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The Effect of CenteringPregnancy Group Antenatal Care on Maternal, Birth, and Neonatal Outcomes Among Low-Risk Women in the Netherlands: A Stepped-Wedge Cluster Randomized Trial

Mary-ann Wagijo[1,2], MSc, Mathilde Crone[1,2], PhD, Birgit Bruinsma-van Zwicht[3], MSc, Jan van Lith[3], MD, PhD, Deborah Billings[4,5], PhD, Marlies Rijnders[6], PhD

Introduction: This study was carried out to assess the effects of participating in CenteringPregnancy (CP) on maternal, birth, and neonatal outcomes among low-risk pregnant women in the Netherlands.

Methods: A total of 2124 pregnant women in primary care were included in the study. Data were derived from the Dutch national database, Perined, complemented with data from questionnaires completed by pregnant women. A stepwise-wedge design was employed; multilevel intention-to-treat analyses and propensity score matching were the main analytic approaches. Propensity score matching resulted in sample sizes of 305 nulliparous women in both the individual care (IC) and the matched control group (control-IC) and 267 in the CP and control-CP groups. For multiparous women, 354 matches were found for IC and control-IC groups and 152 for CP and control-CP groups. Main outcome measures were maternal, birth, and neonatal outcomes.

Results: Compared with the control-CP group receiving standard antenatal care, nulliparous women participating in CP had a lower risk of maternal hypertensive disorders (odds ratio [OR], 0.53; 95% CI, 0.30-0.93) and for the composite adverse maternal outcome (OR, 0.52; 95% CI, 0.33-0.82). Breastfeeding initiation rates were higher amongst nulliparous (OR, 2.23; 95% CI, 134-3.69) and multiparous women (OR, 1.62; 95% CI, 1.00-2.62) participating in CP compared with women in the control-CP group.

Conclusion: Nulliparous women in CP were at lower risk of developing hypertensive disorders during pregnancy and, consequently, at lower risk of having adverse maternal outcomes. The results confirmed our hypothesis that both nulliparous and multiparous women who participated in CP would have higher breastfeeding rates compared with women receiving standard antenatal care.
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Keywords: breastfeeding, CenteringPregnancy, group antenatal care, hypertension, maternal outcome, perinatal health, pregnancy, propensity score

INTRODUCTION

Perinatal mortality rates and some adverse maternal outcomes in the Netherlands are higher than those in other developed countries.[1,2] To improve perinatal care, CenteringPregnancy (CP) was introduced in the Netherlands in 2012.[3,4] With the implementation of CP, standard one-to-one antenatal check-ups are replaced by facilitated group consultations.[5] Individual prenatal consultations are replaced with 9 prenatal group sessions and one postpartum session of approximately 90 to 120 minutes. The sessions are facilitated by a health care provider and co-facilitator. Women receive their usual physical examination, but in addition there is time for interactive education, peer support, and more caregiver-woman interaction.[5,6]

In many studies CP is associated with positive maternal and neonatal outcomes, including a decrease in low birth weight (LBW), preterm birth (PTB) rates,[7,8] infants small for gestational age (SGA), neonatal intensive care (NICU) admission rates, better Apgar scores, and higher breastfeeding rates.[9–14] However, given the robustness of most studies the effects of CP in systematic reviews remains inconclusive. Several systematic reviews found no significant decrease in adverse perinatal outcomes[15–17] among women participating in CP or group antenatal care. The systematic review by Carter et al (combining 4 randomized controlled trials [RCTs] and 10 observational studies) showed a decrease

[1]Department of Public Health and Primary Care, Leiden University Medical Center, Leiden, The Netherlands
[2]Department of Health Promotion, Prevention and Care, Maastricht University, Maastricht, The Netherlands
[3]Department of Obstetrics, Leiden University Medical Center, Leiden, The Netherlands
[4]Group Care Global, Philadelphia, Pennsylvania
[5]University of South Carolina, Columbia, South Carolina
[6]Department of Child Health, Dutch Organization of Applied Scientific Research, Leiden, The Netherlands

Correspondence
Mary-ann R. Wagijo
Email: m.r.wagijo@lumc.nl

ORCID
Mary-ann Wagijo https://orcid.org/0000-0003-0552-624X

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Quick Points

- Robust research on the effect of group antenatal care outside the United States is limited and few studies focus on primary level midwifery care.
- In this study a stepped-wedge cluster randomized controlled design was used to investigate the effect of CenteringPregnancy on maternal and neonatal outcomes in the Netherlands.
- Participation in CenteringPregnancy was associated with positive maternal outcomes, especially for nulliparous women.
- Further research is necessary to confirm the results from this study and to determine the underlying factors of the effect on maternal outcomes to provide leads for the mechanisms that lead to these effects.

in LBW in the overall results, but no significant impact when only RCTs were considered.[15] Other studies in the United States found significant beneficial effects of CP only among low-risk, African American women or stronger associations for certain ethnic groups.[8,18] Considering these inconclusive results, the importance of conducting more robust research to assess the effect of CP is clear. In addition, generalizability of studies is limited because most studies on CP's impact on maternal and birth outcomes were conducted in the United States and/or were focused on high-risk pregnancies. As a result, they may not be completely applicable to other settings, such as Dutch maternity care, given differences in the model of maternity health care.[19,20] In the Netherlands, CP is introduced in primary care midwifery organizations in which women who are considered low risk (87.5% of pregnant women) start their antenatal care.[21] Although these women are considered low risk, this refers only to their medical status for their pregnancy but not to any suboptimal psychosocial circumstances.

