Final Report

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   b. Unpacking group prenatal care: impact & change mechanisms in diverse settings

I. Introduction

Problem and Objective

Despite the highest health care expenditures per capita in the world, the US has the highest infant mortality rate among industrialized nations as well as persistent inequalities in prenatal care (PNC) and outcomes.\(^1\)\(^2\) (Organisation for Economic Co-operation and Development [OECD], 2013a; OECD, 2013b). Preterm birth is a leading cause of infant mortality. (Martin et al., 2013). More than half a million premature infants (< 37 weeks GA) are born each year in the US, and the overall preterm birth rate of 11.5% represents a 36% increase over the last 20 years.\(^3\) (Martin et al., 2013). Although preterm birth rates have declined each year since 2006, there are substantial health disparities associated with prematurity, low birth weight (LBW) and maternal health outcomes. Among African Americans (AA) the preterm birth rate is 16.53%, while the Hispanic rate is 11.58%, and the white rate is 10.29% (Martin et al., 2013). Disparities in the quality of PNC have also been found by race/ethnicity as well as income and provider.\(^3\)^\(^4\) Latinas discussed fewer topics than AAs,\(^10\) and AAs discussed fewer than whites.\(^11\) These variations in the quality of PNC increase the risk of LBW, prematurity and infant mortality.\(^12\)^\(^13\)

Importantly, because the majority of adverse perinatal outcomes occur to women not previously identified as high-risk during pregnancy, there is an urgent need to test innovative models of PNC for medically low-risk women.\(^14\)

The objective of this quasi-experimental study was to test the impact of an innovative group PNC model and to examine the potential mechanisms that contribute to its positive effects for a diverse sample of primarily low-income women in a variety of clinics. Group PNC fundamentally alters the format of PNC for medically low-risk women. Centering Pregnancy\® (CP) is the most widely used group PNC model, with a nationally established format, training and site certification program. In CP, after a first visit, which is the same as individual care (IC), a group of 8-12 women at the same stage of pregnancy attend 10 two-hour visits together. CP provides: (1) substantially more discussion of health promotion content (15 hours versus under 3 hours), designed to increase the health promotion topics discussed by women; (2) group support from women at the same stage of pregnancy, designed to increase women’s perceived social support; and (3) a collaborative patient-provider relationship and self-management activities designed to increase pregnancy-related empowerment.\(^15\)

CP is growing in popularity across the nation with investments by organizations such as the Centers for Medicaid and Medicare Strong Start Initiative and March of Dimes. Several studies have found that CP is an effective approach to improving health outcomes, including preterm birth, especially among socially high-risk women.\(^16\)^\(^18\) In 2009, the only randomized clinical trial (RCT) of CP at the time, reported infant outcomes found that the prematurity rate was significantly reduced overall for a large sample of low-income AA and Latina women; the reduction was even larger for AAs.\(^19\) These RCT results suggested that CP was effective under experimental conditions, so there was a need to determine whether this innovative model can be effective in real world clinical settings. Initiating CP requires a relatively substantial expenditure, especially when clinics serve primarily low-income populations, Moreover, no previous study has examined the mechanisms through which CP affects health outcomes, which is essential for replication. Our study aimed to fill research gaps and strengthen the evidence base for innovative models of PNC.

Our study took advantage of a unique opportunity to study the effect of CP and its potential causal mechanisms. The Illinois chapter of the March of Dimes had supported the initiation of CP in ten agencies across the state. Nine of these agencies and an additional agency providing CP, participated in this research. Collectively, these agencies serve a diverse population of mostly low-income women receiving both CP and IC in urban, suburban, and rural settings. Interviews were conducted at baseline (<21 weeks pregnant), late pregnancy (>34 weeks), and 1-week postpartum.
Study Aims and Hypotheses

This quasi-experimental study tested the effects of the CP on health outcomes for a diverse group of mostly low-income women obtaining care in a variety of real-world practice settings, and explored potential mechanisms to account for the effects of CP. The study aims and hypotheses were:

Aim 1. To test the effect of CP on potentially modifiable health outcomes.
H1. Compared to the IC group, the CP group will show more positive health outcomes including:
H1.a. late pregnancy outcomes of health knowledge, healthy behaviors, prenatal weight gain, intentions to breastfeed, intention to use the recommended infant sleep position, perceived stress, depressive symptoms, anxiety, prenatal care satisfaction, and PNC visit adherence;
H1.b. birth and early postpartum outcomes of prematurity, LBW, breastfeeding initiation and use of the recommended infant sleep position.

Aim 2. To examine the mechanisms through which CP affects health outcomes.
H2.a. Compared to the IC group, the CP group will report more health promotion content discussed, social support, and pregnancy-related empowerment.
H2.b. CP’s effects on health outcomes (H1a-b) will be mediated by prenatal health content discussed, social support, and pregnancy-related empowerment.

