenatal care initiation and number of visits attended when determining adequacy of prenatal care (Kotelchuk, 1994). The APNCU Index is based on ACOG's typical prenatal care schedule for a nulliparous, low risk pregnancy and assumes that pregnant women who begin prenatal care during the first trimester and have a term delivery should have 14 expected visits. The APNCU index then reduces the number of expected visits based on gestational age at prenatal care initiation and delivery. For example, if a pregnant woman began care at 16 weeks gestation and delivered at 38 weeks gestation, then the expected number of visits would be 10 (four fewer visit opportunities). The APNCU index calculates the ratio of attended visits to expected visits. The ratio is then combined with timing of initiation and grouped into four adequacy of care categories: Inadequate (less than 50% of expected visits or initiation after the 4th month of pregnancy), Intermediate (50%-79% of expected visits and initiation before the 5th month of pregnancy), Adequate (80%-109% of expected visits and initiation before the 5th month of pregnancy), Adequate Plus (≥ 110% of expected visits and initiation before the 5th month of pregnancy; Kotelchuk, 1994). For the current review of literature, the terms *adequate prenatal care* and *inadequate prenatal care* are based on the APNCU index definitions.

Risk factors associated with poor prenatal care compliance. In addition to identifying as a Black, non-Latinx woman, previous research has identified other factors associated with late initiation, very late initiation, and inadequate prenatal care. Sociodemographic and psychosocial factors such as age, insurance, education, employment, income, and proximity to health care services impact access to and uptake of prenatal care. Reproductive health factors, including

reproductive history and pregnancy intendedness, also affect the frequency of prenatal care. Additionally, previous findings suggest IPV, mental health, and substance use are associated with prenatal care attendance (Haug, Osorno, Yanovitch, & Svikis, 2017).

Sociodemographic factors. National epidemiological studies consistently report associations between sociodemographic factors such as younger age, single/never married, unemployment, public insurance, less than high school education, and low income and both late entry into prenatal care and inadequate prenatal care. For example, using 1995 through 2002 birth and death certificate data from the National Center for Health Statistics, Partridge and colleagues (2012) found inadequate prenatal care was associated with younger age (<20 years), single marital status, and less education (<12 years). Osterman and Martin (2018) reported similar findings in an analysis of national 2016 birth certificate data. Young women (<15 years) were least likely to receive adequate prenatal care, and women with higher educational attainment and private insurance were more likely to receive adequate prenatal care than those with lower educational attainment and public insurance (Osterman & Martin, 2018).

Many regional studies in the US report similar correlates (Baer et al., 2018; Hulsey, Laken, Miller, & Ager, 2000; Pagnini & Reichman, 2000). Moreover, according to one literature review, women with lower socioeconomic status and those who are uninsured are more likely to initiate prenatal care late compared to women who have insurance and higher socioeconomic status (Gadson, Akpovi, & Mehta., 2017).

Several neighborhood factors, such as poverty level, sense of safety, transportation, and proximity to healthcare services, can create additional barriers for women seeking prenatal care, and these barriers disproportionately affect women who are already at risk for late entry and inadequate prenatal care based on their sociodemographic profiles. In a qualitative study in

Wisconsin, African American women identified poverty, lack of safety, limited transportation, and inflexible clinic hours and locations as barriers to attending prenatal care (Mazul, Ward, & Ngui, 2017). In New York City, Perloff and Jaffee (1999) found women who entered prenatal care very late were more likely to live in neighborhoods considered primary care shortage areas or in neighborhoods with 30 percent or more of the population living below the poverty line. Adams et al. (2005), using data from the Center for Medicare and Medicaid Services across four states (Texas, Florida, Georgia, and New Jersey), found greater availability of safety net providers was associated with adequate prenatal care attendance (Adams, Galvin, & Benedict, 2005). Among Medicaid participants in New Jersey, Pagnini and Reichman (2000) found that living in a home that lacked the "basic necessities for promoting good health" decreased the likelihood that pregnant women would initiate prenatal care during the first trimester.

Reproductive health. Reproductive history factors can also play a role in prenatal care initiation and compliance. Previous research found that a pregnant woman's parity could have different effects for different groups of women. For example, Baer et al. (2018) found that, in a statewide study of California's birth certificate data, being nulliparous was a risk factor for late prenatal care initiation for some women while a protective factor for others. Specifically, among Black women with public insurance, being nulliparous was associated with a greater likelihood of initiating prenatal care during the first or second trimester as opposed to the third trimester (Baer et al. 2018). However, in Detroit, MI among a predominantly African American sample of women, researchers found parity did not have a significant impact on timing of prenatal care initiation (Hulsey et al., 2000).

Other studies suggest that a woman's parity may not be what is interfering with prenatal care, but instead it is the number of children residing in the home and issues with childcare. In a

Massachusetts study of pregnant women who received Medicaid between 2005 and 2006, Weir and colleagues (2011) found that women who had children in the household were less likely to receive adequate prenatal care than those with no children at home. Similarly, a study of a Tennessee sample of pregnant women participating in a community health plan between 1996 and 1997, found those reporting problems with childcare were more likely to receive inadequate prenatal care than those without childcare issues (Gazmararian, Arrington, Bailey, Schwarz, & Kaplan, 1999).

Pregnancy specific factors. In addition to reproductive history variables, pregnancy specific factors may also affect prenatal care utilization. Several studies have shown that pregnancy intendedness can impact the timing of prenatal care initiation. Typically, pregnancy intendedness is categorized in three ways—intended, mistimed, and unwanted. Unintended pregnancies include both those that are mistimed ("wanted later") and those that are not wanted at all ("now or in the future"; Guttmacher Institute, 2019). In 2011, 45% of pregnancies in the US were considered unintended (Finer & Zolna, 2016). As noted previously, in 2015, a higher percentage of Black, non-Latinx mothers experienced an unintended pregnancy compared to mothers from other racial or ethnic groups (ACOG, 2015).

As a group, women with unintended pregnancies initiate prenatal care later than women with intended pregnancies. For example, a 1993 to 1995 Baltimore, MD study found pregnant women with unwanted pregnancies were more likely to initiate prenatal care very late compared to women with wanted or mistimed pregnancies (Orr et al., 2008). Similarly, Cheng et al. (2009) found women with mistimed or unwanted pregnancies were more likely to have late initiation of prenatal care than women with planned pregnancies (Cheng, Schwarz, Douglas, & Horon, 2009). In New Jersey, among Medicaid recipients, pregnant women who had unwanted pregnancies

were much more likely to have late initiation to prenatal care than women with wanted pregnancies (Pagnini & Reichman, 2000). A different study of pregnant women seeking prenatal care in a tertiary care clinic in Detroit, MI, found that women with intended and unintended pregnancies did not differ significantly on prenatal care initiation; however, women who had considered an abortion, were more likely to initiate late prenatal care compared to women who had not considered abortion (Hulsey et al., 2000).

In contrast to the robust association between pregnancy intendedness and timing of prenatal care initiation, the relationship between intendedness and adequacy of prenatal care are less consistent. In Tennessee, among a sample of pregnant women participating in a community health plan, reporting a mistimed or unwanted pregnancy was associated with receiving inadequate prenatal care (Gazmararian et al., 1999). Conversely, Mikhail (2000) found that African American women recruited from communities in central California with unintended pregnancies were as likely to receive adequate prenatal care as women with planned pregnancies. It is possible that women who experience unintended pregnancies tend to begin prenatal care later than women with planned pregnancies because they recognize that they are pregnant later, but once they do, they complete all subsequent prenatal care visits.

Intimate partner violence. Another correlate of prenatal care attendance is IPV, particularly surrounding the pregnancy period. Globally, IPV was found to negatively affect prenatal care utilization which in turn could impact health outcomes (Jamieson, 2018; Metheny and Stephenson, 2017). Similar patterns have been found in US samples. Using the national 2004 to 2008 Pregnancy Risk Assessment Monitoring System (PRAMS) data, Cha and Masho (2014) examined the relationship between physical violence and prenatal care utilization in a sample of (n=202,367) women. They found those who experienced preconception (12 months prior to

pregnancy) and/or prenatal (during pregnancy) physical violence by a former or current partner were two times more likely to receive inadequate prenatal care than women who did not experience physical violence (Cha & Masho, 2014). A smaller study in Tennessee among pregnant women participating in a community health plan found that violence during pregnancy was associated with late initiation of prenatal care (Gazmararian et al., 1999).

Mental health. Mental health variables, particularly depression, can also influence prenatal care utilization. In a sample of pregnant women using opioids and receiving prenatal care in one of two hospitals in Illinois between 2009 and 2015, Hensley and colleagues (2018) found that women with a diagnosis of Major Depressive Disorder attended fewer of the recommended number of prenatal care visits than women without the diagnosis. In another study, Sidebottom et al. (2017) examined associations among prenatal depressive symptoms, social support, and adequacy of prenatal care using prenatal intake risk assessments from five community health centers in Minnesota combined with 2005-2009 Minnesota birth certificate data (Sidebottom, Hellerstedt, Harrison, & Jones-Webb, 2017). They found a significant interaction between social support and depression for late initiation of prenatal care; women with moderate to high depressive symptoms and low social support were at highest risk for late initiation of prenatal care while women with moderate to high depressive symptoms and good partner support were least likely to initiate late prenatal care (Sidebottom et al, 2017). These data suggest social support may serve as a protective factor, especially for women with more severe depression symptoms.

Additionally, Sidebottom et al. (2017) found symptoms of depression and lack of social support to be risk factors for inadequate prenatal care. Similarly, a study of low-income pregnant women in Tennessee found that lack of support from the father of the baby was associated with

inadequate prenatal care (Gazmararian et al., 1999). Likewise, Shaffer and Lia-Hoagberg (1997) found that among a sample of pregnant women attending urban prenatal clinics in Minnesota, partner social support was positively correlated with adequacy of prenatal care. Women with higher ratings of partner social support were more likely to have adequate prenatal care than women with lower ratings of partner social support.

Substance use. Substance use and abuse have also been associated with uptake of prenatal care services (Jansson et al., 1996). In a study using California birth certificate data between 2007 and 2012, mothers with a delivery discharge diagnosis of drug or alcohol abuse or dependence were more likely to have very late prenatal care initiation compared to those without such a diagnosis (Baer et al., 2018). Similarly, in New Jersey, among Medicaid recipients, pregnant women who smoked cigarettes, drank alcohol, or used drugs during pregnancy were more likely to have late initiation of prenatal care than women who did not use those substances (Pagnini & Reichman, 2000). In a Massachusetts study of pregnant women receiving Medicaid between 2005 and 2006, those who were diagnosed with a substance use disorder (according to claims data) were more likely to have late initiation of prenatal care and less likely to receive adequate prenatal care than those without a substance use disorder diagnosis (Weir et al., 2011).

Postpartum Care

Disparities in adequacy of postpartum care. During the postpartum period, women are adjusting to physical, social, and psychological changes, and many women remain at risk for severe medical complications and mental health conditions. Maternal morbidity and mortality during postpartum hospitalizations are increasing (Callagahan, Creanga, & Kuklina, 2012). Further, approximately 1 in 9 women experience depression after pregnancy (CDC, 2017), and the majority of women who achieve drug abstinence during pregnancy experience relapse

postpartum (Forray, Merry, Lin, Ruger, & Yonkers, 2015). Therefore, the postpartum period is an important time for intervention as well as prevention of physical and mental health problems.

In 2018, ACOG released a committee opinion calling for postpartum care to be redefined as the "fourth trimester" with ongoing care to optimize women's health and wellbeing (ACOG, 2018). However, the majority of women only attend one postpartum visit which typically occurs around 6 weeks after delivery. In general, approximately three in four women (70-90%) attend their first postpartum visit (Morgan, Hughes, Belcher, & Holmes, 2018; Yee et al., 2017). Compliance is lower among women who receive Medicaid, ranging from 50% to 81% (Masho et al., 2018; Rankin et al., 2016). Additionally, there are significant racial and ethnic disparities in postpartum visit attendance rates. Among pregnant women receiving Medicaid, two statewide studies found that compared to White women, Black women were less likely to attend their postpartum visit (de Bocanegra et al., 2017; Rankin et al., 2016).

Furthermore, postpartum racial disparities extend beyond postpartum care access into postpartum mental health, breastfeeding, and contraception use. Howell and colleagues (2005) found that compared to White women, African American women were more likely to report postpartum symptoms of depression (Howell, Mora, Horowitz, & Leventhal, 2005). Black women are also less likely to initiate and continue breastfeeding (Jones, Power, Queenan & Schulkin, 2015) and less likely to receive contraceptive services than white women (de Bocanegra et al., 2017). Identifying correlates for postpartum care nonattendance is a crucial step for improving attendance and reducing disparities.

Risk factors associated with poor postpartum care compliance. A number of sociodemographic and psychosocial factors such as age, insurance, income and employment have been associated with postpartum care access and utilization. Many are similar to those

found for prenatal care attendance. Chronic physical and mental health conditions serve as barriers to care for some women and incentives to care for others. However, substance use has been consistently associated with lack of postpartum care. Moreover, pregnancy specific factors including pregnancy intendedness, prenatal care attendance as well as maternal and infant birth outcomes also affect the postpartum care utilization.

Sociodemographic factors. It is well established that younger age, less than high school education, unemployment status, low income, and public or no insurance are all associated with postpartum visit nonattendance. Many studies of postpartum visit compliance have been conducted with statewide public datasets. For example, in a study of Maryland PRAMS data from 2012 to 2013 (n=2204), Morgan and colleagues (2018) found that women with less than or equal to a high school education and women who were not working during pregnancy had significantly higher odds of postpartum visit nonattendance compared to those with higher education and those with employment during pregnancy. Often these studies focus on women receiving Medicaid or public assistance. In California, de Bocanegra and colleagues (2017) found those younger than 20 years of age were less likely to receive postpartum care than those over the age of 20 years (n=199,860). In a Massachusetts study (n=1,882), being a teenager and having a "work-limiting" disability were associated with not attending a postpartum care visit (Weir et al., 2011). Although Masho et al. (2018) found that among a sample of Medicaid recipients in Virginia age and education were not significantly associated with postpartum care attendance, women with younger age and less than or equivalent to a high school education had lower odds of attendance (n=25,692).

Studies based in a single group, typically in urban academic medical centers, report similar findings. In California, Chen and colleagues (2018) found that being less than 30 years of

age and having less than or equivalent to a high school education were associated with postpartum visit nonattendance. Similarly, in New York, Wilcox and Garrett (2016) found that being less than 20 years of age and having Medicaid or no insurance was associated with postpartum visit nonattendance (n=3441). In Oregon, Baldwin et al. (2018) conducted secondary analysis examining predictors for postpartum visit attendance among women who participated in an RCT and intended to receive an intrauterine device (n=197). They found that women who were younger and unemployed, as well as those who had an income less than $50,000 and had Medicaid, were less likely to attend a postpartum visit compared to older, employed women with higher incomes and private insurance (Baldwin, Hart, & Rodriguez, 2018). Additionally, among a sample of pregnant women from Los Angeles County in California (n=4,075), women who were younger as well as those who had lower income (<$20,000) and had public insurance had the lowest odds of postpartum care attendance (DiBari et al., 2014). DiBari and colleagues (2014) also found that women who were either separated, divorced, or never married were less likely to attend a postpartum care visit than married women.

Moreover, neighborhood factors can influence utilization of postpartum care services. Specifically, lack of transportation and living further away from healthcare providers have been linked to postpartum care nonattendance. In a multisite study between 1995 and 1996, researchers found that reporting problems with transportation to visits was negatively associated with postpartum visit attendance (Bryant, Haas, McElrath, & McCormick, 2006). In Oregon, among women participating in a parent RCT for intrauterine device utilization, women who reported that they did not have a car were less likely to attend a postpartum visit than women who had access to a car (Baldwin et al., 2018). In California, among women receiving Medicaid

in 2012, living in a primary care shortage area was associated with postpartum care nonattendance (de Bocanegra et al., 2017).