Data on the effect of CP in low-risk women in the Netherlands are, so far, limited to one retrospective cohort study showing decreased use of pain relief during birth and higher breastfeeding initiation rates.[3] More studies are required to consider a nationwide scale-up of CP in the Netherlands.[3] This article reports on the findings of the effect of CP compared with individual care (IC, otherwise known as standard antenatal care) on perinatal outcomes among low-risk women. Given the existing literature, our hypotheses are that adverse maternal, birth, and neonatal outcomes among low-risk women engaging in CP will be at least comparable with women receiving standard IC; however, we expect breastfeeding rates to be higher amongst CP women, based on prior research conducted in the Netherlands.[3]

METHODS

Design and Setting

A stepped-wedge cluster randomized controlled design was used in an urban/suburban setting in the northern part of South Holland province, a region where CP was not offered before the start of the study. With the stepped-wedge cluster RCT design, the intervention was implemented stepwise over time in randomly selected clusters, from control to intervention phases, until all clusters were exposed.[22] This design was chosen because it also takes differences within the midwife practices into consideration and made it possible to recruit women for the control and intervention group from the same midwifery practice. Furthermore, randomization at individual level was not appropriate for this study, because IC sessions were also provided by professionals who were trained for CP sessions and most likely the CP training would influence the individual sessions.[23] Midwifery practices included in this study also wanted to take part in this study, because it enabled them to acquire the skills needed to implement CP and offer group care to their patients. Thirteen participating primary care midwifery centers were divided into 3 regions based on zip code. All regions started to collect control data from November 2013 onwards (control period) until they implemented CP (intervention period). Every region was randomly assigned to a start date for CP with a between-step period of 3 months. Participating practices in the regions received opaque envelopes with their start date. The first region-initiated CP in April 2014, the second region July 2014, and the third region in October 2014.

During the intervention period, from April until October 2014, all pregnant women attending participating midwifery centers could choose between CP and standard IC. Because randomization of women to CP or IC was considered almost impossible to achieve, propensity score matching was used to remove differences caused by factors other than CP, comparable with the studies by Crockett et al.[11,24] The Consolidated Standards of Reporting Trials (CONSORT) statement[25] was filled in for this study and can be found in the supplementary materials. The study was approved by the Commission of Medical Ethics of the Leiden University Medical Center.

Participants

The health care providers at the participating centers provided written and verbal information regarding the study to all women who registered for antenatal care. All women who chose to participate in the study provided written informed consent at their initial intake appointment. Inclusion criteria were as follows: sufficient ability to communicate in Dutch (with assistance from a familiar translator/interpreter), antenatal follow-up in primary care, and first antenatal appointment before 24 weeks gestational age. Exclusion criteria: women who were referred to specialized care immediately after intake due to an increased risk of complications and/or no informed consent for collection of pregnancy outcomes from routine midwifery care data as registered in the Dutch Perinatal Data Registry (Perined). Participants under the age of 18 needed to provide their own consent and informed consent from parents or caregivers.

Intervention

Before the implementation of CP, all women received IC during the control period, comprising 10 to 17 antenatal check-ups of approximately 15 minutes. At the designated time point, each region started with the intervention period. Subsequently, intervention data were collected with CP participants who attended 8 to 9 group consultations during pregnancy and one postpartum, in a group comprised of 8 to 12 women of approximately the same gestational age. Group sessions replaced the individual visits that women would have attended otherwise. The group sessions started at 12 to 16 weeks of pregnancy and ended at approximately 36 weeks, with a follow-up session 6 weeks postpartum. Group sessions had a duration of 90 to 120 minutes. Women participating in CP only received more individual prenatal check-ups if they had complications that did not require a referral to secondary care and after the last antenatal session in the period before giving birth. A previous study conducted in the Netherlands revealed that 87% of the CP participants attended 7 or more CP sessions.[26] Groups were facilitated by a certified midwife and a co-facilitator. During each consultation, women received the same health assessments as in IC: blood pressure measure, fundal height assessment, and a check of fetal heart tones. However, women were taught to perform some health assessments by themselves in CP. For example, women took and documented blood pressure measurements in the group space using an electronic blood pressure monitor provided by the midwifery practice and measured their own maternal weight. In case of doubts about the results or deviant results, measurements were repeated by the midwife with a conventional blood pressure monitor. Health assessments requiring specific medical knowledge were performed solely by the midwife, such as fundal height assessment, checking fetal heart tones, and fetal presentation. There was no minimum number of group sessions required. However, midwives were trained to encourage women to attend at least more than one session (preferably at least 3). Previous research showed that discontinuation of CP was rare among women in the Netherlands once they began participating in CP.[26]

Prior to the implementation of CP, care providers and co-facilitators received a two-day training and three half days of supervised sessions from experienced Dutch trainers who were trained by the Centering Healthcare Institute (CHI). The health care professionals from the midwifery practices also had the possibility to contact CHI for assistance and guidance whenever they were in need of additional information or help with providing CP sessions.[5,23] For model fidelity and sustainability, the Dutch Centering Institute has a quality system in place that midwifery practices are asked to attend after their initial training and includes feedback sessions, reporting on groups sessions, and participation in national monitoring conducted by the Dutch Organization of Applied Scientific Research.

Data Collection and Measures

All women included in the study, from the start of the control period until the end of the intervention period, received questionnaires to fill out at approximately 12, 28, and 36 weeks' gestation, and at 6 weeks postpartum. The current study used the data from the baseline questionnaire (at 12 weeks), including sociodemographic characteristics, psychosocial characteristics, health behavior, and women's knowledge of pregnancy.