II. Review of the Literature

Any innovation in PNC that can reduce rates of prematurity can have major benefits for infants, their families, and the national health-related budget. Preterm birth costs were more than $26 billion in 2005. Most preterm infants require a lengthy and costly hospital stay, averaging about three weeks or more at an average cost of $77,000 per infant, compared to hospital cost for a healthy full term infant that averages $1,700. Medical costs for the first-year of life are approximately 10 times greater for preterm infants ($32,325) than for term infants ($3,325). Preterm infants have higher rates of chronic and acute morbidities, developmental delays, behavioral problems, difficulty in school, lower childhood IQ, and increased long-term health care, special education, and social services costs. Currently, the two most widely recognized strategies for improving adverse pregnancy outcomes are expansion of preconception and well-woman care across the life course and improving access to high quality PNC. Our research focused on the latter, exploring the effects of an evidence-based innovation in PNC delivery group PNC, which can maximize the contribution of PNC to reducing adverse pregnancy outcomes without increasing overall health care delivery costs. This innovative model holds promise to move our nation towards achieving the goals of HP 2010 and beyond.

CP has been implemented in over 300 sites nationwide, and there are numerous data-based studies that have examined CP. Positive outcomes of CP have been reported, but there are inconsistencies. When we began our study, the only randomized controlled trial (RCT) examining preterm birth and other birth outcomes of CP compared three groups: CP, enhanced CP (focused on HIV/STD prevention), and IC. Women (n=1047) received care at two university-hospital based clinics and included AA, Latina, and white women ages 14-25. CP groups had a 40% reduction in preterm labor, and a 33% risk reduction in preterm birth. Importantly, AAs realized even greater benefits from CP with a 41% risk reduction in preterm births as compared to AA in IC. In a prospective matched cohort design (N=458) in three urban clinics serving low-risk ethnic minority women, there was a small but statistically significant increase in birth weight for infants born to women in CP versus IC, and among preterm infants, CP infants were larger related to an average two week lengthening of gestation. A more recent RCT by Kennedy and colleagues (2011) did not find differences in preterm birth or low birth weight between women in CP and IC. A study of CP for urban adolescents with a retrospective and concurrent comparison group found significantly lower preterm and LBW rates. One study compared state-level birth data and outcomes for women in CP (n=379, mostly white low-income women) with enhanced content on oral health coupled with dental visits, and found CP women had fewer preterm births (6.6% vs 12.6% for the State). A small observational study with AA found a trend to lower prematurity and higher birthweight. An earlier descriptive study also found low rates of preterm delivery (3.6%) and LBW (5.4%) for 111 ethnically diverse women in one clinic.
Several studies have found other positive outcomes of CP: more knowledge, \(^\text{19,124}\) increased breastfeeding, \(^\text{19,126}\) greater PNC adherence, \(^\text{123,126}\) increased satisfaction, \(^\text{16,123}\) less depression, \(^\text{19}\) and increased prenatal weight gain. \(^\text{126}\) Only one of the 12 studies of CP had mixed results for health behaviors. This small study (n=125) measured behavior in white mostly low-income women in CP and IC. \(^\text{128}\) Women in CP attended more PNC and birth classes, but IC women were more likely to report concerns to a provider, consume fiber, and avoid risky sexual practices. Women in CP had lower scores on a health behaviors index. However, this cross-sectional study collected data only during the third trimester and the authors report that differences in the total scores were related to behaviors that were less relevant to women in CP.

Little research has examined potential mechanisms of change in CP-why CP patients have better outcomes. A qualitative study of 234 women in the military randomized to CP and IC identified that women in CP felt a sense of community and friendship made them feel less alone and more empowered. \(^\text{129}\) Some women reported a need for more individual provider time and suggested opportunities for fathers to have their own group. In our own pilot study, implementing CP in a public health clinic, focus groups with clinic staff and participants found that women enjoyed group care and “telling their stories,” felt prepared for labor, and experienced enhanced relationships with their providers. \(^\text{126}\) Providers reported that the model is “empowering for women as they learn more about themselves, their health and the healthcare system.” Providers and participants also said women were more satisfied with PNC as they never had to wait before their appointments, and were more involved in their prenatal as well as infant care. Based on these prior studies, we identified three potential key mechanisms of CP through which we hypothesize that CP has its impact on health outcomes: increased health promotion content, increased support, and increased pregnancy-related empowerment.