Physical health. The relationship between physical health variables and postpartum attendance has received less attention. However, findings to date are fairly consistent. In a large multisite study in 1995 and 1996, women with chronic health conditions (i.e., heart disease, hypertension, diabetes, etc.) were more likely to attend postpartum visit than those without any chronic conditions (Bryant et al., 2010). Regional studies have found similar results. A study using 2003-2009 insurance claims data from Baltimore, MD found that Medicaid recipients with chronic hypertension were more likely to attend a postpartum visit than those without hypertension (Bennett, Chang, Levine, Wang, Neale, Werner, & Clark, 2013). Among a sample of women diagnosed with severe pre-eclampsia in Pennsylvania between 2011 and 2013, those who also had diabetes were more likely to attend a postpartum visit than those without diabetes (Levine, Nkonde-Price, Limaye, Srinivas, 2017).

Mental health. Studies of the relationship between mental health conditions and postpartum care attendance have been less consistent. For example, among a sample of pregnant women who attended an academic medical center in Illinois between 2008 and 2014 and who were screened for depressive symptoms, a positive screen for antenatal depressive symptoms was a significant risk factor for postpartum care nonattendance (Shim, Stark, Ross, & Miller, 2018). However, in a study of Medicaid recipients in Virginia, women with a history of depression had higher odds of attending a postpartum visit than those without such symptoms (Masho et al., 2018). Additionally, Bennett and colleagues (2013) found Baltimore women with Medicaid who had a depressive disorder were more likely to attend a postpartum visit compared

to those without the disorder. Similarly, they found presence of other mental disorders was also associated with nonattendance.

Substance use. Postpartum substance use has been associated with postpartum care nonattendance and is relatively common, especially among women who use substances before or during pregnancy. Forray and colleagues (2015) found that the majority of women who achieved abstinence during pregnancy, relapsed during the postpartum period to at least one substance. According to another study of women who reported frequent drinking prior to pregnancy, 38% endorsed postpartum "risky drinking"—more than seven drinks a week or at least four drinks on one occasion twice during the past 28 days (Jagodzinski & Fleming, 2007). Among a sample of women who quit smoking cigarettes during pregnancy, 50% relapsed by their postpartum visit (Gyllstrom, Hellerstedt, & Hennrikus, 2012).

In general, women with substance use disorders tend to have lower postpartum visit attendance rates than women who do not suffer from substance use disorders. For example, women receiving medication assisted treatment for opioid use disorder had a 30% postpartum visit attendance rate (Kotha, Chen, Lewis, Dunn, Himes, & Krans, 2019). Substance use, including smoking, drinking alcohol, and using drugs, serves as a risk factor for postpartum care nonattendance.

Among Medicaid recipients from Virginia, women who smoked were significantly less likely to attend a postpartum visit compared to women who did not smoke, and women who experienced drug and alcohol dependence were also less likely to attend a postpartum visit compared to those without drug and alcohol dependence (Masho et al, 2018). In Baltimore, MD among women receiving Medicaid, drug and alcohol use was identified as a predictor for nonattendance (Bennett et al., 2013). Similarly, in Massachusetts in 2007 among Medicaid

recipients, women with a substance use disorder were significantly less likely to attend a postpartum visit than women without a substance use disorder (Weir et al., 2011).

Reproductive health. Multiparity has been associated with postpartum care nonattendance. For example, multiparity has been found to increase the odds of postpartum visit nonattendance. Among a sample of majority African American women from Detroit, MI, having three or more previous deliveries was the only significant predictor of a missed postpartum visit appointment (Hulsey et al., 2000). Comparably, in Massachusetts, among pregnant women using Medicaid in 2007, having two or three other children in the home was associated with postpartum nonattendance (Weir et al., 2011). In California, women with three or more previous children were significantly less likely to attend a postpartum visit than women with no previous children (Chen et al., 2018).

Pregnancy specific factors. Pregnancy intendedness, pregnancy risk, and level of prenatal care attendance have been shown to be correlates of postpartum care attendance. Research exploring the relationship between pregnancy intendedness and receipt of postpartum care is limited. However, DiBari and colleagues (2014) found that women with unintended pregnancies were less likely to attend a postpartum visit compared to women with planned pregnancies.

Pregnancy risk has been shown to be associated with postpartum care attendance; however, results are inconclusive. Among a sample of women from California, having a high-risk pregnancy was associated with postpartum visit nonattendance (Chen et al., 2018). Contrastingly, in a different study, women with pregnancy complications (i.e., gestational diabetes, diabetes, hypertension, anemia, cervical incompetence, etc.) were significantly more likely to attend a postpartum visit compared to those without pregnancy complications (Masho et

al., 2018). Bennett and colleagues (2013) found that in a sample of women from Baltimore, MD with Medicaid, those that had preeclampsia and gestational diabetes were more likely to attend a postpartum visit compared to women without such pregnancy complications.

Late initiation and inadequate prenatal care have consistently been associated with postpartum care nonattendance. Among a sample of RTC participants in Oregon, Baldwin et al. (2018) found that late initiation and inadequate prenatal care were associated with lack of postpartum care. Among Medicaid recipients in Virginia, women who did not attend prenatal care were less likely to attend a postpartum visit compared to women who received prenatal care (Masho et al., 2018). Among a sample of pregnant women from Los Angeles County in California, women who had no prenatal care were much less likely to attend a postpartum visit compared to women who received prenatal care (DiBari et al., 2014). York et al. (2000) found that among African American women from an urban tertiary medical care center, those who did not receive any prenatal care were significantly less likely to attend a postpartum visit compared to women who received prenatal care, even if it was inadequate. Further, infants born to women who received inadequate or no prenatal care attended fewer well child visits and received fewer immunizations compared to women wo received intermediate or adequate prenatal care (York, Tulman, & Brown, 2000). In a sample of women with severe pre-eclampsia, Levine and colleagues (2017) found that those who attended less than five prenatal care appointments were less likely to attend a postpartum visit compared to women who attended at least five prenatal care visits.

Maternal and infant birth outcomes. A mother's route of delivery has been shown to influence receipt of postpartum care. Bennett and colleagues (2013) found that, among a sample of Medicaid recipients from Baltimore, MD, women who delivered via cesarean section had

higher odds of attending a postpartum visit than women who did not have a cesarean section. Similarly, a study in a New York academic medical center found consistent results (Wilcox et al., 2016). Among women diagnosed with severe pre-eclampsia, having a cesarean delivery was associated with higher rates of postpartum visit attendance (Levine et al., 2017). In contrast, a study of Medicaid recipients in California found that women who had a cesarean delivery had lower odds of attending a postpartum visit compared to women who did not have a cesarean delivery (de Bocanegra et al., 2017). Notably, a study of Medicaid recipients in Virginia, found that delivery route was not significantly associated with postpartum visit attendance (Masho et al., 2018).

Infant birth outcomes can also influence postpartum care attendance. Masho and colleagues (2018) found that women who delivered low birth weight babies had lower odds of attending a postpartum visit compared to women with normal weight babies. In a California study from 2015, Chen and colleagues (2018) found women who had a history of a previous miscarriage were more likely to attend a postpartum visit than women without such pregnancy history. In a statewide study of Maryland PRAMS data from 2012 to 2013, Morgan and colleagues (2018) identified experiencing an infant loss as a strong predictor for postpartum visit nonattendance.

Interventions to Improve Peripartum Care

RCTs of interventions targeting peripartum visit attendance have yielded positive results. Till et al. (2015) found that pregnant women who receive incentives, such as cash or gift cards, are more likely to attend prenatal care visits more frequently and receive adequate prenatal care (Till, Everetts, & Haas, 2015). Additionally, “augmented care” has been shown to be an effective intervention among African American women with high-risk pregnancies. Klerman and

colleagues (2001) found that compared to women with usual care, those who received augmented care were more likely to attend prenatal care visits and childbirth classes (Klerman, Ramey, Goldenberg, Marbury, Hou, & Cliver, 2001). Patient navigation and care coordination have been shown to improve substance use disorder treatment participation and postpartum visit attendance in pregnant women as well (Cochran et al., 2018; Yee et al., 2017). The parent RCT for the current study aimed to reduce health disparities in maternal and infant health by increasing prenatal care attendance using an intervention that combined behavioral incentives and patient navigation.

Statement of Problem and Hypothesis

In clinical research, underrepresentation of racial and ethnic minorities and women has been a long-standing problem, one that often limits generalizability of study findings. Improvements have been spearheaded by NIH policy changes like the Revitalization Act (NIH, 2017). Additionally, the adoption of CONSORT guidelines has improved tracking of study participants and encouraged documentation of the number of individuals ascertained; the number who fail to meet different inclusion/exclusion criteria; and those who consent to study participation as well as follow-up and study retention rates (Begg et al., 1996).

Historically, much less was known, about similarities between individuals who consented to an RCT and those who did not, and data were typically limited to basic demographic variables (e.g., gender, age; Park et al., 1998). More recently, research comparing individuals who do and do not consent to RCTs have examined a broader range of variables. In most cases, information was obtained during the screening process to determine eligibility for the clinical trial. While small in number, such studies have identified group differences in socioeconomic status,

condition severity and/or level of impairment (e.g., Kelpin et al., 2018; Kennedy-Martin et al., 2015; Lally et al., 2018).

Understandably, such variability is due in part to the unique purpose of each study (e.g., depression, substance use disorders). Underrepresented subgroups such as women and racial minorities often face a greater number, and potentially different, barriers to research participation and warrant greater attention. Using existing data from a CDC-funded RCT targeting health disparities in maternal and infant birth outcomes, the current study had a unique opportunity to compare psychosocial characteristics of pregnant, African American women at risk for poor prenatal care compliance who enrolled in an RCT investigating health care navigation and behavioral incentives to those who elected to decline study participation. The RCT compared an intervention that combined patient navigation and behavioral incentives to a usual care control group. Analyses found no intervention to control group differences in the primary outcome, making sample representativeness of particular importance.

It is well established that prenatal care and postpartum care are important for reducing maternal and infant morbidity and mortality (ACOG, 2018; Partridge et al, 2012). Racial and ethnic health disparities in maternal peripartum health and infant birth outcomes make it particularly important to encourage peripartum care in African American women. While risk factors associated with late initiation, very late initiation, and inadequate prenatal care and postpartum care nonattendance have been identified, to our knowledge, there have not been other studies investigating predictors of prenatal and postpartum care attendance in African American women at risk for poor prenatal care compliance. The current study used the same RCT data to address this gap in the literature.

The specific aims of the current study were as follows:

Specific aim 1. Examine sample representativeness by comparing women who did and did not consent to RCT participation. Two hypotheses were tested:

1) Women who consent to the RCT will endorse fewer risk factor questionnaire items than those who do not consent to the research.
2) Women who enroll in the RCT will have lower scores on the risk factor questionnaire than women who decline study participation.

Specific aim 2. Identify sociodemographic, pregnancy specific, IPV, mental health, substance use, and social support variables predictive of prenatal care attendance within a sample of pregnant, African American women at risk for poor prenatal care compliance. The following hypothesis was tested:

1) When controlling for sociodemographic risk factors in the initial block and pregnancy risk level and reported barriers to prenatal care in the second block, the following factors will significantly improve the prediction for ratio of attended to expected prenatal care visits in the second block: Pregnancy intendedness, IPV, mental health, substance use, and social support.

Specific aim 3. Identify sociodemographic, adequacy of prenatal care, mental health, substance use, and birth outcome variables associated with postpartum care attendance within a sample of pregnant, African American women at risk for poor prenatal care compliance. The following hypothesis was tested:

1) When controlling for sociodemographic risk factors in the initial block and adequacy of prenatal care in the second block, the following factors will significantly improve the prediction for the number of postpartum care visits attended in the third block: Mental health, substance use, and maternal and infant birth outcomes.

Methods

Participants

For this secondary data analytic study, participants were drawn from a database containing n = 903 pregnant, African American patients who completed an anonymous screening questionnaire assessing risk for poor prenatal care compliance. From this pool, n = 271 women met RCT eligibility criteria. Of the n = 271 women eligible for RCT participation, n = 122 declined to participate and n = 149 provided informed consent. Of the women who participated in the RCT, n = 123 were included in the regression analyses for the current study (See Figure 1).

Inclusion criteria. Inclusion criteria for RCT enrollment were as follows: Score $\geq$ 4 on the risk factors screening questionnaire, pregnant with an estimated gestational age $\leq$ 26 weeks, seeking prenatal care at an urban, outpatient Obstetrics and Gynecology clinic, African American, at least 16 years of age, residing in the City of Richmond or surrounding counties, and able to speak and understand English. One additional inclusion criterion for the current study was having a live birth. Women who transferred care to another hospital following study enrollment were able to continue study participation as long as their visit and birth outcome data could be tracked (n=13).

Exclusion criteria. Patients were ineligible for the RCT if they presented with a serious psychiatric or cognitive impairment that prevented them from providing informed consent. Women with unknown birth outcomes were excluded from the current study analyses (n=15) because they were missing data for the critical outcome variable. Without a known gestational age at delivery the APNCU index ratio could not be calculated for the regression analyses.

Informed consent. The study was approved by Virginia Commonwealth University's Institutional Review Board under "Reaching Out to Richmond – Addressing Barriers to Care: Project ABC," protocol number HM11936 and all participants provided informed consent.

Design and Procedures

Participants were enrolled from July 1, 2010 to March 16, 2011. Research team members approached pregnant women at their first prenatal visit and inquired about research participation. Women were first invited to complete an anonymous screening questionnaire to determine RCT eligibility. Those who endorsed items that placed them at risk for poor prenatal care compliance (score $\geq$ 4) and met RCT inclusion criteria were eligible to participate in the RCT (n = 271). From this sample, for Specific Aim 1 (n = 271), n = 149 women who consented to the RCT were compared to n = 122 who did not enroll.

Women who provided informed consent to the RCT (n = 149) proceeded with the baseline assessment. Typically, this was completed within 14 days of study enrollment. The women (n = 123) who completed the baseline assessment and had a live birth comprised the sample for Specific Aims 2 and 3.

Following the baseline assessment, RCT participants were randomized to either the Patient Navigator + Behavioral Incentives (PNBI) intervention group (n = 71) or the assessment + standard care (ASC) control condition (n = 78). The RCT utilized an intervention package strategy so women assigned to the PNBI intervention group received both a patient navigator (PN) and behavioral incentives (BI). The Patient Navigators (PN) helped participants identify and address barriers to prenatal care and advocate for needed treatment services. The behavioral incentives were designed to promote sustained engagement with the recommended prenatal care

treatment. Women assigned to the ASC control group received standard care and no additional services.

RCT participants completed follow-up assessments at the beginning of the second and third trimesters as well as at six and twelve weeks postpartum for a total of four follow-up assessments. All study participants were compensated for their time and effort at the initial screening and all assessments. A participant could receive a maximum of $205 for completing all study assessments, regardless of RCT group assignment. Additionally, maternal and infant birth outcomes were abstracted from hospital records.

The current study was a secondary data analysis investigating the representativeness of the study sample and predictors of prenatal and postpartum care attendance among RCT participants. The primary objective of the original RCT was to examine the effects of patient navigation and behavioral incentives on prenatal care attendance, operationalized as total number of individual, group, and high-risk prenatal care visits. Previous analyses have shown there was no statistical difference between the women in the PNBI and ASC groups for such primary outcome measures.