Perinatal outcome data were extracted from Perined, the Dutch national database in which routine midwifery care data pertaining to pregnancy, birth, postpartum outcomes, and (re)admissions are stored. The purpose of Perined is to gain insight about the quality of the care, which then informs possibilities for improving care. Data are registered in 3 separate databases and can be linked: one for primary midwife-led care (perinatal database-1), one for secondary obstetric care (perinatal database-2) and one for neonatal care (neonatal database). Indications for referral to secondary care (obstetrician-led care) are outlined in the Dutch obstetric indication list and guidelines from the Royal Dutch Association of Midwives.[27,28] Perined data are collected by 99% of primary care practices and 100% of obstetric care providers.[29]

Baseline Characteristics

The following sociodemographic characteristics were collected from the questionnaire and/or the Perined database: ethnicity, level of education, age, employment, partner status, social-economic status (SES), health behavior, pregnancy knowledge, psychosocial characteristics, and health care use.

Ethnicity was coded based on the country of origin of the biological parents of the women. If both parents were born in the Netherlands, women were coded as Dutch. If one parent was born in another country, they were registered as non-Dutch, and the birth country of the parent was coded as high-, low-, or middle-income country based on the classification of the World Bank.[30,31] Level of education was determined by the highest level of education completed by the pregnant woman and classified according to the International Standard Classification of Education[32] according to the following levels: low (no education, primary education only or lower secondary education), average (higher secondary education or postsecondary nontertiary education) or high (recognized tertiary education). Age was categorized as 22 years or younger, 23 to 28 years, 29 to 35 years, or 36 years or older. Employment was categorized into 3 categories: both prospective parents had paid work, one parent had paid work, or neither parent had paid work. Partner status was categorized as having a partner or not. The SES of the neighborhood was based on the ZIP code of the address of the women and referred to the average income, the proportion of individuals with a low income, with low education, and without a paid job for this ZIP code. The SES-scores were categorized into 3 groups: low SES-score (less than the twentieth percentile), average SES-score (between twentieth and eightieth percentile), and high SES-score (greater than the eightieth percentile). Furthermore, parity was self-reported and categorized into nulliparous or multiparous. Additionally at baseline questions were asked about smoking, eating, and physical activity behavior, lifestyle and pregnancy knowledge, stress and coping behavior, and health care use. A more in-depth description of these collected data can be found in the protocol published by Van Zwicht et al, and Crone et al.[23,33]

Maternal, Birth, and Neonatal Outcomes

All variables regarding adverse outcomes were extracted from Perined and dichotomized. Maternal adverse outcomes were hypertension and related disorders (HELLP, preeclampsia) and gestational diabetes. The registration in Perined only requires the specific indications for consultation, referral, admission to hospital, or treatment in obstetric-led care. If no other indications were registered, no adverse outcomes were assumed. *An adverse maternal outcomes* indicator was created, composed of all available variables in Perined, indicating that for any of these outcomes a woman had either been referred to obstetric-led care for consultation or transfer of care, had been admitted to a hospital, or received treatment. We only included variables referring to the current pregnancy, omitting variables related to the obstetric history because of the low risk status of women receiving antenatal midwifery care.

Labor and birth outcomes included referral to obstetric-led care, use of pharmaceutical pain relief, induction of labor, assisted vaginal birth, cesarean birth, place of birth (hospital or home), and postpartum hemorrhage (> 1000 mL). The following adverse neonatal outcomes were included: SGA (weight at birth lower than the tenth percentile), birth weight (weight at birth <2500 g), neonatal intensive care unit (NICU) admission greater than or equal to 24 hours postpartum, low Apgar score (<7 after 5 min), and preterm birth (<37 weeks' gestation).

Because the prevalence of adverse maternal and child outcomes was expected to be low, these variables were analyzed separately but also as a composite variable. Therefore, the following Perined variables were combined into 3 composite variables: adverse child outcome, nonoptimal birth events, and adverse maternal events. An adverse child outcome was defined as suffering from at least one of the neonatal adverse outcomes: SGA, low Apgar score, birth defects, hospitalization, and prematurity. It is unlikely that participation in CP will directly lead to reducing birth defects. However, birth defects are an element of the Big 4 of perinatal deaths in the Netherlands, which is why it was included in this study.[34] Nonoptimal birth events included having a postpartum hemorrhage, assisted birth, or induction of labor. Adverse maternal outcomes were based on gestational diabetes and gestational hypertension.

Statistical Analysis

First, we extracted sociodemographic characteristics and neonatal and maternal outcomes of women who consented to use their Perined data from the Perined database and compared them with those who did not complete the baseline questionnaire (nonrespondents) and those who responded to the baseline questionnaire. All further analyses were conducted separately for nulliparous and multiparous women that had responded to the questionnaires. First, we performed an intention-to-treat analysis, comparing all women in the intervention period with all women in the control period, adjusting for baseline differences in sociodemographic characteristics. Multilevel logistic regression analyses were conducted to calculate odds ratios (ORs) with a 95% CI. We employed multilevel techniques to account for the clustering effects among pregnant women in midwifery practices. We used a correction in all analyses for the time point when the practices started with CP, to reduce the influence of possible temporal effects.