### III. Study Design and Methods

#### A. Study design and Intervention

We used a quasi-experimental two-group design to examine the outcomes of a group model of PNC, CP, compared to IC. CenteringPregnancy (CP) is an innovative evidence-based group visit model of PNC. CP fundamentally changes the way PNC is offered. After an initial individual provider-patient prenatal visit that includes standard tests and services, a group of 8 to 12 women receive complete PNC across 10 visits with the same small group of women having similar expected delivery dates (S.S. Rising, Kennedy, & Klima, 2004). Visits start at 14-18 weeks gestation (4 visits occur monthly followed by 6 biweekly visits). The last session may be a postpartum visit for some women, providing opportunities to share experiences regarding birth and mothering. The first 30 minutes of each visit or session women includes self-management activities (e.g., assessing and recording their own weight, blood pressure, and gestational age; and completing self-assessment sheets related to the core health promotion content of each session to stimulate discussion); a brief one-on-one assessment with the PNC provider (e.g., women’s health nurse practitioner, midwife, physician) with an opportunity to ask questions; and time for women to socialize. During the next 90 minutes the group discusses health promotion topics and their pregnancy experiences facilitated by the provider and an assistant (co-facilitator). Each session has an overall plan with “core” health promotion content (see www.centeringhealthcare.org), but any concerns women express are also discussed. (Sharon Schindler Rising, 1998; Rotundo, 2011). Health promotion topics are consistent with the content recommended by the Expert Panel on PNC and geared to the stage of pregnancy of each visit. The intervention is highly interactive with multiple learning formats: discussion, activities (e.g., word puzzles), and videos. Invited resource persons (e.g., nutritionist) share their expertise. Involvement of family support persons is encouraged. The Centering Health Institute provides a national training program for providers or group facilitators, and offers core materials for the intervention including a detailed “Mom’s Notebook” for each participant (see www.centeringhealthcare.org) and a Facilitator’s Guide to assist with implementation.
B. Sample and Recruitment

We recruited women receiving care in 10 agencies (22 sites) serving predominantly low-income women with diverse racial and ethnic backgrounds in urban, suburban, and small town/rural areas of Illinois. Each site provides CP and IC, and types of providers include MDs and Advanced Practice Nurses (APN) such as certified nurse midwives. Sites were mainly community clinics or Federally Qualified Health Centers with one hospital-affiliated outpatient clinic.

Women were enrolled in the study between September 2010 and March 2013 with data being collected through December 2013. Criteria for inclusion in the study were: 1) the ability to speak and understand English or Spanish; 2) the intent to continue receiving care at the clinic where they are recruited; 3) to begin PNC before 21 weeks’ gestation; and 4) to have a low-risk pregnancy (as evaluated by a medical professional during the initial visit).

Women at the clinics were informed of the study using flyers that included a short description of the study and contact information for the researchers. Interested women could call either a toll-free project phone number or enter their contact information on the bottom section of the study flyer. Clinics routinely sent flyers with the potential subject’s contact information to the study team. The women were then contacted by research staff via telephone call or text message. During the initial telephone call, the potential subject was screened to determine study eligibility. Out of 1882 women who contacted and assessed for eligibility, 842 were not eligible, 75 declined and 1040 completed a baseline for a 93% participation rate. (Figure 2). A comparison between with those participated and those who declined was not possible because we only had characteristics for women who enrolled. Participants were initially paid $10 for each interview, then we obtained additional funding to increase the amount to $20 for each interview. This study was approved by the UIC Institutional Review Board.

C. Data Collection, Variables and Measures

Data were obtained from three telephone interviews at baseline (<21 weeks gestation) and during late pregnancy (≥34 weeks gestation), and a brief postpartum interview or postcard (1 week postpartum).

Variables and Operational Measures

**Background Factors** (measured at baseline interview and used as control factors)

**Personal Factors**

1) **Reproductive history**: gravidity (prior pregnancies, abortions, stillbirths, and live births), a history of prematurity or LBW; whether had any prior adverse outcome, history of sexually transmitted infections, BMI, and gestational age at entry to care. All women in the study will be medically low-risk at their first prenatal visit.

2) Self-identified **race** (black, white, other) and **ethnicity** (AA, Latina-Mexican, Puerto Rican, other Latina, non-Latina “American”, other)

3) **Maternal age** was the mother’s age in years at baseline.

4) **Educational level** was defined as: (a) years of school completed; and (b) whether graduated from high school or obtained a General Education Diploma (GED).

5) **Income** was the women’s self-reported household monthly income.

6) **Receipt of each public benefit** was measured individually (Medicaid, public assistance/TANF, Food Stamps, and/or WIC) and as the total number benefits a woman reports receiving (Score 0-4).

**Prenatal Care Site Factors**

1) **Type of site** was measured as: Federally Qualified Health Center (FQHC) or community clinic, public health department clinic, hospital-based outpatient clinic, or private practice.

2) **Type of provider** (main prenatal care provider) was measured as whether any type of physician or advanced practice nurse.