Specific Aim 1: Measures

Risk factor screening questionnaire. The 22-item risk factors screening survey was administered by a research assistant in interview format. The anonymous survey collected no identifying information and was not linked to subsequent assessments for those who enrolled in the study. Items focused on sociodemographic variables, recent and problem substance use, symptoms of depression, and IPV variables (see detailed description below). A total risk factor score was calculated with some items weighted more than others for a maximum score of 21 (see Appendix 1). Women who scored $\geq$ 4 on the screener were eligible for participation in the RCT.

Sociodemographic characteristics. Sociodemographic data in the risk questionnaire included age, race, marital status, living arrangement, employment, education, receipt of social services, insurance, and relationship with child protective services. Based on sociodemographic characteristics, women could score up to four risk factor points.

Substance use. Recent cigarette use, alcohol use, prescription drug misuse, and illicit drug use were assessed separately with four items: 1) "When did you last smoke a cigarette?" 2) "When did you last drink something containing alcohol?" 3) "When did you last take prescription drugs not prescribed to you by a doctor or take an amount greater than what a doctor prescribed?" and 4) "When did you last use illicit drugs?" Response options for all four items were the following: never, today, past 7 days, past month, past 3 months, past 6 months, past year, more than a year ago. Lifetime experience of problems with alcohol use, prescription drug misuse, and illicit drug use were assessed separately using three items (e.g., Have you ever had problems due to your use of alcohol? yes/no). Substance use in the home was assessed using two questions. "Does anyone living with you have problems with alcohol (yes/no) or drugs (yes/no)?" Women could score up to 10 risk factor points based on substance use variables.

Depression. Depressive symptoms were assessed using a modified version of the Patient Health Questionnaire-2 (PHQ-2; Kroenke, Spitzer, &Williams, 2003). The validity of the PHQ-2 as a brief depression screener has been established in primary care and pregnant populations (sensitivity, 69-84%; specificity, 79-84%%; Arroll et al., 2010; Vlenterie, Ras, Roeleveld, Pop-Purceleanu, & Gelder, 2017). Participants reported yes/no to two items (past 30 days): 1) felt down, depressed, or hopeless more days than, and 2) little interest or pleasure in doing things more days than not. Women could score up to two risk factor points; one point for each item endorsed.

Intimate partner violence. The 3-item Partner Violence Screen (PVS) was included to assess two dimensions of partner violence—physical violence and perceived safety (Feldhaus, Koziol-McLain, Amsbury, Lowenstein, & Abbott, 1997). Physical violence was assessed by one item, "Have you been hit, kicked, punched, or otherwise hurt by someone within the past year?" (yes/no). Two questions assessed perceived safety: 1) "Do you feel safe in your current relationship?" (yes/no), and 2) "Is there a partner from a previous relationship who is making you feel unsafe now?" (yes/no). The validity of the PVS as a brief screen for partner violence has been established in health care settings (sensitivity, 65%-71%; specificity, 80%-84%) (Feldhaus et al., 1997; MacMillan et al., 2009). Women could score five risk factor points for endorsing one or more items in this domain.

Specific Aim 2 & 3: Measures

Baseline assessment. The baseline 40-minute assessment was research assistant administered as a face-to-face structured interview. The interview items focused on sociodemographic, barriers to prenatal care, reproductive health, pregnancy intendedness, IPV, depressive symptoms, substance use, physical health, self-esteem, and social support. Validated measurement scales were used when possible.

RCT group assignment. Research assistants tracked RCT group assignment, either PNBI intervention group or ASC control group in the research database. As aforementioned, previous analyses have shown there was no group differences in prenatal care attendance. However, there was a statistically significant group difference in postpartum visit attendance, with those in the PNBI intervention group being more likely to attend the postpartum visit. Therefore, RCT group assignment was included in the hierarchical binary logistic regression as a confounding variable.

Sociodemographic characteristics. Sociodemographic data in the baseline assessment included age, race, ethnicity, marital status, living arrangement, employment, education, annual income, receipt of social services, insurance, and number of children in the home.

Barriers to prenatal care. Participants were shown a list of potential barriers to prenatal care and asked to state whether or not each issue had been a concern for them to date in their current pregnancy. The list of barriers included the following: financial and insurance concerns, clinic scheduling problems, lack of transportation, inflexible work schedule, hectic personal schedule, lack of childcare, and other concerns. For the regression analysis, number of reported barriers to care were summed for a total number of barriers ranging 0 to 6.

Parity. Parity was not assessed directly on the baseline assessment. Number of children was assessed by one item, "How many children less than 18 years of age live in your household?"

Pregnancy intendedness. Pregnancy intendedness was assessed by two items: 1) Thinking back to just before you got pregnant, how did you feel about becoming pregnant?" (I wanted to be pregnant sooner, I wanted to be pregnant then, I wanted to be pregnant later, I didn't want to be pregnant at all). Those who reported that they wanted to be pregnant sooner or at the time they began the current pregnancy will be grouped as not an unintended pregnancy (no=0); those that reported they wanted to be pregnant later or not at all will be grouped as an unintended pregnancy (yes=1). 2) Contraception use prior to conception was determined by the item, "When you got pregnant with your current baby, were you or the father doing anything to prevent pregnancy including rhythm, withdrawal, barrier, hormonal, or long-term methods?" (yes/no). Only the first item was used in the regression analyses.

Intimate partner violence. A 3-item modified version of the Abuse Assessment Screen (AAS) was used to assess for physical, sexual, and emotional abuse (Soeken, McFarlane, Parker, & Lominack, 1998). The AAS has been validated for use in pregnant women (Deshpande & Lewis-O'Connor, 2013). Participants were asked to consider three items (yes/no) during the 12 months prior to pregnancy (preconception IPV) and during the current pregnancy (prenatal IPV). For the regression analysis, items were conflated into one categorical IPV variable (0 = none, 1 = IPV at one time point—preconception IPV or prenatal IPV, 2 = both preconception and prenatal IPV) and then dummy coded.

Depression. The 20-item Center for Epidemiologic Studies Depression Scale (CES-D) was used to assess depressive symptoms (Radloff, 1977). The diagnostic validity of the CES-D has been established in the general population and primary care settings for the cutoff of 16 (sensitivity, 87%; specificity, 70%) (Vilagut, Forero, Barbaglia, & Alonso, 2016). Less is known about use with pregnant populations. One study found that the CES-D has acceptable reliability and validity among a sample of African American and White pregnant women (Cronbach's alpha = 0.898; Canady, Stommel, & Holzman, 2009). The 4-point frequency scale (rarely/none of the time, some of the time, occasionally, most/all of the time) when summed, has scores ranging from 0-60 with higher scores indicating greater symptoms of depression. The standard cutoff score indicating risk for clinical depression is ≥16 which will be used as an indication of depressive symptoms. In order to preserve variability in the regression analyses, the continuous total score was used.

Cigarette smoking. Recency of smoking was assessed with one item. "When did you last smoke a cigarette?" Response options were the following: today, past 7 days, past month, past 3

months, past 6 months, past year, more than a year ago, never. For analyses, reported use was recoded into a continuous variable (0-7) with higher scores indicating more recent use.

Alcohol use. Recency of alcohol use was assessed with one item. "When did you last drink something containing alcohol?" Response options were the following: today, past 7 days, past month, past 3 months, past 6 months, past year, more than a year ago, never. For analyses, reported use was recoded into a continuous variable (0-7) with higher scores indicating more recent use. Additionally, drinking behaviors three months prior to pregnancy were assessed with two items, "How many days per week would you drink alcohol?" (response options: every day, six days, five days, four days, three days, two days, once a week, less than once a week) and "How many drinks would you have each time you drank?" (response options: 1, 2, 3, 4, 5, 6, 7-10, 11-13, 14 or more). These items were not included in regression analyses.

Prescription drug misuse. Recency of prescription drug misuse was assessed with one item, "When did you last take prescription drugs not prescribed to you by a doctor or take an amount greater than what a doctor prescribed?" Response options were the following: today, past 7 days, past month, past 3 months, past 6 months, past year, more than a year ago, never. For analyses, reported use was recoded into a continuous variable (0-7) with higher scores indicating more recent use. Because few participants endorsed any prescription drug misuse, this variable was conflated with the illicit drug use variable. Most recent use across both prescription drug misuse and illicit drug use was included in the conflated variable.

Illicit drug use. Recency of illicit drug use was assessed with one item, "When did you last use illicit or street drugs?" Response options were the following: never, today, past 7 days, past month, past 3 months, past 6 months, past year, more than a year ago. For analyses, reported use was recoded into a continuous variable (0-7) with higher scores indicating more recent use.

Additionally, drug use three months prior to pregnancy was assessed with one item, "How many days per week would you use drugs?" (response options: every day, six days, five days, four days, three days, two days, once a week, less than once a week). These items were not included in regression analyses.

Environmental relapse risk. Substance use in the home was assessed using two questions. "Does anyone living with you have problems with alcohol (yes/no) or drugs (yes/no)?"

Physical health. Health conditions were self-reported in response to the question, "Have you ever been told by a doctor that you have, or have you ever been treated for any of the following: diabetes, gestational diabetes, hypertension?"

Self-esteem. The 10-item Rosenberg self-esteem scale (RSES) was used to assess general feelings of self-esteem (Rosenberg, 1965). Five items were reverse scored. Responses on the 4-point agreement scale (strongly agree, agree, disagree, strongly disagree) for each item (with 0 = strongly disagree and 3 = strongly agree) are summed, with a total score range of 0-30. Higher scores indicate greater feelings of self-esteem. Psychometric properties have been determined for use in the general US population (Sinclair, Blais, Gansler, Sandberg, Bistis, & LoCicero, 2010), but psychometric data could not be found for use among pregnant women.

Social support. A 15-item modified version of the Interpersonal Support Evaluation List (ISEL) was used to assess social support. Items were a subset of the 40-item Interpersonal Support Evaluation List (Cohen, & Hoberman, 1983). Four items were reverse scored. Responses on the 4-point agreement scale (completely true, somewhat true, somewhat false, completely false) for each item (with 4 = completely true and 1 = completely false) are summed, with a total score of 15-60. Higher scores indicate more social support. Psychometric properties

have been determined for use in the general US population, but psychometric data could not be found for use among pregnant women. The current study used total score as a measure of social support in the regression analysis. Also, relationship with father of the baby was assessed using one item, “Are you currently in a relationship with the father of your baby?” (yes/no). This item was not included in regression analyses.

Follow-up assessments. Follow-up assessments were conducted at the beginning of the second and third trimesters as well as at six and twelve weeks postpartum. Each follow-up assessment lasted approximately 20 minutes and contained a subset of baseline items. Birth outcome variables were included in the first postpartum follow-up assessment.

Birth outcomes. Maternal and infant birth outcomes were only used in the analyses addressing Specific Aim 3. Items assessed included the following: route of delivery, estimated gestational age at delivery, birth weight, and neonatal intensive care unit (NICU) admission. Infants born prior to 37 weeks gestation were considered preterm. Infants weighing less than 2,500 grams at birth were considered low birth weight.

Dependent variables. Number of prenatal and postpartum care appointments attended were tracked using electronic medical records. Prenatal care appointments consisted of individual, group, and high-risk prenatal appointments. Number of postpartum care visits included appointments during the first 12 weeks postpartum. Estimated gestational age at first PNC visit was also recorded.

For the current study, prenatal care attendance was operationalized as the percentage of expected visits attended adjusted for estimated gestational age at first prenatal care appointment and delivery (based on the APNCU index). A categorical variable of adequacy of prenatal care (adequate plus/adequate, intermediate, and inadequate) was calculated based on the APNCU

index. Attended prenatal care visits include individual, group, and high-risk prenatal care appointments. For analyses, women were grouped based on high-risk pregnancy (yes/no). Those who attended two or more visits in the high-risk prenatal care clinic were identified as having a high-risk pregnancy.

Although, the research protocol required women to attend two postpartum visits, clinically, most women only attend one postpartum visit. In order to create a more clinically relevant outcome variable, postpartum care attendance was operationalized as a categorical variable (yes/no). Women who attended at least one postpartum visit during the first 12 weeks postpartum were coded as a 1 (yes). Women who did not attend any visits during the postpartum timeframe were coded as a 0 (no).

Data Analysis

Statistical analyses were performed using SPSS version 26 (IBM Corp. Released 2019. IBM SPSS Statistics for Macintosh, Version 26.0. Armonk, NY: IBM Corp). Descriptive statistics were generated for sociodemographic data (age, marital status, employment, education, insurance, income, receipt of social services), substance use (alcohol, tobacco, prescription misuse, illicit drug use and related problems), mental health (depression symptoms), chronic health condition (presence of hypertension, diabetes, gestational diabetes, etc.) IPV, pregnancy intendedness, home environment (partner/family alcohol or drug problems), adequacy of prenatal and postpartum care (timing of initiation and percentage of expected visits attended) and birth outcome variables (gestational age at delivery, birth weight, neonatal intensive care unit admission, and route of delivery).

Specific Aim 1: Determine the representativeness of the RCT sample. Hypotheses were tested by conducting Pearson χ^2 and T-test analyses using the data from the risk factor

screening questionnaire (n=271). Specifically, researchers compared individual endorsed risk items, total number of endorsed risk items, and total score on risk factor screening questionnaire for women who were eligible and consented to participate in the RCT (n=149) and those who were eligible but declined to participate (n=122). Significance was set at 0.05 for univariate analyses.

Specific Aim 2: Identify predictors of prenatal care attendance. The hypothesis that pregnancy specific, IPV, mental health, substance use, and social support factors would significantly improve the prediction for percentage of expected prenatal care visits attended was tested by conducting a hierarchical linear regression using the data from the RCT baseline and follow-up assessments (n=122). Risk and protective factors identified by the literature for late initiation, very late initiation, and inadequate prenatal care were tested in the model.

Sociodemographic factors were entered into the initial block. Barriers to PNC and pregnancy risk level were entered into the second block. Pregnancy specific, IPV, mental health, substance use, and social support factors were entered into the third block (See Table 9). The dependent variable was the ratio of expected prenatal care visits attended. The IPV variable was dummy coded before being entered into the model. Significance was set at 0.05 for regression analyses. Variables were assessed for missing data, normality, and outliers. Rates of missing data were very low. In order to account for missing data in CES-D total score, the expectation maximization method was used. For the unintended pregnancy variable, the data was treated as is; cases with missing values were excluded from the analyses (n=1).

Variables reaching a significance level of $< .05$ in the first hierarchical linear regression analysis were included in an additional linear regression model. The additional analysis provided

a regression equation that can be used as a clinical tool to help predict the percentage of expected visits a pregnant woman is likely to attend based on her individual risk and protective factors.

Specific Aim 3: Identify predictors of postpartum care attendance. The hypothesis that mental health, substance use, and maternal and infant birth outcome factors would significantly improve the prediction for postpartum care visit attendance was tested using a hierarchical binary logistic regression with data from the RCT baseline and follow-up assessments (n=118). Risk and protective factors identified in the literature as correlates of postpartum care nonattendance were tested in the model.

RCT group and age were entered into the initial block. Adequacy of prenatal care was dummy coded and entered into the second block. Mental health, substance use, and maternal and infant birth outcome factors were added into the third block (See Table 10). The dependent variable was postpartum visit attendance (yes/no), with no visit attendance as the reference group. Significance was set at 0.05 for regression analysis. Variables were assessed for missing data, normality, and outliers. Rates of missing data were very low. In order to account for missing data in CES-D total score, the expectation maximization method was used. For the route of delivery variable, the data was treated as is; cases with missing values were excluded from the analyses (n=5). The Winsorizing method was used to minimize the effect of outliers in the gestational age at delivery variable (Tukey, 1961). Gestational age at birth of 26, 25, and 24 weeks were coded as 31, 30, and 29 weeks, respectively.

Results

Specific Aim 1: Representativeness of the RCT sample.