Second, we conducted multilevel logistic regression analyses separately for the CP group and IC group in the intervention period. Women who decided to participate in CP differed in several characteristics from women who did not participate.[26] Theoretically, if women had been offered CP in the control period, we would have expected a comparable distribution of CP and IC participants. If we had performed a per protocol analysis, the CP group would have been compared with all women in the control period without differentiating between these potential participants (compliers) and potential nonparticipants (noncompliers). A Compliers Average Causal Effect (CACE) analysis identifies potential CP participants in the control period and compares them with the actual CP participants in the intervention period. CACE analysis was possible because the study met the most important assumptions regarding random treatment assignment, stable unit treatment value (low risk of contamination), monotonicity (practices were not likely to do the opposite of what they were assigned to do), and women in the control group were not likely to receive the intervention (practices were not trained yet during the control period and CP was not implemented).[35,36] For the CACE analyses, we selected women in the control group from the control period of the study who were comparable with the women in the CP group or the IC group using propensity scores.[37] With propensity scores, it is possible to identify respondents that are as similar as possible on a diverse set of characteristics. Given these characteristics, the propensity score assessed the probability of being in the hypothetically CP or IC group in the control period. In this study, the propensity scores were calculated using social demographic, psychosocial, health behavior, and health care use characteristics from the baseline questionnaire.[23] Propensity scores were calculated separately for the CP and IC group; propensity scores of control women were matched to the scores of the actual CP or IC participants to model potential CP/IC participants in the control period; it yielded, for both nulliparous and multiparous participants, a sample of comparable control and CP women and a sample of comparable control and IC women.[38,39] Multiple imputation was used to impute missing variables on the outcome variables, in order to reduce bias due to missing data.[40] Because all women in this study filled out the baseline questionnaire, we had insight on the properties of missing answers in follow-up questionnaires. We assumed missing was at random and imputed missing data based on answers given in the baseline questionnaire. The following groups of variables were included in the imputation models: variables that we used as outcome in the effect analyses of imputed data, variables that were related to the missingness structure, and variables that were strong predictors for the variable we wanted to impute. A total of 20 iterations were used because about 20 to 30 percent of the data were missing. Multiple imputed data sets were pooled using the bar procedure.[41]

Statistical significance was considered at $P < .05$. Analyses were performed with SPSS version 25.0 for Windows and R Studio for propensity score matching.

RESULTS

In Figure 1, a flowchart is presented for participants in the intervention and control period and participation in CP of IC. Table 1 provides an overview of eligible, recruited, and participating women in the study. In total, 3049 pregnant women consented to participate and to share their Perined registrations. The control period comprised 980 women, and the intervention period 2069 women. Of all these women, 2124 women (69.7%) filled out the baseline questionnaire. Women who did not complete the baseline questionnaire were more often younger and from low- or middle-income countries, and more likely to have birthed their children in hospital, used pain relief during birth, and had gestational diabetes. Nonrespondents more often did not engage in CP.

Tables 2 and 3 describe the differences in baseline sociodemographic characteristics and the intention-to-treat analyses for the control and intervention groups that completed the questionnaire, separately for nulliparous and multiparous women. The control group consists of all women who attended antenatal care in the institutions during control period when CP was not yet initiated. The intervention group comprised all women during the intervention period, participating in either IC or CP.

At baseline, among the nulliparous women, the intervention group more often had a partner and a job compared to the control group. Among multiparous women, fewer women originated from a low-or middle-income country (Table 2). The results of the intention-to-treat analysis (Table 3) show a significantly lower risk of an assisted vaginal birth, pregnancy hypertension, adverse maternal outcomes and nonoptimal birth events, and an increased likelihood of breastfeeding initiation among nulliparous women in the intervention group compared to women in the control group. There were no differences between the intervention and control groups for multiparous women (Table 3).

In total, 465 (32.7%) women participated in CP during the intervention period. After propensity score matching, we compared the CP group and the IC group to comparable samples of women in the control period (control-CP group and control-IC group). The results of these multilevel analyses are presented in Table 4 (nulliparous women) and Table 5 (multiparous women). Nulliparous women attending CP were less likely to suffer from hypertension and composite adverse maternal outcomes compared to the control-CP group. Breastfeeding initiation was significantly higher amongst women in CP compared with women in the control-CP group. IC nulliparous women were less likely to have an assisted vaginal birth and nonoptimal birth events compared with the control-IC group. Among multiparous women, only breastfeeding initiation rates were significantly higher for CP participants compared with their control-CP group.

DISCUSSION

The main findings in this study are that nulliparous women participating in CP experienced a decreased risk for both composites of adverse maternal outcomes and developing hypertensive disorders. Expectedly, higher breastfeeding initiation rates were found among nulliparous and multiparous women participating in CP as compared to women in IC. Current literature on the effects of CP has provided limited information on maternal medical events among CP women. Most studies have focused on neonatal or maternal psychosocial outcomes and satisfaction with CP. Because of the robustness of this study, it will contribute to the research gap by providing results of the impact of CP in a health care system not based in the United States with an important focus on primary level midwifery care. Other countries with similar health care systems will be able to use the results of this study to bolster CP adoption and implementation or scale-up.