3) **Place of residence** was measured as location of prenatal clinic urban/large city, a Chicago suburb, or smaller Illinois city, or rural area; and as urban vs. non-urban.
Independent Variable–Type of PNC (measured at baseline):

On enrollment into PNC and the research project, participants chose to be either in CP (Intervention) or in IC (comparison group). We asked each woman during screening if she was receiving PNC in a group or individually. Because the number of CP groups was limited (clinics typically started one group/month) and some women could not meet when a group was scheduled, not all women were able to attend a CP group. If the woman was in IC, we asked her whether she was offered CP, and if so why she chose to attend IC rather than CP. Subgroup analyses will compare women in CP with women in IC who desired to be in CP to examine the issue of self-selection. Reasons for not joining CP are listed in the Results section.

CP Mechanisms (Mediators):

1) Prenatal Health Promotion Content Discussed (late pregnancy interview only) was defined as the number of pregnancy-related health topics recommended for PNC Public Health Service that women recall having discussed with the provider during PNC. The operational measure is an index or count of topics discussed (range 0-27) developed by Vonderheid, et al.

2) Social support (baseline and late pregnancy interview) was defined as the degree of material and emotional assistance a woman perceives that she has available to her. The Medical Outcomes Study (MOS) Social Support Survey contains one question about an individual’s network and 19 items on a 5-point Likert scale related to four functional domains: emotional/ informational, tangible, affectionate, and positive social interaction. MOS has good test-retest reliability (0.78), high convergent and discriminant validity, and high reliability (Cronbach alpha=0.97 in pregnant women).

3) Pregnancy-related empowerment (baseline and late pregnancy interview) was defined as the capacity to nurture and create health for self and family during pregnancy and early parenting. Empowerment is measured using the 18-item Pregnancy-Related Empowerment scale developed by C. Klima (Co-I). The scale has established content validity, comprehensibility, and reliability (Cronbach alpha=.87).

Maternal Health Outcomes:

Late Pregnancy: (Health Knowledge, Health Behaviors, Perceived Stress, Depressive Symptoms and Anxiety also measured at baseline and controlled for in the analysis)

1) Health Knowledge is defined as the degree of correct knowledge women have regarding pregnancy and health related topics. The operational measure is The Prenatal Health Knowledge scale (41-items scored correct/incorrect - % correct) developed by Dr. Vonderheid, originally based on the Prenatal Health Knowledge Scale developed by Larsen. The new scale has well-established content validity, improved item clarity and appropriateness for women with low literacy levels with modest internal consistency (Cronbach’s alpha =.63).

2) Health Behaviors was defined as the degree to which a woman follows recommended health behaviors during pregnancy, including both general healthy behaviors and behaviors specific to pregnancy and preparation for parenting. The operational measure is the 24-items based on the Prenatal Healthy Behaviors Scale originally developed by Hart and modified by Vonderheid. The scale has established content validity, appropriateness and comprehensibility, and a Cronbach alpha of .62. Whether smoking, drinking alcohol and using street drugs were also measured individually and in combination.

4) Intent to Breastfeed was defined as a woman’s plan to breastfeed her baby, and will be assessed by a single item that asks if the woman intends to breastfeed.

5) Intent to use recommended infant sleep position was defined as a woman’s intention to plan to use the recommended infant sleep position (supine), assessed by a single item which asks what infant sleep position a woman intend to use.

6) Perceived stress reflects a woman’s interpretation of whether she believes her life to be stressful measured with the PSS-4, a four-item inventory of feelings of stress which has been used in the National Health Survey Cohen. This is a well established measure of perceived stress that correlates well with the longer 16-item version.
7) **State Anxiety was measured using** the State Anxiety subscale of the State-Trait Anxiety Instrument (STAI)\(^{168}\) which contains 20 items on a 4-point Likert scale measuring present feelings of apprehension, tension, nervousness, and worry. The scores range from 20-80. Concurrent and construct validity have been demonstrated.\(^{168, 169}\) The subscale is reliable in pregnant women (Cronbach alpha = 0.83-0.91).\(^{46, 170}\)

8) **Depressive symptoms** were measured using the Center for Epidemiologic Studies' Depression Scale (CES-D)\(^{171}\). A customary cutoff score of >15 is used to identify those with “elevated” levels of depressive symptoms who should be referred for diagnosis of clinical depression. The instrument was used with pregnant women in previous studies.\(^{62, 172-175}\)

9) **Satisfaction with PNC** (late pregnancy interview only) was defined as the degree to which a woman feels that the quality of PNC she received was high and met her needs. Satisfaction was measured using a revised 14-item prenatal satisfaction scale originally developed by Handler et al.\(^{67}\) The reliability (alpha .97) of this measure has been established in similar low-income minority samples.\(^{67, 107, 144}\)

**Post-Delivery (measured by mother’s self-report).**

1) **If premature** was defined as whether the infant was born at <37 weeks completed gestation. We will ask each mother for the date of delivery and then calculate gestational age at delivery based on LMP from first interview. We will also use birth certificate information to validate self-report.