CONSORT diagram. During study recruitment, n=903 women completed the risk factor screening questionnaire and n=271 were eligible for RCT participation (See Figure 1). Of those

who were eligible, n=149 (55.0%; Consenters) enrolled in the RCT and n=122 (45.0%; Non-consenters) elected not to participate in the RCT. Among the non-consenters, n=65 (53.3%) were not interested in RCT enrollment and n=57 (46.7%) expressed interest but did not complete the informed consent process (i.e., could not be contacted, did not return RA phone calls, or were no shows for their scheduled assessment visits).

Descriptive statistics. First, we examined sociodemographic characteristics of Consenters (n=149) and Non-consenters (n=122). Findings are summarized in Table 1.

Table 1.

Sociodemographic Characteristics of Consenters and Non-consenters who Completed the Risk Factor Screening Questionnaire

Sociodemographic Characteristics	Consenters n=149	Non-consenters n=122
Age (Mean ± SD)	24.9 ± 5.5	25.6 ± 6.3
	n (%)	n (%)
Marital Status		
Single	123 (82.6)	95 (77.9)
Married/Living Together	22 (14.8)	16 (13.1)
Divorced/Separated	4 (2.7)	9 (7.4)
Other	0 (0)	2 (1.6)
Living Situation		
With other adults (family, friends, partner)	116 (77.9)	73 (59.8)
Alone	12 (8.1)	9 (7.4)
Alone with children	21 (14.1)	39 (32.0)
Unstable arrangements	0 (0.0)	1 (0.8)
Employment		
Full-time/Part-time	41 (27.5)	36 (29.5)
Unemployed	91 (61.1)	78 (63.9)
Student	17 (11.4)	8 (6.6)
Education		
Less than high school education	41 (27.5)	50 (41.0)
High school education/GED	67 (45.0)	51 (41.8)
Some college	34 (22.8)	17 (13.9)
College degree	7 (4.7)	4 (3.2)
Insurance		
Private	14 (9.4)	12 (9.8)
Medicaid/VCC/Medicare	123 (82.6)	96 (78.7)

None	11 (7.4)	14 (11.5)

Univariate analyses. Next, rates of risk factor endorsement for women who and did not consent to the RCT were analyzed to test the two hypotheses for Specific Aim 1 (summarized in Table 2). The first hypothesis that women who consented to the RCT would endorse fewer risk factors than those who did not consent was not supported. For sociodemographic screener items, only education showed a group difference with RCT consenters more likely to have at least a high school education compared to non-consenters ($p = .022$). No group differences were found for substance use, depressive symptoms, or IPV items on the screener. Further, the two groups did not differ on total number of risk factors endorsed during screening (See Table 2). Similarly, the second hypothesis that women who enrolled in the RCT would have lower scores on the risk factor questionnaire than women who declined study participation was not supported. There were no differences in total scores on the risk factor questionnaire between women who did and did not enroll in the RCT (See Table 2).

Table 2.

Sociodemographic and psychosocial characteristics of women who did and did not consent to RCT participation.

Risk Factors	Consenters n=149	Non-consenters n=122	P-value
	n (%)	n (%)	
Sociodemographic			
Single	123 (82.6)	95 (77.9)	.334
Unemployed	91 (61.1)	77 (63.1)	.731
Less than high school education	41 (27.5)	50 (41.0)	**.020**
Receipt of social services	112 (75.2)	86 (70.5)	.388
Public/no insurance	134 (90.5)	108 (90.0)	.882
Under 18 years of age	5 (3.4)	5 (4.1)	.747
Open case with Child Protective Services	9 (6.0)	8 (6.6)	.848
Substance Use			
Tobacco/nicotine use (past 3 months)	114 (77.0)	94 (77.0)	.997

Tobacco/nicotine use (past week)	84 (56.8)	64 (52.5)	.480
Alcohol use (past 3 months)	89 (59.7)	66 (54.1)	.351
Alcohol use (past week)	9 (6.0)	10 (8.2)	.489
Prescription drug misuse (past 3 months)	16 (10.7)	10 (8.3)	.507
Prescription drug misuse (past week)	2 (1.3)	2 (1.7)	.827
Illicit drug use (past 3 months)	50 (33.6)	31 (25.6)	.157
Illicit drug use (past week)	16 (10.7)	12 (9.9)	.826
Alcohol problems (lifetime)	8 (5.4)	5 (4.3)	.681
Prescription drug problems (lifetime)	3 (2.0)	1 (0.8)	.431
Illicit drug problems (lifetime)	12 (8.1)	5 (4.1)	.187
Individual(s) living with you with alcohol problems	12 (8.1)	4 (3.3)	.097
Living with someone who has problems with other drugs	6 (4.1)	3 (2.5)	.467
Depressive Symptoms (past month)			
Felt down depressed hopeless	85 (57.0)	69 (56.6)	.935
Little interest or pleasure in doing things	95 (63.8)	75 (61.5)	.699
Intimate Partner Violence			
Ever hit, kicked, punched or hurt by someone (past year)	27 (18.1)	19 (15.6)	.578
Feeling unsafe in current relationship	3 (2.3)	6 (5.7)	.176
Previous partner makes you feel unsafe	13 (8.7)	14 (11.5)	.452
	Mean (SD)	Mean (SD)	
Number of Risk Items Endorsed	7.77 (2.34)	7.53 (2.33)	.389
Total Risk Factor Score	6.29 (2.62)	5.78 (2.15)	.085

Note. For all analyses, significance at $p \leq .05$.

Specific Aim 2 & 3: Predictors of prenatal care and postpartum visit attendance

CONSORT diagram. After analyzing differences between consenters and non-consenters, analyses focused on women who enrolled in the study. Among those who provided informed consent and were randomized to either the experimental or control groups, n=26 (17.4%) were excluded from further analyses for the following reasons: n=11 (7.4%) experienced a miscarriage or termination of pregnancy and n=15 (10.1%) were missing critical outcome data (See Figure 1). Participants were categorized as missing outcome data if they did not have documented delivery outcomes as the APNCU index ratio could not be calculated for regression analyses. These participants included women who withdrew from study participation

following the baseline assessment, did not return attempts to contact, moved to different states, or were incarcerated during the duration of the study. The final sample for Specific Aims 2 and 3 included n=123 (82.6%) women.

Descriptive statistics. Sociodemographic characteristics for these women are summarized in Table 3. Participants who enrolled in the RCT and had a documented live birth, were, on average, 24.8 (SD = 5.5) years of age. Most were unemployed (63.4%), had public insurance (83.9%), and made less than $10,000 dollars per year (75.6%). About half of the participants were single (45.5%) and 46.3% had a high school diploma or GED. The majority were living with family, friends, or a sexual partner (78.0%) and 78.9% received social services. Nearly all participants endorsed at least one barrier to prenatal care (95.1%). The most common barriers to care were systematic rather than personal, including lack of insurance, inflexible clinic schedule, and lack of transportation.

Table 3.

Baseline Sociodemographic Characteristics of RCT Participants who had a Live Birth

Sociodemographic Characteristics	Participants n=123
Age (Mean ± SD)	24.8 ± 5.5
	n (%)
Marital Status	
Single	56 (45.5)
Married/Living Together	28 (22.7)
Divorced/Separated	3 (2.4)
Partnered/In a relationship	36 (29.3)
Living Situation	
With other adults (family, friends, partner)	96 (78.0)
Alone/Alone with children	23 (18.7)
Unstable arrangements	4 (3.3)
# of children in household [Median (min-max)]	1 (0-6)
Employment	
Full-time/Part-time	31 (25.2)
Unemployed	79 (63.4)
Other	14 (11.3)

Education	
< High school education	36 (29.3)
High school education/GED	57 (46.3)
Some college	23 (18.7)
College degree	7 (5.7)
Insurance	
Private	10 (8.1)
Medicaid/VCC/Medicare	103 (83.9)
None	10 (8.1)
Income	
< $10,000	93 (75.6)
$10,000 - $24,999	21 (17.0)
$25,000 – $50,000+	9 (7.3)
Receipt of Social Services	97 (78.9)
Barriers to Care	
Lack of finances/insurance	117 (95.1)
Inflexible clinic schedule	29 (23.6)
Lack of transportation	22 (17.9)
Hectic personal schedule	14 (11.4)
Inflexible work schedule	10 (8.1)
Lack of childcare	6 (4.9)
Endorsed any barriers to care	118 (95.9)

Psychosocial and health characteristics are summarized in Table 4. Overall, 37% of women reported they had experienced IPV during their current pregnancy or the 12 months prior to pregnancy. Over half the women (69.1%) were identified as at risk for clinical depression. On average, women endorsed relatively high social support scores.

Table 4.

Baseline Psychosocial and Health Characteristics of RCT Participants who had a Live Birth

Psychosocial & Health Characteristics	Participants n=123
	n (%)
IPV	
Preconception only	14 (11.4)
Prenatal only	9 (7.3)
Both preconception and prenatal	23 (18.7)
Physical Health	
Presence of chronic condition	19 (15.4)
Mental Health	

CES-D score ≥16 (at risk for clinical depression)	85 (69.1)
Total CES-D score (Mean ± SD)	22.7 ± 11.2
Self-esteem	
Total RSES score (Mean ± SD)	28.6 ± 3.4
Social support	
Total ISEL score (Mean ± SD)	45.5 ± 9.3

Substance use factors are summarized in Table 5. Over half the women endorsed using at least one substance within the past month; 65.0% smoked cigarettes, 23.6% drank alcohol, and 30.9% used illicit drugs.

Table 5.

Baseline Substance Use among RCT Participants who had a Live Birth

Substance Use	Participants n=123
	n (%)
Cigarette Smoking	
Today	46 (36.6)
Past week	21 (17.1)
Past month	13 (10.6)
Past 3 months	13 (10.6)
More than 3 months ago	7 (5.7)
Alcohol Use	
Past week	4 (3.3)
Past month	25 (20.3)
Past 3 months	41 (33.3)
More than 3 months ago	36 (29.3)
Illicit Drug Use	
Today	3 (2.4)
Past week	20 (16.3)
Past month	15 (12. 2)
Past 3 months	18 (14.6)
More than 3 months ago	28 (22.7)
Prescription Drug Misuse	
Past week	2 (1.6)
Past month	3 (2.4)
Past 3 months	5 (4.1)
More than 3 months ago	8 (6.5)
Someone living with you has problems with alcohol (n = 96)	6 (6.3)

Someone living with you has problems with drugs (n = 96)	6 (6.3)

Pregnancy and peripartum care characteristics are summarized in Tables 6 and 7. The majority of women reported their current pregnancy was unintended (77.2%). Most women experienced a medially low risk pregnancy (72.4%). On average, women initiated prenatal care during their first trimester (11.5 weeks gestation) and attended approximately 10 prenatal care visits. Many women met criteria for adequate or adequate plus prenatal care (68.3%) and attended at least one postpartum visit (81.3%).

Table 6.

Baseline Pregnancy Characteristics for RCT Participants who had a Live Birth

Pregnancy Characteristics	Participants n=123
	n (%)
Unintended Pregnancy	95 (77.2)
Contraception Use at Conception	37 (30.1)
EGA (weeks) at New OB Appointment (Mean ± SD)	11.5 ± 5.2

Table 7.

Peripartum Care for RCT Participants who had a Live Birth

Peripartum Care	Participants n=123
	n (%)
Pregnancy Risk Level	
High Risk	34 (27.6)
Low Risk	89 (72.4)
Total # PNC Appointments (Mean ± SD)	10.2 ± 3.8
Adequacy of PNC	
Inadequate	26 (21.1)
Intermediate	13 (10.6)
Adequate/Adequate Plus	84 (68.3)
Postpartum Visit Attendance	
No visit	23 (18.7)
1+ visits	100 (81.3)

Birth outcomes are summarized in Table 8. Most women had a standard vaginal delivery (64.2%) and only about 1 in 5 women had babies who were born preterm (19.5%) or with a low birth weight (20.3%)

Table 8.

Birth Outcomes for RCT Participants who had a Live Birth

Birth Outcomes	Participants n=123
	n (%)
Route of Delivery	
Standard Vaginal Delivery	79 (64.2)
Cesarean Section	39 (31.7)
Undocumented	5 (4.1)
Gestational age at delivery (Mean ± SD)	37.8 ± 3.1
Preterm Birth	24 (19.5)
Low Birth Weight	25 (20.3)
NICU Admission	16 (13.0)

Specific Aim 2: Predictors of prenatal care attendance.

Multivariate analysis. To test the hypothesis that pregnancy specific, IPV, mental health, substance use, and social support factors would significantly improve the prediction for percentage of expected prenatal care visits attended, a hierarchical linear regression was conducted. One case with missing values was excluded from the analyses. In the initial block when age, less than high school education, and living with other adults were entered, the model significantly predicted prenatal care attendance, $F(3, 117) = 2.99$, $p = .034$, $R^2 = .07$. When high risk pregnancy and total number of barriers to prenatal care were added to the second block of the model, they significantly improved the prediction, $\Delta R^2 = .17$, $\Delta F(2, 115) = 13.04$, $p < .001$. The first and second block variables together predicted prenatal care attendance, $F(5, 115) = 7.37$, $p < .001$, $R^2 = .24$. The pregnancy intention, IPV, mental health, substance use, and social support variables in the third block did not significantly improve the prediction, $\Delta R^2 = .05$, $\Delta F(8,$

107) = .91, p = .511. All variables together significantly predicted prenatal care attendance, F(13, 107) = 3.38, p < .001, R^2 = .29. The overall model accounted for 29.1% of variance in prenatal care attendance.

As shown in Table 9, having a high-risk pregnancy (p < .001) and having fewer barriers to prenatal care (p = .013) were significantly associated with attending more expected prenatal care visits.

Table 9.
Hierarchical Linear Regression Predicting Ratio of Observed to Expected Prenatal Care Visit Attendance (n=122)

	Model 1				Model 2				Model 3			
Predictor Variables	B (95% CI)	b	*t*	P Value	B (95% CI)	b	*t*	P Value	B (95% CI)	b	*t*	P Value
Sociodemographic												
Age	.01 (-.00, .02)	.15	1.59	.114	.00 (-.01, .01)	.06	.70	.486	.01 (-.00, .02)	.12	1.28	.204
< High school education (0, no; 1, yes)	.03 (-.00, .02)	.04	.45	.657	.05 (-.06, .15)	.08	.89	.377	.07 (-.04, .17)	.10	1.18	.241
Living with other adults (0, no; 1, yes)	-.14 (.09, .14)	-.19	-2.11	.037	-.10 (-.21, .20)	-.14	-1.64	.103	-.11 (-.23, .01)	-.16	-1.87	.064
Barriers to PNC (0 - 6)	-	-	-	-	.07 (-.12, -.03)	-.25	-3.03	.003	-.07 (-.12, -.01)	-.22	-2.51	**.013**
Pregnancy Specific												
High-risk pregnancy (0, no; 1, yes)	-	-	-	-	.25 (.14, .36)	.39	4.54	<.001	.23 (.12, .35)	.36	3.93	**<.001**
Unintended pregnancy (0, no; 1, yes)	-	-	-	-	-	-	-	-	.02 (-.10, .13)	.02	.25	.804
IPV					-	-	-	-				
Preconception or prenatal IPV (0, no; 1, yes)	-	-	-	-	-	-	-	-	-.03 (-.16, .10)	-.04	-.49	.628
Both preconception & prenatal IPV (0, no; 1, yes)	-	-	-	-	-	-	-	-	.06 (-.09, .20)	.08	.79	.430
Mental Health					-	-	-	-				
Total CES-D Score	-	-	-	-	-	-	-	-	-.00 (-.01, .00)	-.05	-.50	.620
Substance Use					-	-	-	-				
Recency of cigarette use	-	-	-	-	-	-	-	-	-.01 (-.02, .02)	-.05	-.50	.622
Recency of alcohol use	-	-	-	-	-	-	-	-	.01 (-.02, .034	.04	.42	.674
Recency of drug use	-	-	-	-	-	-	-	-	-.01 (-.03, .01)	-.07	-.74	.461
Social Support					-	-	-	-				
Total ISEL score	-	-	-	-	-	-	-	-	.01 (-.00, .01)	.17	1.60	.113
R^2	.071				.243				.291			
R^2 Change	.071				.172				.048			

Clinical relevance. In an additional analysis, the two predictors reaching the significance level of $p < .05$, barriers to PNC and high-risk pregnancy, were entered into a linear regression model to provide a regression equation that could be used clinically as a tool to help predict the ratio of attended to expected PNC visits. Below is the regression equation.

$$\text{Predicted Ratio of Attended to Expected PNC Visits} = \left[\text{High-risk Pregnancy} \times .282\right] + \left[\text{Sum of Barriers to PNC} \times -.085\right] + 1.03$$

***Instructions for clinicians*.** In order to calculate ratio of attended to expected PNC visits, the value for high-risk pregnancy should be determined and entered (0=no, 1=yes) and the six categories of barriers (finances/insurance, clinic schedule, transportation, personal schedule, work schedule, and childcare) to PNC should be totaled and entered (range 0 to 6).