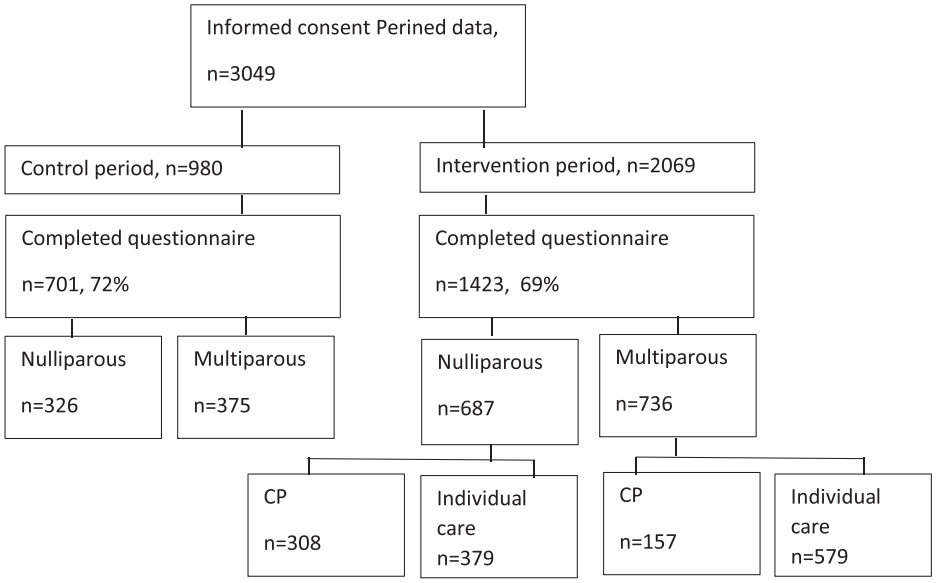

Figure 1. Flow Chart Participants in Intervention and Control Period and in CenteringPregnancy and Individual Care

Table 1. Differences in Sociodemographic Characteristics and Child, Birth, and Maternal Outcomes Between Respondents and Nonrespondents to the Baseline Questionnaire (N = 3049)

Characteristic	Nonrespondent, % (n = 925)	Respondent, % (n = 2124)	*P* value
Intervention			
Control	30.2	33.0	.011
Non-CP	50.9	45.1	
CP	18.9	21.9	
Parity			
Nulliparous	44.6	46.7	.306
Multiparous	55.4	53.3	
Sociodemographic characteristics in Perined			
Age, y			
< 25	11.1	7.1	<.001
25-29	34.3	34.9	
30-34	34.3	41.8	
35-39	20.4	16.2	
Neighborhood socioeconomic status			
< Twentieth percentile	17.7	18.8	.772
Twentieth percentile to eightieth percentile	64.1	63.4	
> Eightieth percentile	18.2	17.7	
Ethnicity: high-income country			
Yes	89.7	95.2	<.001
No	10.3	4.8	
Child, birth, and maternal outcomes			
Referral to specialized care	57.1	56.6	.842
Pain medication in labor	36.5	32.2	.022
Induced labor	19.5	18.6	.615
Vaginal birth, assisted	20.1	19.2	.584
Cesarean birth	10.3	10.2	.958
Hospital birth	79.9	76.5	.038
Postpartum hemorrhage	5.1	5.7	.546
SGA (< tenth percentile)	6.3	6.2	.935
Birth weight <2500 g	3.0	2.9	.816
NICU admission	7.9	7.2	.498
Apgar score <7	2.8	2.3	.445
Prematurity (<37 wk)	4.2	4.2	.533
Gestational diabetes	3.4	2.0	.040
Hypertension	7.6	7.4	.881
Breastfeeding	74.5	75.8	.437
Adverse child outcomes[a]	20.0	20.2	.922
Nonoptimal birth events[b]	36.8	36.0	.712
Adverse maternal outcomes[c]	10.8	9.4	.235

Abbreviations: CP, CenteringPregnancy; NICU, neonatal intensive care unit; SGA, small for gestational age.
[a] At least one adverse child outcome, including SGA (< tenth percentile), low Apgar score, birth defects, NICU admission, and prematurity.
[b] At least one nonoptimal birth event, including postpartum hemorrhage, cesarean birth, and induction of labor.
[c] At least one adverse maternal outcome, including gestational diabetes and hypertension.

Table 2. Differences in Sociodemographic Characteristics Reported in Baseline Questionnaire Between the Control and Intervention Period for Nulliparous and Multiparous Women (N = 2124)

	Nulliparous		Multiparous	
Characteristic	Control, % (n = 326)	Intervention, % (n = 687)	Control, % (n = 375)	Intervention, % (n = 736)
Level of education				
Low	8.9	6.4	8.3	8.8
Average	32.2	35.4	34.9	37.1
High	58.9	57.9	56.8	53.9
Age, y				
<23	5.5	5.2	2.4	1.0
23-28	43.3	44.5	27.2	25.1
29-35	45.4	44.1	60.0	61.8
>35	5.8	6.1	10.4	12.1
Ethnicity				
Dutch	85.0	84.9	84.5	89.4[a]
Low/middle-income country	8.9	7.0	9.3	5.3
Other high-income country	6.1	7.9	5.9	5.3
Partnered	95.4	98.1[a]	99.7	99.5
Employment				
Both partners employed	82.8	90.0[b]	79.7	83.0
One partner employed	15.6	9.2	18.4	15.9
Not employed	1.5	0.9	1.9	0.9

[a] $P < .05$
[b] $P < .0.01$

In line with other studies,[9,18,42] we also found higher rates of breastfeeding initiation amongst women in CP, which is a beneficial outcome for maternal and infant health.[43] Despite already high breastfeeding initiation rates in the Netherlands, CP still increased this rate.[44] Unfortunately, Perined only registers data on breastfeeding initiation and not on breastfeeding continuation, and the study by Lanting et al also showed that only a minority of infants in the Netherlands are breastfed after 6 months of age.[44] Further research is required to investigate if CP also leads to higher rates of breastfeeding continuation. No differences were found in adverse neonatal outcomes between women receiving CP and women receiving IC. Different international studies have also shown inconclusive results regarding neonatal outcomes.[15–17] Further subgroup analyses into different vulnerable groups (based on sociodemographic, health, and psychosocial characteristics) should be undertaken because some studies have only found differences or stronger effects for certain vulnerable groups.[8,18]