2) **If low birthweight** was defined as whether the infant weighed 2500 gm or less.

3) **Breastfeeding at discharge** was defined as whether a woman initiated breast feeding after delivery.

4) **Use of recommended sleep position** was defined as use of the recommended sleep position during the first week at home.

**D. Statistical Analysis**

Initial descriptive analyses were performed to examine sample characteristics. Psychometric analyses were conducted to establish internal consistency using Cronbach’s alpha for scales. Cronbach alphas were similar across administrations with most scales having acceptable reliability (>0.70), Knowledge and health behaviors were lower, though these scales were not designed to measure a unidimensional construct. Individual care (IC) and Centering Pregnancy (CP) study groups were defined by an intent-to-treat variable indicating the intended form of PNC reported upon enrollment. Study groups were compared to identify any differences on baseline demographic, reproductive health, psychosocial and prenatal care characteristics related to self-selection and random variation. These differences (p<0.10), were adjusted for as covariates when hypotheses were tested. Covariates were also selected from among variables that were substantively related to an outcome, or are commonly controlled (age, race/ethnicity, education). Covariates used in all adjusted analyses include age group (<20 years, 20-34, 35+), race/ethnicity (African American, Hispanic, White/other), multiparous vs. primaparous, receipt of cash or WIC assistance, employment status (yes, no), receiving PNC from a physician vs. advanced practice nurse, education (less than high school, high school, and greater than high school), partner status (yes, no), interpersonal safety measure (score), and history of preterm birth or low birth weight, (yes, no). In addition, the continuous depression score and use of drugs, alcohol, or tobacco at baseline (yes, no) were used in all analyses except for analyses that examined the depression outcome or health behavior outcomes, respectively. We also compared women who did not complete the study with those remaining to identify any differences due to attrition for the entire sample. No additional covariates were identified by comparing those who completed the study to those who were missing data at postpartum follow-up.

All outcomes were analyzed using a generalized linear mixed model approach with an identity link function for continuous outcomes and a logit link for binary outcomes. Clinic code was included as a random variable in each analysis to account for dependency in the data due to attending the same clinic. In models where the outcome was measured at baseline and later, the participant ID was also included as a random intercept to account for the correlation within person over repeated measurements. For continuous measures, residuals were examined for normality in the fully adjusted model and found to
deviate for all but the health behaviors outcome. The Box-Cox method was applied to find the optimal transformations to improve normality[Box & Cox, 1964]. When conclusions from models using the transformed variable were consistent with those using the original scale, the results from the latter are shown. For depression, the results differed, thus, the adjusted means were based on the transformed value, but back transformed to the original scale. A p value of <0.05 was considered statistically significant.

IV. Findings

Description of Study Participants

Hispanic women comprised the largest racial group followed by Black non-Hispanic, then White non-Hispanic women in both study conditions (Table 1). The average age of group and individual care women was 24.86 and 25.24, respectively. Approximately 18% of all women were less than 20 year of age in both study conditions. Fifty two percent of women were multiparous. Thirty percent of women had less than 12 years of education and nearly all women were enrolled in public insurance. Nearly all of the women had a spouse, partner or boyfriend. Approximately one-quarter of the women were current students and 43% of all women were employed full or part-time. The average number of persons per household was three. The majority of women had an annual household income below $18,000. More than half of the women had an annual household income less than $12,000 and approximately 20% had an annual household income from $12,000 to $17,999. About half of the women were receiving Food Stamps and WIC. Nearly one-third of the women were receiving cash assistance (TANF). The number of health problems before pregnancy ranged from 0 to 4 and the number of health problems during pregnancy ranged from 0 to 5. The majority of women did not have health problems before pregnancy.

Baseline Comparisons by Study Conditions: CenteringPregnancy and Individual Care

There were baseline differences between study conditions on parity, prior adverse pregnancy outcome, reporting MD as provider and employment status (Table 1). More women in individual care were multiparous, had a prior adverse pregnancy outcome, had a MD rather than a midwife and were employed. Differences that approached statistical significance included receipt of WIC and cash assistance. More women in group received WIC and cash assistance. Mean depression scores also differed significantly by study condition. Women in group care had a higher depression score mean than women in individual care.

Baseline Differences between Women who participated in CP, Women who were Offered Centering and Chose Individual care, and Women who were Not Offered Centering

There were statistically significant baseline differences between women who participated in CP and women who were offered CP but chose IC (Table 2). These baseline differences included receipt of cash assistance (TANF), parity and mean depression scores. Women who participated in CP were more likely to receive cash assistance, less likely to be multiparous and had a higher depression score mean than women who were offered CP and choose IC. Smoking status approached statistical significance between the groups, with women in CP being less likely to report smoking than women who were offered CP and choose IC.