Specific Aim 3: Predictors of postpartum care attendance.

Multivariate analysis. To test the hypothesis that mental health, substance use, and maternal and infant birth outcome factors would significantly improve the prediction for postpartum care visit attendance, a hierarchical binary logistic regression was conducted. Cases with missing values were excluded from the analyses (n=5). When age and RCT group assignment were entered in the initial block of the model, it did not significantly predict postpartum attendance, $\chi 2\ (2) = 4.98$, $p = .090$. The initial model explained approximately 6.7% (Nagelkerke R Square) of the postpartum visit attendance and correctly classified 81.4% of cases. When adequacy of prenatal care attendance was added to the second block, the model significantly predicted postpartum visit attendance, $\chi 2\ (4) = 28.76$, $p < .001$. Variables in the first and second blocks of the model together explained approximately 35.0% (Nagelkerke R Square) of the postpartum visit attendance and correctly classified 85.6% of cases. The final overall

model, including mental health, substance use, and birth outcome variables, was statistically significant, $\chi 2$ (10) = 32.12, $p < .001$, and correctly classified 87.3% of cases. As a whole, the predictors included in the final model explained approximately 38.6% (Nagelkerke R Square) of the postpartum visit attendance.

As shown in Table 10, when controlling for other predictors, having less than adequate prenatal care attendance was significantly associated postpartum visit nonattendance. Compared to women with adequate prenatal care, women with inadequate prenatal care were 79% less likely to attend a postpartum visit ($p = .033$) and those with intermediate prenatal care were 97% less likely to attend a postpartum visit ($p < .001$).

Table 10.
Hierarchical Binary Logistic Regression Predicting Postpartum Visit Attendance (n=118)

	Model 1				Model 2				Model 3			
Predictor Variables	B	Standard Error	P Value	Odds Ratio (95% CI)	B	Standard Error	P Value	Odds Ratio (95% CI)	B	Standard Error	P Value	Odds Ratio (95% CI)
RCT Group (0, ASC; 1, PNBI)	1.11	.52	.034	3.02 (1.09, 8.39)	1.42	.63	.025	4.12 (1.20, 14.16)	1.28	.67	.054	3.61 (.98, 13.38)
Sociodemographics												
Age	.01	.04	.887	1.01 (.93, 1.09)	-.01	.05	.800	.99 (.90, 1.08)	-.02	.05	.756	.98 (.88, 1.09)
PNC												
Inadequate PNC (0, no; 1, yes)	-	-	-	-	-1.27	.64	.046	.28 (.08, .98)	-1.57	.74	**.033**	.21 (.05, .88)
Intermediate PNC (0, no; 1, yes)	-	-	-	-	-3.43	.78	<.001	.03 (.01, .15)	-3.68	.86	**<.001**	.03 (.01, .13)
Mental Health												
Total CES-D Score	-	-	-	-	-	-	-	-	.02	.03	.589	1.02 (.96, 1.08)
Substance Use												
Recency of cigarette use (0 – 7)	-	-	-	-	-	-	-	-	-.02	.12	.873	.98 (.78, 1.24)
Recency of alcohol use (0 – 7)	-	-	-	-	-	-	-	-	-.20	.18	.288	.82 (.56, 1.18)
Recency of drug use (0 – 7)	-	-	-	-	-	-	-	-	-.00	.14	.977	1.00 (.76, 1.30)
Birth Outcomes												
SVD (0, no; 1, yes)	-	-	-	-	-	-	-	-	-.77	.75	.308	.46 (.11, 2.00)
Gestational age at birth (weeks)	-	-	-	-	-	-	-	-	-.135	.727	.394	.87 (.64, 1.19)
R^2	.067				.350				.386			

Discussion

The purpose of the present study was to 1) examine sample representativeness by comparing demographic and psychosocial characteristics of pregnant, African American women who did and did not enroll in an RCT focused on improving prenatal and postpartum care attendance and 2) identify predictors of prenatal and postpartum care attendance in African American women at risk for poor compliance. The study analyzed existing data from a CDC-funded RCT targeting health disparities in maternal and infant birth outcomes.

Specific Aim 1: Representativeness of the RCT sample

Specific Aim 1 examined sample representativeness by comparing women who consented to RCT participation (n=149; consenters) with those who did not (n=122; non-consenters). Across 25 demographic and psychosocial risk variables, only one group difference was found, supporting RCT sample representativeness.

Specific Aims 2 & 3: Predictors of prenatal care and postpartum visit attendance

Specific Aims 2 and 3 analyzed data for the n=123 RCT participants who had a live birth and critical outcome data. Hierarchical linear regression identified variables predictive of prenatal care attendance, including higher total barriers to prenatal care as a risk factor and high-risk pregnancy as a protective factor for prenatal care attendance. Similarly, hierarchical binary logistic regression was used to identify variables predictive of postpartum care attendance. Analyses identified adequate prenatal care as a predictor for postpartum care attendance.

Summary of Findings

Specific Aim 1: Representativeness of the RCT sample. The present study found that consenters and non-consenters endorsed similar demographic and psychosocial risk factors, with only one difference; non-consenters were twice as likely to report less than high school education

compared to RCT participants. No group differences were found in the number of risk factors endorsed or total risk scores.

Specific Aim 2: Predictors of prenatal care attendance. Using hierarchical linear regression, two predictors of prenatal care attendance were identified—having a high-risk pregnancy and having fewer barriers to prenatal care. The final overall model significantly predicted prenatal care attendance, $F(13, 107) = 3.38$, $p < .001$, $R^2 = .29$ and accounted for 29.1% of variance in prenatal care attendance.

Specific Aim 3: Predictors of postpartum care attendance. Using hierarchical binary logistic regression, the model found adequate prenatal care to be a significant predictor of postpartum care attendance. Further, the final model as a whole explained 38.6% (Nagelkerke R Square) of the variance, and correctly classified 87.3% of cases.

Discussion of Findings

Representativeness of the RCT sample. With one exception, women who consented to the RCT did not differ from non-consenters on any demographic or psychosocial variables. These results were surprising, as previous studies medical care settings have found differences between persons who do and do not enroll in clinical trials across a range of demographic and psychosocial variables. For example, members of minority racial and ethnic groups are less likely to participate in clinical trials than White individuals. Such patterns have persisted even after the NIH Revitalization Act of 1993 (Durant et al., 2011; Anwuri et al., 2013). Within cancer trials, regardless of race or ethnicity, low socioeconomic status (e.g., lower education and income levels) has consistently been associated with decreased research participation (Ford et al., 2008; Guiliano et al., 2000; Sateren et al., 2002; Unger et al., 2013).

While no RCTs targeting prenatal care compliance have examined participant representativeness, differences between consenters and non-consenters in studies of mental health conditions have been reported. Findings are limited, however, as available measures are often limited to demographic variables and screening criteria. To illustrate, in a study focused on improving participant physical health and reducing substance use during psychosis, Lally et al. (2018) found that those giving informed consent had lower illness severity and less functional impairment than those not enrolled in the RCT.

In a primary care based RCT targeting heavy/problem substance use, Kelpin and colleagues (2018) had a unique opportunity to look at a broader array of variables because recruitment involved completion of an anonymous health behavior survey. They found individuals providing informed consent to the RCT targeting substance use were more likely to report a variety of psychosocial and mental health problems, often of greater severity, than those who declined RCT participation. In fact, the majority of group differences identified between consenters and non-consenters were for variables unrelated to RCT inclusion criteria.

The Kelpin et al. (2018) study is particularly noteworthy, as it recruited non-pregnant women from the same clinic used for the present study. Unfortunately, the present study was limited to demographic variables and items which formed the basis for study inclusion. Although the present study only identified one difference between consenters and non-consenters, these findings were consistent with the Kelpin et al (2018) study, in that, when assessing representativeness based on inclusion criteria, few differences were identified.

Disparities in peripartum care. Sadly**,** racial and ethnic disparities are prominent in prenatal health care access and services, likely contributing to disparate maternal and infant health outcomes. Research has shown that Black, non-Latinx women are more likely to receive

late, inadequate, or no prenatal care than White, non-Latinx women (Osterman & Martin, 2018; Partridge et al., 2012). Black, non-Latinx women are also more likely to experience fetal growth restriction, preterm birth, fetal death, and maternal death than mothers from any other racial or ethnic group (ACOG, 2015; Bryant et al., 2010). Racial disparities extend beyond delivery outcomes into postpartum care access and wellbeing. Compared to White women, Black women are less likely to attend their postpartum visit or receive contraception services (de Bocanegra et al., 2017; Rankin et al., 2016). They are more likely to report symptoms of postpartum depression and difficulty with breastfeeding than White women (Howell et al., 2005; Jones et al., 2015).

In light of these staggering health disparities, the current study used existing data from a CDC-funded RCT targeting health disparities in maternal and infant birth outcomes to investigate predictors of peripartum care attendance. While risk factors associated with late initiation and inadequate prenatal care as well as postpartum care nonattendance have been identified, there have been no published studies of predictors of prenatal and postpartum care attendance within a group of pregnant, African American women who are at risk for poor prenatal care compliance.

Importantly, within this more homogeneous sample of African American women at high risk for poor prenatal care attendance, predictors of prenatal and postpartum care attendance were able to be identified. Within the at-risk group, predictors of peripartum care attendance were similar to findings in previous literature.

Predictors of prenatal care attendance.

Sociodemographics. Epidemiological studies in the US have consistently found associations between sociodemographic factors such as, younger age, being single/never

married, and having less than a high school education, and both late entry into prenatal care and inadequate prenatal care (Baer et al., 2018; Gadson et al., 2017; Hulsey et al., 2000; Osterman & Martin, 2018; Pagnini & Reichman, 2000; Partridge et al., 2012). Many utilized data from the National Center for Health Statistics or state-wide birth certificate databases, with nationally or regionally representative samples. In contrast, the present study focused on a group of African American women from a single urban prenatal clinic. This restricted the range of many of the demographic variables as it was a safety net clinic that served predominately low-income, racial and ethnic minorities. Also, willingness to participate in the RCT may have further restricted the sample heterogeneity. Hence, it is not surprising that sociodemographic factors did not predict prenatal care attendance.

Barriers to care. In contrast to sociodemographic variables, barriers to prenatal care were found to predict prenatal care attendance, with a larger number of barriers to care associated with poorer prenatal care attendance. While nearly everyone reported lack of finances/insurance as a barrier to care, other barriers were reported much less often, leading to more variation in the total number of barriers variable than many of the other sociodemographic variables.

Different from the literature on sociodemographic variables as predictors of prenatal care attendance, the majority of studies investigating the barriers to prenatal care have been conducted in predominately low-income populations rather than nationally representative samples. Previous literature, mostly among Medicaid recipients, identified several barriers to care for women seeking prenatal services including, lack of transportation, inflexible clinic hours, inaccessible healthcare providers, and poverty (Mazul et al., 2017; Pagnini & Reichman, 2000; Perloff & Jaffee 1999). Particularly relevant to the current study population, in a qualitative study of low-income African American women, participants identified poverty, lack of safety, limited

transportation, and inflexible clinic hours and locations as barriers to attending prenatal care (Mazul et al., 2017). Like the Mazul et al. (2017) study, women in the current study identified systematic barriers to prenatal care (i.e., lack of finances/insurance, inflexible clinic schedules, lack of transportation) as opposed to psychosocial barriers (i.e., hectic schedule, inflexible work schedule, and lack of childcare) as the most prevalent barriers preventing receipt of prenatal care. Further investigation is needed to determine the individual impact of these barriers on prenatal care received among this population. Other potential barriers also warrant further examination, such as fear of legal consequences (e.g., Child Protective Services involvement) due to substance use and other health risk behaviors (Polak, Haug, Drachenberg, & Svikis, 2015).

High risk pregnancy. The present study found high-risk pregnancy to be a predictor of prenatal care attendance, as well. While consistent with the literature, this finding must be interpreted with caution given the measure used to characterize adequacy of prenatal care. Specifically, the present study used Kotelchuck's APNCU index, one of several potential measures, because it is the most widely used measure of prenatal care adequacy, and it accounts for important factors (i.e., timing of initiation, gestational length, and ACOG recommended schedule of visits) that are not accounted for in other measures or in number of prenatal care visits alone (Kotelchuck, 1994; Kogan et al., 1998).

Unfortunately, one shortcoming of the APNCU index is that it was developed for low risk, "uncomplicated," pregnancies, and compares number of PNC visits attended to the ACOG recommended schedule of PNC visits, regardless of a woman's pregnancy risk level. Women with complex or medically high-risk pregnancies (i.e., medical or obstetric problems) often require more frequent monitoring throughout their pregnancy than women with medically low-risk pregnancies and are more likely to have shorter gestational lengths because a preterm

delivery is more likely for this group (AAP & ACOG, 2017). Thus, most women with high-risk pregnancies will have a higher ratio of attended to expected prenatal care visits than women with low-risk pregnancies.

For this reason, the APNCU index, among other measures of prenatal care adequacy, may not be the best measure of "adequate care" for women with high-risk pregnancies (Stringer, 1998). For example, previous studies have found women who have preterm and low birth weight babies are disproportionately represented in the adequate plus category (≥ 110% of expected visits and initiation before the 5th month of pregnancy) of the APNCU index, supporting the notion that women with higher risk pregnancies attend more appointments (Chen, Wen, Yang, & Walker, 2007; Koroukian & Rimm, 2002). Due to the design of the parent RCT targeting health disparities in maternal and infant birth outcomes, approximately one in four women in the current study had a high-risk pregnancy. For these women, the ratio of attended to expected visits is likely not an accurate measure of adequate care or predictive of reduced risk of adverse maternal and neonatal outcomes simply due to the nature of a high-risk pregnancy.

Further, recent literature suggests that using the APNCU index among women with low-risk pregnancies may also lead to inaccurate conclusions. Carter and colleagues (2016) found that attending ≥10 prenatal care appointments was associated with higher rates of pregnancy intervention without improvement in neonatal health outcomes, suggesting the current ACOG guidelines may require too many visits for women with low-risk pregnancies.

In order to help remedy the shortcomings of measuring adequacy of PNC based on quantity of visits, the quality of PNC visits should be assessed. PNC visits should be assessed for the ACOG Guidelines for Perinatal Care (2012) suggested components including the following: 1) assess well-being of women and fetus; 2) provide ongoing, timely, and relevant prenatal

education; 3) complete recommended health screenings and review results; and 4) detect medical and psychosocial complications and institute appropriate interventions.