This is the first study reporting the effect of CP on gestational hypertension, which was also a part of our composite adverse maternal outcome (gestational diabetes and gestational hypertension). According to this study, nulliparous women participating in CP were at a significantly lower risk of developing gestational hypertension. Most of the women participating in CP in the Netherlands are highly educated women.[26] A study in the Netherlands examining the effect of maternal education level on gestational hypertension showed that pregnant women with a higher education level are at less risk of developing hypertension during pregnancy,[45] which could be an explanation for the decrease in hypertension rates. However, with the propensity score matching, we adjusted for baseline differences, including education level. The decrease in gestational hypertension might also be attributed to education about healthy lifestyle offered during CP sessions, possibly influencing lifestyle decisions that decrease the risk of hypertension. A study assessing the accuracy of self-measurement of blood pressure compared with blood pressure measurements by research nurses found that self-measurement resulted in higher blood pressure scores.[46] Given these results, we do not expect the decrease in hypertension to be caused by the self-measurement aspect in the CP group. Another explanation could be that, given the higher satisfaction rates among CP participants,[3] women feel less stressed and calmer when measuring their blood pressure compared with individual check-ups. The setting of a CP session is more social and offers participants more time in their antenatal session compared with women receiving IC. Further research that investigates differences in health behaviors and psychological distress of women experiencing antenatal care could provide more information on the potential mechanisms that explains this effect.

Strengths and Limitations

The stepped-wedge cluster RCT design of this study takes away differences in time and variations among midwifery practices, as midwifery practices provide their own

Table 3. Differences in Birth and Perinatal Outcome Variables in Nulliparous and Multiparous Pregnant Women in Primary Care Between the Control Period and the Intervention Period (N = 2124)

	Nulliparous			Multiparous		
Outcome	Control, % (n = 326)	Intervention, % (n = 687)	aOR (95% CI)[a]	Control, % (n = 375)	Intervention, % (n = 736)	aOR (95% CI)[a]
Referral to specialized care	68.1	70.3	1.05 (0.78-1.41)	43.2	45.7	1.07 (0.83-1.40)
Pain relief	41.7	45.4	1.12 (0.85-1.47)	20.5	21.6	1.01 (0.73-1.38)
Inducing labor	20.6	22.3	1.04 (0.75-1.46)	17.9	14.8	0.78 (0.56-1.10)
Assisted birth	35.0	27.8	**0.69 (0.52-0.92)**	9.1	9.4	1.04 (0.67-1.60)
Cesarean birth	15.6	11.1	0.70 (0.46-1.03)	8.3	7.9	0.95 (0.60-1.52)
Place birth, hospital	85.3	86.3	1.10 (0.75-1.62)	68.3	67.5	0.99 (0.76-1.31)
Postpartum hemorrhage	4.6	6.4	1.26 (0.68-2.35)	4.8	6.0	1.13 (0.67-1.92)
SGA, (< tenth percentile)	5.2	5.8	1.11 (0.63-1.93)	5.9	7.2	1.18 (0.72-1.94)
Birth weight <2500 g	3.1	4.4	1.20 (0.64-2.24)	2.1	1.8	1.04 (0.54-1.99)
NICU admission	10.4	10.5	0.87 (0.56-1.36)	3.5	4.5	1.15 (0.65-2.04)
Low Apgar score, <7	2.5	3.5	1.17 (0.61-2.25)	2.1	1.2	0.86 (0.45-1.67)
Prematurity, <37 wk	6.4	5.2	0.88 (0.52-1.51)	3.2	2.9	0.97 (0.53-1.76)
Gestational diabetes	2.5	1.5	0.82 (0.41-1.63)	1.9	2.4	1.98 (0.73-5.28)
Hypertension	13.8	10.0	0.72 (0.48-1.09)	4.8	3.4	0.83 (0.47-1.44)
Breastfeeding, yes	77.9	81.8	**1.35 (1.02-1.80)**	70.9	71.7	1.07 (0.84-1.36)
Adverse child outcome[b]	26.1	24.2	0.86 (0.66-1.13)	15.5	16.4	1.05 (0.78-1.43)
Nonoptimal birth event[c]	49.7	43.7	**0.75 (0.60-0.95)**	28.0	26.9	0.95 (0.74-1.21)
Adverse maternal outcome[d]	16.3	11.5	**0.66 (0.48-0.92)**	6.7	5.8	0.99 (0.36-1.55)

Bold text highlights a significant difference (P <.05).
Abbreviations: aOR, adjusted odds ratio; NICU, neonatal intensive care unit, SGA, small for gestational age.
[a]Reference group comprises participants during the control period. Adjusted for randomization region and in the nulliparous for having a partner and employment status, in the multiparous group for ethnicity.
[b]At least one adverse child outcome, including SGA (less than tenth percentile), low Apgar score, birth defects, NICU admission, and prematurity.
[c]At least one nonoptimal birth event, including postpartum hemorrhage, assisted birth, and induced labor.
[d]At least one adverse maternal outcome, including gestational diabetes and hypertension.

intervention and control groups. The professionals' attitudes and behaviors in individual consultations during the intervention period were likely influenced by lessons learned in CP training, since the same professionals trained to facilitate CP groups provided both CP and IC. Therefore, randomly assigning women to either CP or IC could have led to a biased control group.[23] Additionally, randomization at the individual level was not possible because midwifery centers were hesitant to participate in the study due to an expected loss of patients if women were not allowed to choose the type of antenatal care they received. Furthermore, an RCT at the individual level was unsuitable because of the relatively low caseload per center, which would have resulted in groups too small (of women of approximately the same gestational age) to start and continue CP.