The other comparison group, women who participated in CP and women who were not offered CP, and thus participated in IC, also showed significant baseline differences: parity, reporting a MD provider, drug use, and mean health behaviors score. More women who were not offered CP were multiparous, had a MD rather than a midwife and scored higher on the health behaviors scale. This group was less likely to report drug use at baseline than those women participating in CP. Differences that approached statistical significance included age of participants, race and mean social support score. Women who were not offered CP were more likely to be older and of black ethnicity than women who participated in CP. Additionally, women who were not offered CP had a mean social support score that was lower than women participating in CP.
Reasons for Choosing Individual Care over Centering Pregnancy at Baseline

Of the 336 women who were offered Centering Pregnancy and chose individual care, the most common reasons for choosing individual care included: scheduling conflicts due to work/school (16.7%), not enough information to make a decision (15.5%), privacy (12.5%), not comfortable in groups (11.9%) and wanted individual time with provider (11.0%) (Table 3).

Thirty seven women (11%) expressed that were still considering Centering Pregnancy for their care type. Since these responses were recorded at baseline, participants still had the option to switch care type. There were also 15 women (4.5%) who indicated that they were intending on beginning Centering Pregnancy when group visits became available for their delivery period. When asked at baseline about what type of PNC they were currently attending, 48 women were unsure/don’t know. Ultimately, 6 of the 48 women who were unsure of care type at baseline choose Centering Pregnancy later in their pregnancy. Women who unsure of their care type were excluded from Table 3.

Baseline Differences between Women who were Retained through 1-Week Post-Partum Interview and those Women who did not Complete the Study

Significant demographic differences between women who were retained and those who did not complete the postpartum interview included: whether the woman reported at baseline that her provider was a MD and having a history of low birth weight infant (Table 4). Women who completed the entire study were less likely to have a history of a low birth weight infant, and more likely to have a MD provider.

Outcomes Differences between Centering Pregnancy and Individual Care based on t-tests and Chi²

Late pregnancy psychosocial outcomes and birth and infant care outcomes are shown for the total sample and by study condition in Table 5. Initial analyses to examine differences between study group were t-tests and Chi². For the majority of late pregnancy psychosocial outcomes, there were no significant differences between women who participated in group care and those who received individual care. Statistically significant differences between study conditions for two late pregnancy outcomes: mean health promotion content discussed and percentage of women at or above the depression cut-off. Women participating in group care had a higher mean score for health promotion content (discussed more topics), and more women in group had depression scores at or above the cut-off score; however, more women in group had depression scores at or above the cut-off score at baseline.

Overall, birth outcomes were positive for women in the sample; preterm birth and low birth weight occurred at a lower rate than would be expected for our study population. The mean gestational age for all women was 38.73 weeks with 7.9% of infants born preterm and 6.89% of infants born low birth weight. Eight percent of the sample initiated breastfeeding at hospital discharge and approximately 75% of women identified the correct infant sleeping position at one week postpartum. With regards to birth outcomes and infant care, there were no significant differences by study condition. Additionally, the number of health problems (acute or chronic) during late pregnancy ranged from 0 to 4 for the total sample and the majority of women did not experience health problems during pregnancy. There were no differences in number of health problems during pregnancy between study conditions.

Main effects of Centering Pregnancy compared to Individual Care on potentially modifiable health outcomes (Study Aim 1)

We examined whether CP group had a show more positive health outcomes including:

H1.a. late pregnancy outcomes of health knowledge, healthy behaviors, prenatal weight gain, intentions to breastfeed, intention to use the recommended infant sleep position, perceived stress, depressive symptoms, anxiety, prenatal care satisfaction, and PNC visit adherence;
H1.b. birth and early postpartum outcomes of prematurity, LBW, breastfeeding initiation and use of the recommended infant sleep position.

For all women in the sample, depression scores were lower in late pregnancy compared to baseline. Compared to the IC group, the decrease in depression from baseline to late pregnancy was significantly greater for the CP group (p=.017; Table 6). Trends in the data showed that women in CP had more favorable changes in health behaviors, knowledge about pregnancy and parenting, stress, and anxiety although these changes were not statistically significant. Among birth and early postpartum outcomes, there were no statistically significant differences in preterm birth rates (CP 8.2% vs IC 7.75%), mean birthweight (CP 3245.0 grams vs IC 3316.9), breastfeeding initiation rate (CP 83.72% vs IC 83.46%), and use of recommended sleep position (77.92% vs 81.55%).

Examining the mechanisms through which CP affects health outcomes (Study Aim 2)

Differences in the hypothesized mechanisms of CP (health promotion content discussed, social support, and pregnancy-related empowerment) were also examined. While all women reported high levels of social support (Table 6), women in the IC group showed an increase in social support from baseline to late pregnancy, whereas the CP group was very similar over time (treatment x time interaction p=.0078). A trend in the data showed that women in CP had more favorable changes in empowerment, but these changes were not statistically significant. Compared to the IC group, the CP group discussed more health promotion content topics (p=.02) (Table 7).