Unintended pregnancy. While prior studies consistently found unintended pregnancy was associated with less prenatal care utilization, the present study did not find this effect. There may be several reasons for this finding. First, the association between unintended pregnancy and late (>12 weeks gestation) prenatal care initiation is more robust than the relationship between unintended pregnancy and inadequate prenatal care (Cheng et al., 2009; Gazmararian et al., 1999; Hulsey et al., 2000; Mikhail 2000; Orr et al., 2008; Pagnini & Reichman, 2000). For example, in a study of n=9,048 mothers from the Maryland Pregnancy Risk Assessment Monitoring System between 2001 and 2006, Cheng et al. (2009) found compared to women with planned pregnancies, women with unintended pregnancies were more likely to have late initiation of prenatal care, but not inadequate care. Further, in a study conducted in Baltimore, Maryland among n=913 Black women, those with unwanted pregnancies at their first prenatal visit were nearly six times more likely to initiate very late (>27 weeks gestation) prenatal care than women with wanted or mistimed pregnancies (Orr et al., 2008).

Unfortunately, the parent RCT, for the current study, required eligibility restrictions for timing of PNC initiation (<26 weeks gestation) in order to optimize the opportunity to detect an intervention effect. As a result, many women who would have been categorized as late entry to prenatal care were excluded from the study, limiting the current study's ability to identity an association between variables such as unintended pregnancy and prenatal care utilization. While this effect may be present among African American women at-risk for poor prenatal care utilization, it was unable to be assessed due to the methodological limitations.

Additionally, among this sample of women at-risk of poor prenatal care utilization, rates of unintended pregnancy were 77%, much higher than those of pregnant women in the general population (45%) and the aforementioned studies (41%-45%) (Cheng et al., 2009; Finer & Zolna, 2016; Orr et al., 2008). Although, unintended pregnancy is a known racial health disparity, with a higher percentage of Black mothers experiencing an unintended pregnancy compared to mothers from other racial or ethnic groups (ACOG, 2015), the rate of unintended pregnancy among this sample was particularly high. This finding speaks to the elevated risk profile and homogeneity of the sample, making it more difficult to detect a significant effect.

Psychosocial factors. In the overall regression model, high-risk pregnancy and fewer barriers to care were the only significant predictors of prenatal care attendance. The addition of psychosocial variables did not significantly improve the model. These findings were unexpected as previous studies have identified substance use, depressive symptoms, lack of social support, and IPV variables as risk factors for poor prenatal care attendance (Baer et al., 2018; Cha & Masho, 2014; Jamieson, 2018; Pagnini & Reichman, 2000; Sidebottom et al., 2017). The lack of significant relationships may be due to the high rates of endorsement across these psychosocial variables. Substance use, depressive symptoms, and IPV items were included on the risk factor screening questionnaire, and consequently, rates among this sample were much higher than those of pregnant women in the prior studies and the general population.

As an example, in a US national survey in 2012, 16% of pregnant women reported smoking cigarettes, 9% reported drinking alcohol, and 6% reported using illicit drugs (Forray, 2016). In New Jersey, among Medicaid recipients, 25% of pregnant women smoked cigarettes, 8% drank alcohol, and 8% used drugs during pregnancy (Pagnini & Reichman, 2000). At the baseline assessment for the current study, pregnant women endorsed substantially higher rates of

substance use within the past month; 65% smoked cigarettes, 24% drank alcohol, and 31% used illicit drugs.

Similarly, according to a systematic review of literature in 2015, within the general population of high-income countries, the prevalence of antenatal depression ranged from 7% to 20% (Biaggi, Conroy, Pawlby, & Pariante, 2016). Sidebottom and colleagues (2017) used prenatal intake risk assessments from Minnesota community health centers as well as 2005-2009 Minnesota birth certificate data (n=2341) to compare adequacy of prenatal care of women different levels of depression; 16% had moderate/high depressive symptoms. In the current study, 69% of women were identified as at-risk for clinical depression, at least three times the rate in the general population and the Sidebottom et al. (2017) study.

Lastly, between 2009 and 2010, the Centers for Disease Control and Prevention reported the prevalence of physical IPV among pregnant women during pregnancy was 3.2% and 3.9% during the 12 months prior to pregnancy (US Department of Health and Human Services, 2013). Cha and Masho (2014), using the national 2004 to 2008 PRAMS data (n=202,367), found approximately 6% of women experienced preconception and/or prenatal physical violence were two times more likely to receive inadequate prenatal care than women who did not experience physical violence. Women in the current study reported physical IPV rates of 16.3% during pregnancy and 15.4% during the 12 months prior to pregnancy, five times that of the general population and three times the rate reported in the Cha and Masho (2014) study.

In addition to the high prevalence rates, another explanation for the discrepant finding related to IPV is the differences in measurement among studies. In the Cha and Masho (2014) study among others, IPV is defined as physical violence and excludes emotional or sexual abuse. However, in the current study the IPV variable included physical, sexual, and emotional abuse. It

is possible that physical violence alone has a stronger association with prenatal care attendance than when combined with other forms of IPV.

Predictors of postpartum care attendance. Predictors of postpartum visit attendance have received less attention than predictors of prenatal care attendance, and the present study is the first to examine predictors of postpartum care in African American women at risk for poor prenatal care utilization.

RCT group. The original RCT comparing the patient navigation and behavioral incentives (PNBI) intervention to treatment as usual reported a statistically significant group difference in postpartum visits, with PNBI intervention group women more likely than standard care controls to attend postpartum visits. Findings in the current study were consistent. Although, RCT group was not a significant predictor of prenatal care attendance, women in the PNBI group were 3.6 times more likely to attend a postpartum care visit than those in the control group. This is important because it suggests women in the PNBI group benefited from the intervention and speaks to the generalizability of study findings. Within the population of African American women at risk for poor prenatal care compliance, those who do not participant in a similar RCT may have different outcomes.

Sociodemographics. Numerous studies have identified an association between maternal age and postpartum visit attendance, with younger women less likely to receive postpartum care than older women (Baldwin et al., 2018; Chen et al., 2018; de Bocanegra et al., 2017; DiBari et al., 2014; Masho et al. 2018; Weir et al., 2011; Wilcox & Garrett, 2016). Many of these previously published studies relied upon state-wide public databases or urban academic medical center records. The present study did not find any such relationship.

Adequacy of PNC. Late initiation and inadequate prenatal care have consistently been shown to predict postpartum care nonattendance. In Oregon sample of women in an RCT targeting postpartum contraception use, Baldwin et al. (2018) found that both late initiation and inadequate prenatal care were associated with postpartum care nonattendance. Among Medicaid recipients in Virginia, women who did not attend prenatal care were less likely to attend a postpartum visit compared to women who received prenatal care (Masho et al., 2018). York et al. (2000) found that among African American women from an urban tertiary medical care center, those who did not receive any prenatal care were significantly less likely to attend a postpartum visit compared to women who did receive prenatal care, even if such care was inadequate. Consistently, the current study identified adequate prenatal care as a significant predictor of postpartum visit attendance. Specifically, women who received adequate prenatal care were four times more likely than those with inadequate prenatal care and 30 times more likely than those with intermediate prenatal care to attend at least one postpartum visit. This finding may be, in part, a result of the limitations of the APNCU index, particularly related to low risk pregnancy. The majority of the women who fall into the intermediate prenatal care category (50%-79% of expected visits and initiation before the 5th month of pregnancy) likely had a low risk pregnancy and may believe a postpartum visit is unnecessary.

These results suggest that among this at-risk sample improving prenatal care attendance can, in turn, improve postpartum care attendance as well. Previous RCTs of interventions targeting prenatal care attendance have yielded positive results. Till et al. (2015) found that pregnant women who receive incentives, such as cash or gift cards, are more likely to attend prenatal care visits more frequently and receive adequate prenatal care. Klerman and colleagues (2001) found that compared to women with usual care, those who received augmented care were

more likely to attend prenatal care visits. Interventions targeting prenatal care attendance should continue to be explored and implemented as they appear to have a two for one effect on peripartum care attendance rates.

Psychosocial factors. Similar to the analyses for prenatal care, neither depressive symptoms nor substance use were predictive of postpartum visit attendance. Studies of the relationship between depressive symptoms and postpartum care attendance have been inconsistent (Bennett et al., 2013; Masho et al., 2018; Shim et al., 2018). Within the sample most similar to the current study, among Medicaid recipients in Virginia, Masho et al. (2018) found that women with a history of depression (7%) had higher odds of attending a postpartum visit than those without such history. Thus, the lack of findings of the current study were somewhat surprising. Again, this finding may be due to the homogeneous nature of the present sample. Additionally, the inconsistent findings are likely due to variation in measurement of depression. For example, the current study assessed depressive symptoms; however, Masho et al. (2018) assessed history of depression and other studies assessed Major Depressive Disorder.

Prior literature has identified substance use as a risk factor for postpartum care nonattendance. Particularly among Medicaid recipients from Virginia, women who smoked were significantly less likely to attend a postpartum visit compared to women who did not smoke, and women who experienced drug and alcohol dependence were also less likely to attend a postpartum visit compared to those without drug and alcohol dependence (Masho et al, 2018). The present study did not find the same effect.

However, as previously mentioned the current study sample was uniquely at-risk. Additionally, the measurements of substance use varied across studies. While Masho et al. (2018) assessed for alcohol and drug dependence/abuse, the current study assessed most recent

use at the baseline assessment. Recency of use did not predict postpartum care attendance for cigarette use, alcohol use, or drug use. Given the high rates of endorsement of substance use within the past month (65% smoked cigarettes, 24% drank alcohol, and 31% used illicit drugs) in the current study, perhaps it would be more beneficial to assess for problematic use or dependence in future studies rather than most recent use. Particularly because postpartum substance use is relatively common, especially among women who use substances before or during pregnancy, and several studies have suggested risk of relapse to substance use is relatively high during the postpartum period (Forray et al., 2015; Jagodzinski & Fleming, 2007).

Maternal route of delivery. A mother's route of delivery has been shown to influence attendance of postpartum care. In a sample of Medicaid recipients from Baltimore, MD, women who delivered via cesarean section had higher odds of attending a postpartum visit than women who did not have a cesarean section (Bennett et al., 2013). However, among a study of Medicaid recipients in Virginia, delivery route was not significantly associated with postpartum attendance (Masho et al., 2018). Although the result of the current study did not find a significant result when controlling for other demographic and psychosocial variables, women who delivered via cesarean section were twice as likely to attend their postpartum visit compared to women with a standard vaginal delivery.

Study Implications and Applications

Specific Aim 1 of the present study compared demographic and psychosocial risk variables in consenters and non-consenters to an RCT targeting peripartum care compliance. The study found that consenters and non-consenters did not differ across demographic and psychosocial characteristics assessed, thereby supporting sample representativeness. The two groups differed only on education level with consenters more likely than non-consenters to have

less than high school education. Findings suggest RCT participants were similar to the broader sample of African American women at risk for poor prenatal care attendance. Results should be interpreted with caution, however, as consenters and non-consenters could only be compared on the demographic and psychosocial variables that contributed to the risk for poor prenatal care attendance. Consenters could differ from non-consenters in other ways not captured in the present study.

Specific Aim 2 & 3 sought to identify predictors prenatal and postpartum care attendance among a sample of pregnant, African American women at risk for poor prenatal care compliance. Importantly, study findings within this uniquely at-risk sample were similar to those in previous literature, and significant risk factors predictive of both prenatal care and postpartum care attendance were identified.

Specifically, for prenatal care attendance, more barriers to care predicted poorer attendance. The barriers to care included both structural and psychosocial barriers, but the most prevalent barriers were structural. Future interventions should focus on helping women navigate these barriers as well as changing healthcare system and provider practices. Unfortunately, these structural barriers have persisted for the last three decades, despite efforts to remedy (Mazul et al., 2017). Mazul and colleagues (2017) highlight the critical importance of creating a "patient-centered" healthcare system as a way to mitigate some of these barriers. For example, adjusting clinic flows to allow for tardiness, and providing women with reminder phone calls. Support through case management and community resources, may aid women in overcoming such barriers.

Additionally, for the predictors of prenatal care attendance, a regression equation predicting the ratio of attended to expected PNC visits was generated to be used as a clinical tool.

Ideally, this tool will help providers identify women at increased risk for poor prenatal care utilization and encourage early interventions.

For postpartum care attendance, adequate prenatal care was identified as a significant predictor. These findings are timely and could have important implications for healthcare system changes and treatment interventions. Improving postpartum care is an important goal in the field of obstetrics and public health. In 2018, ACOG released committee opinion calling to redefine and optimize postpartum care, and the Healthy People 2020 agenda includes increasing postpartum care as a developmental goal (ACOG, 2018). Results of the current study suggest that efforts to improve prenatal care could also improve postpartum care, even among this at-risk sample.

Study Strengths and Limitations

Many of the strengths and limitations of this study can be attributed, at some level, to the study being a secondary analysis of data from an RCT targeting prenatal care attendance. Strengths include rigorous screening procedures for study enrollment, systematic data collection, use of standardized measures, and the opportunity to focus on health disparities.

Using the initial risk screening questionnaire for the RCT offered a unique opportunity to collect data on a large pool of participants who often may not come to the attention of the research team. Clinical trials rarely have any information on patients who decline research participation beyond basic demographics. The study risk screening questionnaire provided a dataset on the eligible pool of patients in order to examine some potential differences in risk profiles between consenters and non-consenters. Minimal differences were identified between the consenters and non-consenters supporting the representativeness of the study sample. However, the variables assessed were limited to demographics and items which formed the basis

for study inclusion. Group differences may be present for characteristics that were not assessed in the RCT screener questionnaire.

As a function of the RCT, trained RAs completed the screening questionnaire and assessments with participants using an interview format. The interview format was more advantageous than self-report instruments because it enabled the interviewer to probe further for an answer limiting missing data. Additionally, the assessments included psychometrically sound measures which were reliable and valid for use among pregnant women when possible to assess for problems in each domain of interest. Nonetheless pregnant women are more likely to underreport certain risk factors (e.g., alcohol use and drug use) due to social stigma or fear of legal consequences (Kelpin, Rusteikas, Karjane, & Svikis, 2019).

Because the RCT targeted health disparities in maternal and infant birth outcomes using an intervention to improve peripartum care attendance, it created a unique sample. No prior studies have investigated predictors of peripartum care in an all African American sample at risk for poor prenatal care utilization. So, the current study was able to address this gap in the literature.

Unfortunately, in many cases, these strengths of the RCT also introduced methodological limitations including a homogenous sample, restrictive inclusion criteria, and limited generalizability. In order to select the targeted population of women at-risk for poor prenatal care compliance, there were several inclusion criteria. All women who met RCT inclusion criteria had to endorse risk factors and score above the eligibility cut-off score. Therefore, within the study sample there were high rates of endorsement across the risk profile items contributing to a relatively homogenous at-risk sample.

In an effort to provide sufficient opportunity for the RCT intervention to show an effect, RCT inclusion criteria required participants to be seeking prenatal care at ≤26 weeks gestation. However, late initiation of prenatal care is associated with poor housing conditions, less education, lack of insurance, unintended pregnancy, substance use, and psychiatric diagnoses (Cheng et al., 2009; Gadson et al., 2017; Pagnini & Reichman, 2000; Partridge et al., 2012; Sidebottom et al., 2017). Therefore, it is possible that the women at greatest risk were not eligible for RCT participation. Women who begin prenatal care during the third trimester or received no prenatal care may have different demographic and psychosocial characteristics than study participants. Including these women in future studies may allow for a more accurate representation of an "at risk" sample.