Additionally, cluster randomization without a stepped-wedge design was expected to result in unfair competition among independent midwifery centers operating in the same region, given that midwifery care in the Netherlands is subjected to market forces. If midwifery practices in the same region would implement CP at different timepoints, those providing CP before other practices would have had a better marketing edge and possibly gain patients who wanted to attend group care. Like other studies where individual randomization was impossible, we decreased the risk of population bias using propensity score matching and intention-to-treat analysis.[8,10]

Some of the data were collected through questionnaires, which resulted in an underrepresentation of pregnant women with lower literacy or command of the Dutch language and potentially women living in challenging circumstances. Although we included a region with a high percentage of women with lower socioeconomic status and ethnic minorities, their willingness to participate in research was low. However, if they did participate in the study, they participated more often in CP compared with IC.[26]

Another limitation concerns the use of Perined registration data and the linking of data between primary and secondary care when women are referred to an obstetrician. Registration data are primarily recorded for purposes other than research, such as supporting care processes. Jonge et al showed that in 37% of referral cases, at least one indication was mentioned in the maternity care records, which was not included in the Perined registration.[29] Perined only allows a maximum of 3 reasons for referral or interventions, which may force professionals to choose which to document and could, therefore, lead to an underestimation of outcomes considered to be less severe at the time of referral. However, this

Table 4. Multilevel Analyses After Propensity Score Matching Comparing Nulliparous Women in the IC Group With a Comparable Control Group (control-IC) and the Nulliparous Women in the CP Group With a Comparable Control Group (control-CP)

Outcome	Control-IC, % (n = 305)	IC, % (n = 305)	aOR (95% CI)[a]	Control-CP, % (n = 267)	CP, % (n = 267)	aOR (95% CI)[b]
Referral to specialized care	68.9	67.5	0.95 (0.67-1.35)	67.4	71.9	1.16 (0.78-1.72)
Pain relief	42.0	47.5	1.25 (0.90-1.75)	40.8	43.4	1.07 (0.75-1.54)
Induced labor	20.3	23.0	1.04 (0.70-1.56)	21.0	20.2	0.86 (0.56-1.35)
Assisted vaginal birth	35.7	27.2	**0.69 (0.49-0.98)**	33.3	29.2	0.81 (0.55-1.18)
Cesarean birth	16.7	11.8	0.75 (0.47-1.20)	15.0	10.5	0.71 (0.42-1.23)
Place birth, hospital	85.6	87.2	1.10 (0.69-1.77)	83.9	85.0	1.14 (0.70-1.87)
Postpartum hemorrhage	4.6	7.2	1.32 (0.68-2.55)	5.2	4.9	1.03 (0.45-2.36)
SGA (< tenth percentile)	4.9	5.6	1.08 (0.55-2.13)	5.6	6.7	1.30 (0.64-2.61)
Birth weight <2500 g	3.0	3.3	1.05 (0.49-2.28)	3.0	5.2	1.47 (0.67-3.23)
NICU admission	10.5	10.5	0.87 (0.51-1.48)	10.1	11.6	1.17 (0.66-2.07)
Apgar score <7	2.6	4.3	1.32 (0.62-2.82)	2.6	2.6	1.11 (0.47-2.64)
Prematurity (<37 wk)	6.2	3.6	0.74 (0.37-1.48)	6.0	6.4	1.17 (0.58-2.35)
Gestational diabetes	2.0	1.6	0.90 (0.39-2.10)	1.9	1.1	0.90 (0.36-2.29)
Hypertension	13.8	10.2	0.72 (0.43-1.19)	14.6	7.9	**0.53 (0.30-0.94)**
Breastfeeding	77.7	76.7	0.96 (0.68-1.33)	78.7	87.6	**2.23 (1.34-3.69)**
Adverse child outcome[c]	26.6	22.3	0.79 (0.56-1.10)	25.8	28.8	1.19 (0.84-1.68)
Nonoptimal birth event[d]	49.8	43.0	**0.73 (0.56-0.97)**	47.9	43.4	0.82 (0.61-1.11)
Adverse maternal outcome[e]	15.6	11.8	0.70 (0.47-1.05)	16.5	9.0	**0.52 (0.33-0.82)**

Bold text highlights a significant difference (P <.05).
Abbreviations: aOR, adjusted odds ratio; CP, CenteringPregnancy; IC, individual care; NICU, neonatal intensive care unit; SGA, small for gestational age.
[a]Reference group comprises propensity matched participants during the control period to IC participants in the intervention period. Adjusted for midwife practice and region.
[b]Reference group comprises propensity matched participants during the control period to CP participants in the intervention period. Adjusted for midwife practice and region.
[c]At least one adverse child outcome, including SGA (< tenth percentile), low Apgar score, birth defects, NICU admission, and prematurity.
[d]At least one nonoptimal birth event, including postpartum hemorrhage, assisted birth, and induced labor.
[e]At least one adverse maternal outcome, including gestational diabetes and hypertension.

underestimation does occur in both the intervention and control groups.