We also hypothesized that CP’s effects on health outcomes would be mediated by prenatal health content discussed, social support, and pregnancy-related empowerment. Because we found a larger reduction in depression among the CP group compared to the IC group, a mediator model was tested to determine if the positive finding for depression was related to the amount of content covered during PNC. Mediation would be demonstrated if the treatment group effect is attenuated when the mediator is included in the model. When the content variable was added as a predictor in the depression model, the treatment by time interaction parameter was slightly larger suggesting that content covered was not explaining the treatment group differences. Note: The treatment effect was not strictly significant in the portion of the sample who completed the content questions (p=0.0943, 4% additional missing).

V. Discussion and Interpretation of Findings

A. Key Findings and Conclusions

Key findings include that women in CP experienced a greater reduction in depression symptomatology from baseline to late pregnancy (Table 7) and discussed more health promotion content (Table 8). Our findings suggest that CP is an effective intervention for reducing prenatal depression. This reduction is important for healthier pregnancies, fetal attachment, and reductions in postpartum depression. Prenatal depression is a key predictor of postpartum depression that can subsequently lead to lower maternal attachment to the fetus and delayed childhood development (Yarcheski, Mahon, Yarcheski, Hanks and Cannella, 2009; Alhusen, 2013). Therefore, identification of women at risk of prenatal depression and then referral to group care is a viable strategy to improve women’s mental health outcomes.

Discussion of more health promotion content by women in CP might be an indicator of higher quality of care. Because content of care is a characteristic of the health care system amenable to change, it can be targeted to improve the quality and outcomes of PNC. We will examine predictors of health promotion content to develop recommendations for improvements in care quality.

The favorable outcomes for nearly all women in the study and the absence of differences in the majority of psychosocial and birth outcomes suggests that women in our study received excellent PNC regardless of the type of visit model. Women in our study had 2-3 times lower preterm birth rates than the communities served by the clinic; this suggests that the women in the study differ from other women in
the study clinics who chose not to participate. Based on the effect sizes in previous studies, we expected our sample to be large enough to detect differences in all outcomes with the exception of preterm birth. In other words, we expected CP to have a larger effect size than our data showed. Outcomes not found to differ by type of PNC showed effect sizes of $h=.01$ for breastfeeding initiation to $.08$ for baby sleep position (which favored IC) for the dichotomous outcomes [Cohen, 1988]. Typically, an $h=.2$ would be considered a small effect, thus these effects are extremely small. Similarly, Cohen’s $d$ estimates for continuous outcomes were less than the general guidelines for small effects ($0.2$), including those that were statistically significant. This corresponds to an $R^2 < 1\%$ of the variance in each outcome was explained by type of PNC.

### B. Study limitations

There are several limitations to this study. A major limitation of this study is related to fidelity of the Centering Pregnancy model. The Centering Healthcare Institute (CHI) is the national, non-profit organization that provides training to individuals and organizations wishing to implement the group care model. In Illinois, the March of Dimes local chapter supported the initiation and expansion of CP in $10$ agencies across the state. Our study took advantage of this unique opportunity to study the effect of CP and its potential causal mechanisms by engaging all $10$ agencies to participate in our research. We found that although clinic staff (clinical and administrative personnel) attended the CHI Basic Training Workshops and received consultation by CHI staff, implementation of CP faced ongoing challenges. Participating clinics identified a need for additional support with enrolling women into CP groups and obtaining organizational “buy-in”. Recruitment into CP groups was proving to be a major stumbling block for clinics. Sites had difficulty forming CP groups that were sufficiently large to promote fidelity to the model and to be sustainable and cost-effective. Even clinics that offered CP for more than a year had periods with inadequate enrollment despite a sufficient volume of women seeking PNC. CP groups had to be cancelled because the groups were too small to allow providers to meet their productivity goals. Before evaluation of CP could commence, we realized that the clinics needed to strengthen organizational support for CP and their recruitment and retention process. Our study’s CHI consultant recommended working with clinic staff using a social marketing strategy to improve communication about CP. Social marketing is a well-established approach widely used in businesses and commercial enterprises, and has been applied to public health and community health promotion. However, this approach is novel for most clinical staff and requires training to build these skills. We developed workshops to help clinic staff identify how they can use social marketing and build their social marketing skills to promote CP. Emphasis was placed on identifying the customers and using a three step social marketing communication strategy. We describe our social marketing workshops in a publication (Vonderheid, S.C, Klima, C., Norr, K.F., Grady, M. & Westdahl, C. (2013).