Generalizability of our results is limited. The secondary data analytic design constrained the variables available for analyses. The present study was not able to examine broader representativeness of the sample because characteristics outside of the inclusion criteria risk profile were not assessed in the screener and data were not collected from patients who declined participation in the screening for the RCT. A number of women transferred care during study enrollment, so the nature of their care after transfer may have been different from those who continued care at VCU, and several women were missing data for the critical outcome variable, so they were not included in analyses. Additionally, the current study was conducted at only one safety net clinic which serves predominately low-income, racial and ethnic minorities in one region of the United States so results may not be applicable in other clinics or in different regions.

Lastly, for the regression analyses, several variables were conflated. For example, barriers to prenatal care items were summed to create the total number of barriers to care

conflated variable. However, we do not know that the effects of barriers to prenatal care are truly additive; in reality, some barriers likely have a larger impact than others.

Future Directions

The current study serves as an initial investigation into representativeness of participants in a maternal and infant health disparities clinical trial. Using secondary data analyses, the study was limited by variables in the risk factor screening questionnaire. Thus, future research should include a wider array of variables, outside of screening criteria, in the screeners of potential participants. Gaining a better understanding of the eligible pool of participants will ensure the obtained sample is representative and the findings are generalizable to the population of interest.

Additionally, the present study serves as an initial investigation into factors associated with prenatal and postpartum care attendance among this population. The study was limited by variables in the baseline assessment of the RCT. Given the high rates of endorsement of the psychosocial risk factors for poor peripartum care attendance, future research should explore the risk factors in more detail. For example, future studies could assess for presence and severity of substance use disorders in addition to most recent alcohol and drug use (Alvanzo & Svikis, 2008). It would also be helpful to both screen for current depressive symptoms and assess for previous diagnosis of Major Depressive Disorder in addition to screening and assessing for other mental health disorders such as Generalized Anxiety Disorder and Post-traumatic Stress Disorder.

Future research should also expand this health disparities focus to a broader spectrum of patients, including women who enter prenatal care during their third trimester or receive no prenatal care at all. This may need to be coordinated effort through multiple recruitment sites such as Labor and Delivery units and community partners. This research would provide

important information on the women most at-risk for poor prenatal care compliance and provide insight into potentially helpful interventions.

Lastly, more work is needed among this population regarding measurement of adequacy of prenatal care. Some studies have suggested that the ACOG recommendation requires too many prenatal care visits. However, research on this topic is limited. It is important to determine what constitutes adequate prenatal care and how many visits should be recommended, while also accounting for pregnancy risk level. Further, efforts should be made to identify a valid and reliable measure of adequate prenatal care among women with high-risk pregnancies.

Conclusion

In summary, the present study offered an opportunity to compare consenters and non-consenters across demographic and psychosocial screening variables for an RCT targeting health disparities in maternal and infant birth outcomes using an intervention to improve peripartum care attendance. Overall, consenters and non-consenters had minimal group differences across the domains surveyed. A wider array of variables should be explored in future studies to ensure representativeness of research. The present study serves as the initial analysis of predictors peripartum care attendance among a sample of pregnant, African American women at risk for poor prenatal care compliance. Within this at-risk sample, results were similar to previous literature. These findings could have important implications for healthcare system changes and treatment interventions among this population.

References

Adams, E. K., Gavin, N. I., & Benedict, B. (2005). Access for pregnant women on Medicaid: Variation by race and ethnicity. *Journal of Health Care for the Poor and Underserved, 16*(1), 74-95.

Alvanzo, A. H. & Svikis, D. (2008) History of physical abuse and periconceptional drinking in pregnant women. Substance Use & Misuse, 43, 1098-1109.

American Academy of Pediatrics Committee on Fetus and Newborn and American College of Obstetricians and Gynecologists Committee on Obstetric Practice. Guidelines for Perinatal Care, 8th, Kilpatrick SJ, Papile L (Eds), 2017.

American College of Obstetricians and Gynecologists. (2015). Racial and ethnic disparities in obstetrics and gynecology. Obstet Gynecol, Committee Opinion No. 649, 126, e130–134.

American College of Obstetricians and Gynecologists. (2018). Optimizing postpartum care. Obstet Gynecol, Committee Opinion No. 736, e140–150.

Arroll, B., Goodyear-Smith, F., Crengle, S., Gunn, J., Kerse, N., Fishman, … & Hatcher, S. (2010). Validation of the PHQ-2 and PHQ-9 to screen major depression in the primary care population. *Ann Fam Med, 3,* 348-353.

Baer, R. J., Altman, M. R., Oltman, S. P., Ryckman, K. K., Chambers, C. D., Rand, L., & Jeliffe-Pawlowski, L. L. (2018). Maternal factors influencing late entry into prenatal care: A stratified analysis by race or ethnicity and insurance status. *Journal of Maternal, Fetal, & Neonatal Medicine,* 1-7, [epub ahead of print].

Baldwin, M. K., Hart, K. D., & Rodriguez, M. I. (2018). Predictors for follow-up among postpartum patients enrolled in a clinical trial. *Contraception, 98*(3), 228-231.

Begg, C., Cho, M., Eastwood, S., Horton, R., Moher, D., Olkin, I., … & Stroup, D. F. (1996). Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *Jama, 276*(8), 637-639.

Bennett, W. L., Chang, H., Levine, D. M., Wang, L., Neale, D., Werner, E. F., & Clark, J. M. (2014). Utilization of primary and obstetric care after medically complicated pregnancies: An analysis of medical claims data. *Journal of General Internal Medicine, 29*(4), 636-45.

Biaggi, A., Conroy, S., Pawlby, S., & Pariante, C. M. (2016). Identifying the women at risk of antenatal anxiety and depression: A systematic review. *J Affect Disorder, 191*, 62-77.

Blehar, M. C., Spong, C. Grady, C., Goldkind, S. F., Sahin, L., & Clayton, J. A. (2013). Enrolling pregnant women: Issues in clinical research. *Women's Health Issues, 23*(1), e39-e45.

Bryant, A. S., Haas, J. S., McElrath, T. F., & McCormick, M. C. (2006). Predictors of compliance with the postpartum visit among women living in healthy start project areas. *Maternal and Child Health Journal, 10*, 511-516.

Bryant, A. S., Worjoloh, A., Caughey, A. B., & Washington, A. E. (2010). Racial/ethnic disparities in obstetrical outcomes and care: Prevalence and determinants. *American Journal of Obstetrics and Gynecology, 202*(4), 1-17.

Callaghan, W. M., Creanga, A. A., & Kuklina, E. V. (2012). Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstetrics and Gynecology, 120(5)*, 1029-1036.

Canady, R. B., Stommel, M., & Holzman, C. (2009). Measurement properties of the Centers for Epidemiological Studies Depression Scale (CES-D) in a sample of African-American and non-Hispanic white pregnant women. *J Nurs Meas, 17*(2), 91-104.

Carter, E. B., Tuuli, M. G., Caughey, A. B.,Odibo, A. O., Macones, G. A., & Cahill, A. G. (2016). Number of prenatal visits and pregnancy outcomes in low-risk women. *J Perinatol, 36*(3), 178-181.

Center for Disease Control and Prevention. (2011). CDC health disparities and inequalities report—United States. *Morbidity and Mortality Weekly Report, 60*, 1-116.

Centers for Disease Control and Prevention. (2015). U.S. Public Health Service Syphilis Study at Tuskegee. Retrieved from: https://www.cdc.gov/tuskegee/index.html. Accessed April 25, 2019.

Centers for Disease Control and Prevention. (2017). Maternal depression. Retrieved from: https://www.cdc.gov/features/maternal-depression/index.html. Accessed April 25, 2019.

Cha, S. & Masho S. W. (2014). Intimate partner violence and utilization of prenatal care in the United States. *Journal of Interpersonal Violence, 29(*5), 911-927.

Chen, M. J., Hsia, J. K., Hou, M. Y., Wilson, M. D., & Creinin, M. D. (2018). Comparing postpartum visit attendance with a scheduled 2- to 3-week or 6-week after delivery. *American Journal of Perinatology*, [Epub ahead of print].

Chen, M. S., Lara, P. N., Dang, J. H. T., Paterniti, D. A., & Kelly, K. (2014). Twenty years post-NIH Revitalization Act: Renewing the case for enhancing minority participation in cancer clinical trials. *Cancer, 120*(7), 1091-1096.

Cheng, D., Schwarz, E. B., Douglas, E., & Horon, I. (2009). Unintended pregnancy and associated maternal preconception, prenatal and postpartum behaviors. *Contraception, 79*, 194-198.

Cohen, S. & Hoberman, H. (1983). Positive events and social supports as buffers of life change stress. *Journal of Applied Social Psychology, 13*, 99–125.

Cochran, G. T., Hruschak, V., Abdullah, W., Krans, E., Dauaihy, A. B., Bobby, S., … & Tarter, R. (2018). Optimizing pregnancy treatment interventions for moms (OPTI-Mom): A pilot study. *Journal of Addiction Medicine, 12*, 72-79.

De Bocanegra, H. T., Braughton, M., Bradsberry, M., Howell, M., Logan, J., & Schwarz, E. B. (2017). Racial and ethnic disparities in postpartum care and contraception in California's Medicaid program. *American Journal of Obstetrics and Gynecology, 217*(1), 47.e1-47.e7.

Deshpande, N. A. & Lewis-O'Connor, A. Screening for intimate partner violence during pregnancy. *Reviews in Obstetrics and Gynecology, 6*(3-4), 141-148.

DiBari, J. N., Yu, S. M., Chao, S. M., & Lu, M. C. (2014). Use of postpartum care: Predictors and barriers. Journal of Pregnancy, 1-8.

Egger, M., Juni, P., & Bartlett, C. (2001). Value of flow diagrams in reports of randomized controlled trials. *Jama, 15*, 1996-1999.

Feldhaus, K. M., Koziol-McLain, J., Amsbury, H. L., Lowenstein, S. R., & Abbott, J. T. (1997). Accuracy of 3 brief screening questions for detecting partner violence in the emergency department. *Jama, 277*(17), 1357-1361.

Finer, L. B. & Zolna, M. R. (2016). Declines in unintended pregnancy in the United States, 2008-2011. *New England Journal of Medicine, 374*: 843-52.

Forray, A., Merry, B., Lin, H., Ruger, J. P., & Yonkers, K. A. (2015). Perinatal substance use: A prospective evaluation of abstinence and relapse. *Drug Alcohol and Dependence, 150*, 147-155.

Frew, P. M., Saint-Victor, D. S., Isaacs, M. B., Kim, S., Swamy, G. K., Sheffield, J. S., … Ault, K. (2014). Recruitment and retention of pregnant women into clinical research trials: An

overview of challenges, facilitators, and best practices. *Clinical Infectious Diseases, 59*(S7), S400-7.

Gadson, A., Akpovi, B. S., & Mehta, P. K. (2017). Exploring the social determinants of racial/ethnic disparities in prenatal care utilization and maternal outcome. *Seminars in Perinatology, 41*, 308-317.

Gazmararian, J. A., Arrington, T. L., Bailey, C. M., Schwarz, K. S., & Koplan, J. P. (1999). Prenatal care for low income women enrolled in a managed care organization. *Obstetrics and Gynecology, 94*(2), 177-184.

George, S., Duran, N., & Norris, K. (2014). A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *American Journal of Public Health, 104*(2), e16-e31.

Gesche, J., Renault, K., Norgaard, K., & Nilas, L. (2014). Representativeness of participants in a lifestyle intervention study – the difference between study participants and non-participants. *Obesity Facts, 7*, 351-360.

Guttmacher Institute. (2019). Unintended pregnancy in the United States. January 2019 Fact Sheet. Available at: https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states. Accessed on 4/18/19.

Gyllstrom, M. E., Hellerstedt, W. L., & Hennrikus, D. (2012). The association of maternal mental health with prenatal smoking cessation and postpartum relapse in a population-based sample. *Maternal and Child Health Journal, 16*, 685-693.

Hall, W. D. (1999). Representation of blacks, women, and the very elderly (aged > or = 80) in 28 major randomized clinical trials. *Ethnic Disparities, 9*(3), 333-40.

Haug, N.A., Osorno, R. A., Yanovitch, M. A., & Svikis, D.S. (2017). Biopsychosocial approach to the management of drug and alcohol use in pregnancy. In L. C. Edozien & P. M. S. O'Brien (Eds.), Biopsychosocial factors in obstetrics and gynaecology (p. 280–291). Cambridge University Press.

Heiat, A., Gross, C. P., & Krumhoiz, H. M. (2002). Representation of the elderly, women, and minorities in hearth failure clinical trials. *Arch Intern Med, 16*(2).

Hensley, L., Sulo, S., Kozmic, S., & Parilla, B. V. (2018). Opioid addiction in pregnancy: Does depression negatively impact adherence with prenatal care? *Journal of Addiction Medicine, 12*, 61-64.

Howell, E. A., Mora, P. A., Horowitz, C. R., & Leventhal, H. (2005). Racial and ethnic differences in factors associated with early postpartum depressive symptoms. *Obstetrics and Gynecology, 105*(6), 1142-1450.

Hulsey, T. M., Laken, M., Miller, V., & Ager, J. (2000). The influence of attitudes about unintended pregnancy on use of prenatal and postpartum care. *Journal of Perinatology, 20*, 513-519.

Humphreys, K., Maisel, N. C., Blodgett, J. C., & Finney, J. W. (2013). Representativeness of patients enrolled in influential clinical trials: a comparison of substance dependence with other medical disorders. *Journal of Studies on Alcohol and Drugs, 74*(6), 889-893.

Humphreys, K., Weingardt, K. R., & Harris, A. H. (2007). Influence of subject eligibility criteria on compliance with National Institutes of Health guidelines for inclusion of women, minorities, and children in treatment research. *Alcoholism: Clinical and Experimental Research, 31*(6), 988-995.

Jagodzinski, T. & Fleming, M. F. (2007). Postpartum and alcohol-related factors associated with the relapse of risky drinking. *J Stud Alcohol Drugs, 68*(6), 879-885.

Jamieson, B. (2018). Exposure to interpersonal violence during pregnancy and its association with women's prenatal care utilization: A meta-analytic review. Trauma, Violence, & Abuse, 1-18, [epub ahead of print].

Jansson, L., Svikis, D.S., Lee, J., Paluzzi, P., Rutigliano, P. and Hackerman, F. (1996). Pregnancy and addiction: A comprehensive care model. Journal of Substance Abuse Treatment, 13, 321-329.

Jones, K. M., Power, M. L., Queenan, J. T., & Schulkin, J. (2015). Racial and ethnic disparities in breastfeeding. *Breastfeeding Medicine, 10* (4), 186-196.

Kelpin, S.S., Rusteikas, S.G., Karjane, N.W. & Svikis, D.S. (2019). Screening for at-risk alcohol and drug use in the perinatal period: How do young women compare to older adult women? Journal of Pediatric and Adolescent Gynecology, 32(3), 325-329.

Kelpin, S. S. (2016). Representativeness of patients enrolled in a primary care clinical trial for substance use disorders. VCU Scholars Compass: Theses and Dissertations. Available at https://scholarscompass.vcu.edu/etd/.

Kelpin, S. S., Ondersma, S. J., Weaver, M., & Svikis, D. S. (2018). Representativeness of patients enrolled in a primary care clinical trial for heavy/problem substance use. *Substance Abuse*, *39*(4), 469-475.

Kennedy-Martin, T., Curtis, S., Faries, D., Robinson, S., & Johnston, J. (2015). A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results. *Trials, 16,* 495.

Klerman, L. V., Ramey, S. L., Goldenberg, R. L., Marbury, S., Hou, J., & Cliver, S. P. (2001). A randomized trial of augmented prenatal care for multiple risk, Medicaid-eligible African American women. *American Journal of Public Health, 91*(1), 105-11.