Some variable outcomes had low incidence and did not occur in all midwifery practices, conflicting with the correction for midwifery practices in the multilevel analysis. However, this is a general problem with low incidence outcomes. It was not possible to mask pregnant women and midwives for randomization. This could have affected some of the outcomes, for example, overreporting of women starting breastfeeding in the CP group. However, this bias was limited because most maternal and child outcomes are also often registered by professionals in secondary care, who were unaware of whether a pregnant woman participated in CP. Nonmasking can also lead to selection bias. The effects of selection bias were considerably reduced by correcting for differences between practices (multilevel) and women and by applying propensity matching.

Additional bias concerns community cross-over due to geographic overlap between the midwifery practices. However, it is unlikely that this sort of bias occurred as randomization by region decreased the risk of cross-over bias. For example, the Netherlands is a small country, and women are very likely to stay with their original midwife after moving to the same region where the midwife is located.

During the intervention period of this study, all midwifery practices started with the implementation of CP; some practices faced problems in continuing CP sessions or in recruiting pregnant women. This might have decreased the potential effects of CP in our study, as good implementation of CP is associated with better outcomes.[47] Ongoing attention to implementation fidelity of CP is necessary, although this may be challenging.[6,48]

Implications for Future Studies

This study describes the outcomes for medically low-risk women participating in CP and shows some important positive effects for pregnant women. Future research on maternal health should explore CP as a potentially effective intervention for decreasing gestational hypertension. Breastfeeding initiation increased among CP participants; future research should also aim to document breastfeeding continuation. Future research also should aim to document more precisely which structural, content, and implementation components of CP are responsible for the significant findings in this and other studies, which would have significant implications for the execution of group care in clinical practice. Lastly, one systematic review of CP recommended distinguishing

Table 5. Multilevel Analyses After Propensity Score Matching Comparing Multiparous Women in the IC Group With a Comparable Control Group (control-IC) and the Multiparous Women in the CP Group With a Comparable Control Group (control-CP)

Outcome	Control-IC, % (n = 354)	IC, % (n = 354)	aOR (95% CI)[a]	Control-CP, % (n = 152)	CP, % (n = 152)	aOR (95% CI)[b]
Referral to specialized care	42.9	43.2	0.95 (0.70-1.29)	48.7	46.7	1.08 (0.65-1.78)
Pain relief	20.6	21.8	1.00 (0.70-1.45)	22.4	23.0	0.98 (0.55-1.76)
Induced labor	17.8	13.8	0.74 (0.49-1.12)	21.7	15.1	0.68 (0.36-1.27)
Assisted vaginal birth	8.8	9.0	1.00 (0.60-1.67)	10.5	11.2	1.22 (0.55-2.70)
Cesarean birth	7.9	7.3	0.91 (0.53-1.58)	9.2	9.2	1.07 (0.46-2.50)
Hospital birth	67.5	67.2	0.98 (0.71-1.35)	68.4	63.8	1.04 (0.61-1.75)
Postpartum hemorrhage	4.5	5.6	1.11 (0.60-2.08)	3.9	5.3	1.22 (0.44-3.42)
SGA (< tenth percentile)	5.9	7.1	1.13 (0.64-2.02)	5.9	6.6	0.93 (0.37-2.30)
Birth weight <2500 g	2.3	1.4	0.93 (0.43-2.00)	2.0	2.6	1.23 (0.36-4.12)
NICU admission	3.7	4.5	1.12 (0.58-2.18)	3.3	4.6	1.24 (0.42-3.63)
Apgar score <7	2.3	0.6	0.77 (0.34-1.72)	3.3	1.3	0.77 (0.23-2.54)
Prematurity (<37 wk)	3.4	2.0	0.80 (0.39-1.66)	3.9	5.3	1.19 (0.42-3.32)
Gestational diabetes	1.4	2.5	1.27 (0.59-2.73)	0.0	2.0	1.55 (0.40-5.98)
Hypertension	4.8	2.8	0.76 (0.38-1.50)	6.6	3.3	0.66 (0.24-1.82)
Breastfeeding	70.9	72.9	1.11 (0.84-1.48)	71.7	80.3	**1.62 (1.00-2.62)**
Adverse child outcome[c]	15.8	14.4	0.89 (0.62-1.27)	19.1	17.1	0.92 (0.53-1.60)
Nonoptimal birth event[d]	27.4	26.0	0.91 (0.69-1.21)	32.9	25.7	0.86 (0.54-1.36)
Adverse maternal outcome[e]	6.2	5.4	0.95 (0.57-1.57)	6.6	5.3	0.94 (0.42-2.09)

Bold text highlights a significant difference ($P < .05$).
Abbreviations: aOR, adjusted odds ratio; CP, CenteringPregnancy; IC, individual care; NICU, neonatal intensive care unit; SGA, small for gestational age.
[a]Reference group comprises propensity matched participants during the control period to IC participants in the intervention period. Adjusted for midwife practice and region.
[b]Reference group comprises propensity matched participants during the control period to CP participants in the intervention period. Adjusted for midwife practice and region.
[c]At least one adverse child outcome, including SGA (< tenth percentile), low Apgar score, birth defects, NICU admission, and prematurity.
[d]At least one nonoptimal birth event, including postpartum hemorrhage, assisted birth, and induced labor.
[e]At least one adverse maternal outcome, including gestational diabetes and hypertension.

among different risk groups to make more evident the benefits of group care: "By teasing out the different high-risk groups, it is possible that the benefits of group care may become more evident."[18] Future studies distinguishing high-risk women from low-risk women in the Netherlands may reveal different and/or more effects among women participating in CP.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Reporting Checklist for Randomized Trial

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