During our initial phase of the study CHI began a Model Implementation Plan (MIP) that included CHI-trained consultants advising sites on required system change necessary to create a successful and sustainable Centering model. This process culminates in site approval for all sites that demonstrate fidelity to the model and the necessary supports to sustain group care. All of the Illinois sites began CP before the MIP program was developed through CHI. During the course of the study, 3 agencies (5 clinics) received site approval. Some agencies continue to work on this process while others have decided not to pursue site approval for several reasons such as lack of commitment to CP at all levels and financial resources to cover the cost of site approval.

Another limitation is the likelihood of cross-contamination. The CP providers offered both CP and IC. The might have treated their IC patients differently based on their CP training. This would have made our study groups more similar and contributed to the lack of differences in outcomes.

Another limitation of this study is a ceiling effect of outcome measures that did not allow us to determine differences between study groups. Women in both study groups had relatively high levels of psychosocial outcomes (e.g., knowledge, social support, empowerment, behaviors, anxiety) at baseline and late pregnancy, high levels of satisfaction with care, and health promotion content discussed at late
pregnancy, high rates of breastfeeding and placing infants in the recommended sleep position, and high levels of positive birth outcomes (rates of full-term infants and normal birth weight infants). It is possible that women at greatest risk were not invited or informed about the study by clinic staff, or were not interested in participating so they did not complete a study flyer with their contact information.

C. Comparison with findings of other studies

Our findings have differences and similarities to the two RCTs that have been conducted. Ickovics and colleagues (2007; 2011) conducted a study with primarily African American and Latina women attending care from two large university-affiliated public hospital clinics in Atlanta, GA and New Haven, CT. Compared to the IC group, the CP group had statistically significant reductions in preterm birth, higher knowledge about pregnancy, higher satisfaction with prenatal care and higher rates of breastfeeding. Similar to our study, they found no difference in birthweight, and psychosocial outcomes (stress, social support, social conflict). However, they did not find differences in depression in contrast to our findings showing women in CP had greater reduction in depression than women in IC. As they examined subgroups, Ickovics tested the impact of CP on women in the top tertile of stress and found that these women had better outcomes that their counterparts enrolled in IC. Consistent with Ickovics, we used Cohen’s measure of stress and the CES-D measure of depression.

Kennedy and colleagues (2011) conducted a RTC at two military settings in California serving primarily white women. In contrast to our findings, compared to the IC group, the CP group was significantly more satisfied with their care. Also in contrast to our study, there were no differences in depression across study conditions. Similar to our study findings, there were no differences in stress, social support and preterm birth. Consistent with Kennedy, we used Cohen’s measure of stress and the CES-D measure of depression.

D. Policy implications

Policy such as the Centers for Medicare and Medicaid’s Strong Start Initiative can promote the initiation and evaluation of CP, but funding spread to thin will leave the clinic vulnerable to not having adequate resources to achieve fidelity to the CP model. The majority of clinics in our study served low-income women and had limited resources to develop a sound CP program. In an era of limited resources, administrators and staff need to be convinced that the long-term payoff of CP is worth early investment of funding and effort. If the trend of reducing and even eliminating reimbursement for adverse events in health care continues, it is possible that there will be a national benchmark for a preterm birth rate and other health outcomes amendable to change by offering higher quality care. If clinics had adequate resources to implement CP, they might be more likely to achieve fidelity and contribute to a substantial reduction in preterm birth similar to the findings of the RCT conducted by Ickovics and colleagues.

Any healthcare innovation requires many changes related to the innovation itself, local clinical context, and strategies used to implement the innovation. Equally important, persons who support the new practice must “sell” the innovation to personnel throughout the health care organization and to patients, pregnant women and their families. We found that social marketing principles and the 3-step communication process provided a conceptually based and empirically tested framework that was helpful for clinic personnel. Social marketing raised awareness of the need to market to multiple “customers” and gave them a simple and effective communication strategy for doing so without negativity. The selling of CP to pregnant women and families, and to clinic personnel will remain essential until CP has become well established in the local prenatal care market.

E. Suggestions for further research

While numerous studies have found favorable outcomes for women in CP compared to women in individual care, findings are inconsistent. The inconsistency across studies is likely related in part to differences in tools used to measure outcomes and variations in fidelity to the model. The Centering
Healthcare Institute now recommends a set of measures to be used and is collecting core information about the outcomes of Centering Pregnancy clinics to more accurately compare outcomes across populations. Our team developed the measure of empowerment that CHI recommends and we used other CHI recommended measures in this study. To minimize the ceiling and floor effects of some measures, we will work on developing short forms of these measures that allow for greater variation and are sensitive to change. We will re-run our analyses using these revised measures. Further research is also needed to examine fidelity of the CP model and outcomes. We will conduct analyses to assess fidelity to the model at each site and how variations in fidelity affect perinatal outcomes. We will develop fidelity scores based on the process evaluation tool used by facilitators and independent observers of group sessions. We will also closely examine which subgroups (e.g., women with high stress levels, adolescents) might benefit from CP.

VI. List of products (See Table 8)