Kogan, M. D., Martin, J. A., Alexander, G. R., Kotelchuck, M., Ventura, S. J., & Frigoletto, F. D. (1998). The changing pattern of prenatal care utilization in the United states, 1981-1995, using different prenatal care indices. *Journal of American Medical Association, 279*(20) ,1623-8.

Kotelchuck, M. (1994). An evaluation of the Kessner adequacy of prenatal care index and a proposed adequacy of prenatal care utilization index. *American Journal of Public Health, 84*(9), 1414-1420.

Kotha, A., Chen, B. A., Lewis, L., Dunn, S., Himes, K. P., & Krans, E. E. (2019). Prenatal intent and postpartum receipt of long-acting reversible contraception among women receiving medication-assisted treatment for opioid use disorder. *Contraception, 99*, 36-41.

Kroenke, K., Spitzer, R.L., & Williams, J.B. (2003). The Patient Health Questionnaire-2: Validity of a two-item depression screener. *Med Care, 41*(11), 1284–1292.

Lally, J., Watkins, R., Nash, S., Shetty, H., Gardner-Sood, P., Smith, S., … & Gaughran, F. (2018). The representativeness of participants with severe mental illness in a psychosocial clinical trial. *Frontiers in Psychiatry, 9*(654), 1-7.

Levine, L. D., Nkonde-Price, C., Limaye, M., & Srinivas, S. K. (2016). Factors associated with postpartum follow-up and persistent hypertension among women with severe preeclampsia. *Journal of Perinatology, 36*(12), 1079-1082.

MacMillan, H. L., Wathen, C. N., Jamieson, E., Boyle, M. H., Shannon, H. S., Ford-Gilboe, M., ... & McNutt, L. A. (2009). Screening for intimate partner violence in health care settings: A randomized trial. *Jama, 302*(5), 493-501.

Mak, W. W. S., Law, R. W., Alvidrez, J., & Perez-Stable, E. J. (2007). Gender and ethnic diversity in NIMH-funded clinical trials: Review of a decade of published research. *Adm Policy Mental Health, 34,* 497-503.

Masho, S. W., Cha, S., Karjane, N., McGee, E., Charles, R., Hines, L., & Kornstein, S. G. (2018). Correlates of postpartum visits among Medicaid recipients: An analysis using claims data from a managed care organization. *Journal of Women's Health, 27*(6), 836-843.

Masho, S.W., Bishop, D. L., Keyser-Marcus, L., Varner, S. B., White, S., & Svikis, D. (2013). Least explored factors associated with prenatal smoking. Maternal and Child Health Journal, 17(7): 1167-1174.

Masho, S.W., Keyser-Marcus, L., Varner, S.B., Stith-Singleton, R., Bradford, J., Chapman, D. and Svikis, D.S. (2011). Addressing perinatal disparities using community-based participatory research: Data into action. Journal of Community Psychology, 39(3), 292-302.

Mazul, M. C., Ward, T. C., & Ngui, E. M. (2016). Anatomy of good prenatal care: Perspectives of low income African-American women on barriers and facilitators to prenatal care. *J Racial Ethn Health Disparities*, *4*(1), 79-86.

Metheny, N. & Stephenson, R. (2017). Intimate partner violence and uptake of antenatal care: A scoping review of low- and middle-income country studies. *International Perspectives on Sexual and Reproductive Health, 43*(4), 163-171.

Mikhail, B. (2000). Prenatal care utilization among low income African American women prenatal care. *Journal of Community Health Nursing, 17*(4), 235-246.

Morgan, I., Hughes, M. E., Belcher, H., & Holmes, L. (2018). Maternal sociodemographic characteristics, experiences and health behaviors associated with postpartum care utilization: Evidence from Maryland PRAMS dataset, 2012-2013. *Maternal and Child Health Journal, 22*, 589-598.

National Institutes of Health. (2017). NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research. Available at: https://grants.nih.gov/grants/funding/women_min/guidelines.htm. Accessed on 4/20/19.

National Institute on Alcohol Abuse and Alcoholism. Rethinking Drinking. Washington, DC: US Department of Health and Human Services; 2009. Report no. 09-3770.

Orr, S. T., James, S. A., & Reiter, J. P. (2008). Unintended pregnancy and prenatal behaviors among urban, black women in Baltimore, Maryland: The Baltimore preterm birth study. *Annals of Epidemiology, 18*(7), 545-551.

Osterman, M. J. K. & Martin, J. A. (2018). Timing and adequacy of prenatal care in the United States, 2016. *National Vital Statistics Reports, 67*(3), 1-13.

Pagnini, D. L. & Reichman, N. E. (2000). Psychosocial factors and the timing of prenatal care among women in New Jersey's HealthStart Program. *Family Planning Perspectives, 32*(2), 56-64.

Park, T. L., Adams, S. G., & Lynch, J. (1998). Sociodemographic factors in health psychology research: 12 years in review. *Health Psychology, 17*(4), 381-383.

Partridge, S., Balayla, J., Holcroft, C. A., & Abenhaim, H. A. (2012). Inadequate prenatal care utilization and risks of infant mortality and poor birth outcome: a retrospective analysis

of 28,729,765 US deliveries over 8 years. *American journal of perinatology*, *29*(10), 787-794.

Perloff, J. D. & Jaffee, K. D. (1999). Late entry into prenatal care: The neighborhood context. *Social Work*, *44*(2), 116-128.

Polak, K., Haug, N.A., Drachenberg, H.E. & Svikis, D.S. (2015). Gender considerations in addiction: Implications for treatment. Current Treatment Options Psychiatry, 2(3); 326-338.

Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurements, 1*, 385-401.

Rankin, K. M., Haider, S., Caskey, R., Chakraborty, A., Roesch, P., & Handler, A. (2016). Healthcare utilization in the postpartum period among Illinois women with Medicaid paid claims for deliver, 2009-2010. *Maternal and Child Health Journal, 20*, S144-153.

Rosenberg, M. (1965). Society and the adolescent self-image. Princeton, NJ: Princeton University Press.

Schaffer, M. A. & Lia-Hoagberg, B. (1997). Effects of social support on prenatal care and health behaviors of low-income women. *JOGNN, 26*, 433-440.

Shim, J. Y., Stark, E. L., Ross, C. M., & Miller, E. S. (2018). Multivariable analysis of the association between antenatal depressive symptomatology and postpartum visit attendance. *American Journal of Perinatology*, [Epub ahead of print].

Sidebottom, A. C., Hellerstedt, W. L, Harrison, P. A., & Jones-Webb, R. J. (2017). Prenatal care: Associations with prenatal depressive symptoms and social support in low-income urban women. *Archives of Women's Mental Health, 20*, 633-644.

Sinclair, S. J., Blais, M. A., Gansler, D. A., Sandberg, E., Bistis, K., & LoCicero, A. (2010). Psychometric properties of the Rosenburg Self-Esteem Scale: Overall and across demographic groups living within the United States. *Evaluation and the Health Professions, 33*(1), 56-80.

Soeken, K. L., McFarlane, J., Parker, B., & Lominack, M. C. (1998). The abuse assessment screen: a clinical instrument to measure frequency, severity, and perpetrator of abuse against women. In: Campbell JC, editor. *Empowering Survivors of Abuse: Health Care for Battered Women and Their Children*. Thousand Oaks, CA: Sage Publications, pp. 195–203.

Stringer, M. (1998). Issues in determining and measuring adequacy of prenatal care. *J Perinatol, 18*(1), 68-73.

Till, S. R., Everetts, D., & Haas, D. M. (2015). Incentives for increasing prenatal care use by women in order to improve maternal and neonatal outcomes. *Cochran Database of Systematic Reviews, 12*, CD009916.

Tukey, J. W. (1961). Statistical and quantitative methodology. In D. P. Ray (Ed.), *In Trends in Social Sciences*. New York: Philosophical Library.

Unger, J. M., Hershman, D. L., Albain, K. S., Moinpour, C. M., Petersen, J. A., Burg, K., & Crowley, J. J. (2013). Patient income level and cancer clinical trial participation. *Journal of Clinical Oncology, 31*(5), 536-542.

U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau. Child Health USA 2013. Rockville, Maryland: U.S. Department of Health and Human Services, 2013.

Vilagut, G., Forero, C. G., Barbaglia, G., & Alonso, J. (2016). Screening for depression in the general population with the Center for Epidemiologic Studies Depression (CES-D): A systematic review with meta-analysis. *PLoS One, 11*(5), 1-17.

Vlenterie, R., van Ras, H. W. P., Roeleveld, N., Pop-Purceleanu, M., & van Gelder, M. M. H. J. (2017). Epidemiological evaluation of the Patient Health Questionnaire-2 in a pregnant population. *Journal of Psychosomatic Research 101,* 96-103.

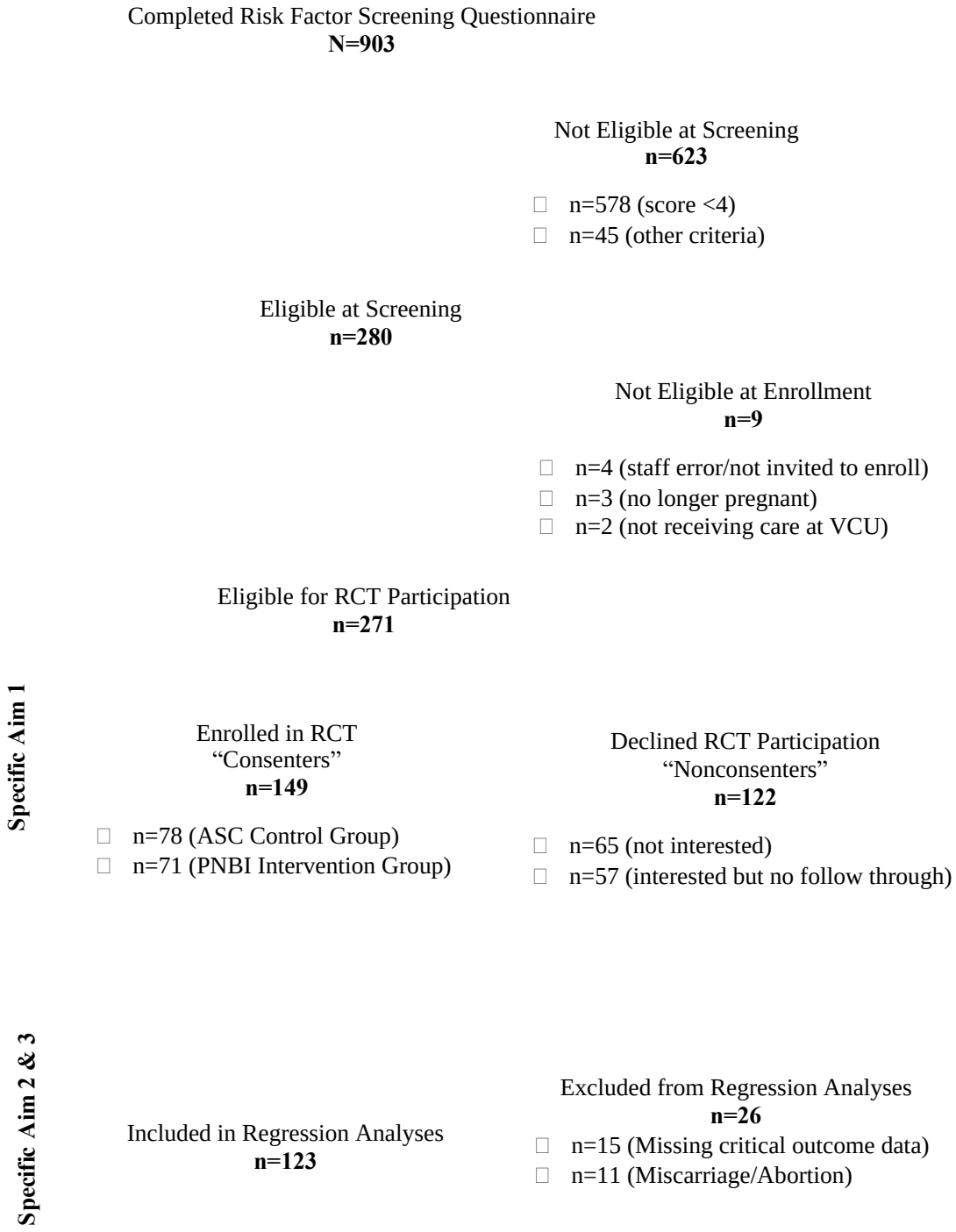
Weir, S., Posner, H. E., Zhang, J., Willis, G., Baxter, J. D., & Clark, R. E. (2011). Predictors of prenatal and postpartum care adequacy in a Medicaid managed care population. *Women's Health Issues, 21*(4), 277-285.

Wilcox, A., Levi, E. E., & Garrett, J. M. (2016). Predictors of nonattendance to the postpartum follow-up visit. *Maternal and Child Health Journal, 20,* S22-27.

Yee, L. M., Martinez, N. G., Nguyen, A. T., Hajjar, N., Chen, M. J., Simon, M. A. (2017). Using a patient navigator to improve postpartum care in an urban women's health clinic. *Obstetrics and Gynecology, 129*(5), 925-933.

York, R., Tulman, L., & Brown, K. (2000). Postnatal care in low-income urban African American women: Relationship to level of prenatal care sought. *Journal of Perinatology*, 1, 34-40.

Figure 1. CONSORT Diagram



Note. Abbreviations: RCT, Randomized controlled trial; PNBI, Patient Navigator + Behavioral Incentives; ASC, Assessment + Standard Care.

Appendix 1. Project ABC Screener Scoring Sheet

Verify that respondent lives within Richmond City or surrounding counties Verify that respondent is currently <26 weeks pregnant	*Verified residence & gestational age*
☐ Single ☐ Unemployed ☐ Less than high school education ☐ Receives TANF, SSI, Food Stamps, or other social services ☐ Insurance: Medicare, Medicaid, VCC, None	*1 point if one or more endorsed*
☐Patient is under 18 years old	*2 points if endorsed*
☐ Patient had an open case with Child Protective Services	*1 point if endorsed*
☐ Has felt down, depressed, or hopeless	*1 point if endorsed*
☐ Has had little interest or pleasure in doing things	*1 point if endorsed*
☐ Has been hit, kicked, punched, or hurt by someone ☐ Does NOT feel safe in current relationship ☐ Partner from previous relationship makes her feel unsafe	*5 points if one or more endorsed*
☐ Someone living with her has problems with alcohol ☐ Someone living with her has problems with drugs	*1 point if one or more endorsed*
☐ Has smoked within past 3 months	*1 point if endorsed*
☐ Has smoked within the past week	*1 point if endorsed*
☐ Has drank alcohol within past 3 months	*1 point if endorsed*
☐ Has drank alcohol within the past week	*1 point if endorsed*
☐ Has abused prescription drugs within past 3 months	*1 point if endorsed*
☐ Has abused prescription drugs within the past week	*1 point if endorsed*
☐ Has used illicit drugs within past 3 months	*1 point if endorsed*
☐ Has used illicit drugs within the past week	*1 point if endorsed*
☐ Has ever had problems because of alcohol ☐ Has ever had problems because of prescription drugs ☐ Has ever had problems because of illicit drugs	*1 point if one or more endorsed*

Point total: _____ out of 21

Vita

Anna Beth Parlier-Ahmad was born on December 3, 1990, in Statesville, North Carolina. She received her Bachelor of Science in Cellular and Molecular Biology from University of North Carolina at Asheville, in 2012. Subsequently, she worked as a research coordinator at Mountain Area Health Education Center in Asheville, North Carolina until 2016. Since then, she has attended Virginia Commonwealth University as a clinical psychology doctoral student in the Behavioral Medicine/Adult concentration. Her research interests include broadly peripartum mental health and substance use.