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Part II: The effect study on the VoorZorg program

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Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: A Randomized Controlled Trial

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Abstract

Objective: antenatal smoking is more prevalent among young women with low socioeconomic status. The aim of our study is to assess whether the VoorZorg programme, compared to usual care, is effective in reducing cigarette smoking among young high risk pregnant women. Furthermore, the effect of VoorZorg on pregnancy outcomes and on breast feeding will be described.

Design: a randomised controlled trial of VoorZorg, a nurse home visitation intervention, was undertaken over a 2½ year period from 2007 to 2009. Data were collected between 16 and 28 weeks gestation, 32 weeks gestation and at two months post partum on cigarette smoking status plus six months post-partum for breastfeeding prevalence. Neonatal birth weight and gestation at birth were also collected. Setting: participants living in 20 municipalities in the Netherlands.

Participants: 460 pregnant women were recruited by different professionals. Inclusion criteria were age < 26 years, ≤ 28 weeks pregnancy with the first child, low educational level and some knowledge of the Dutch language.

Interventions: women in the intervention group received, in addition to usual care, the voorzorg programme which consisted of 40–60 home visits by specialised nurses from pregnancy until two years after birth.

Findings: the percentage of smokers was significantly lower in the intervention group (40%) compared to the control group (48%) during pregnancy ($p = 0.03$) and at two months post birth (49% and 62%; $p = 0.02$). During pregnancy the number of daily cigarettes smoked was reduced in both groups. After birth, the intervention group smoked 50% less cigarettes compared to the control group (C: 8 ± 10 ; I: 4 ± 7 (mean \pm standard deviation (SD)), $p = 0.01$). Furthermore, women in the intervention group did not smoke near the baby (C: 2 ± 5 ; I: 0 ± 0 (mean \pm SD) $p = 0.03$). Birth weight and gestational age were similar in both groups (C: 3147 g, 40 weeks; I: 3144 g, 39 weeks ($p = 0.94$, $p = 0.17$)). Significantly more women in the intervention group were still breast feeding their baby at six months post -birth (C: 6%; I: 13%, $p = 0.04$).

Key conclusions: VoorZorg seemed to be effective in reducing cigarette smoking and in increasing breastfeeding duration. No effect was found on pregnancy outcomes.

Introduction

The VoorZorg programme is a home visitation programme translated and culturally adapted from the Nurse Family Partnership (NFP) programme. The NFP is an effective programme in the United States (US), designed to address risk factors among young pregnant women with low socio-economic status (SES) that compromise fetal and child development and the main goal is primary prevention of child abuse[1].

Maternal cigarette smoking is one of the most preventable causes of adverse pregnancy outcomes [2]. Women who smoke during pregnancy are at a higher risk for preterm birth, low birth weight and placental complications [3]. In addition, more babies with Sudden Infant Death Syndrome are reported among women who smoked [4]. Complications during birth, like fetal distress or maternal infection, lead to 66% higher medical costs among smokers compared to non-smokers [5,6]. Moreover, the child is at risk of developing behavioural problems such as externalising behaviour, because nicotine exposure can affect brain development even after adjustment for other risk factors like socio-economic status [7–9]. To prevent child morbidity and mortality, it is important to reduce maternal cigarette smoking during pregnancy and after birth.

The prevalence of women smoking during pregnancy is high in developed countries [3]. In the US, 12% of pregnant women smoke, which is similar to that reported in Sweden [10]. In Australia the percentage of women who smoked during pregnancy is higher (17%) [11]. The prevalence is highest amongst women with low SES [3,12]. Mohsin et al. showed that 43% of young women (< 20 y) with low SES in Australia smoked during pregnancy [11]. Professionals should focus on young women with low SES, by offering them a targeted intervention to stop cigarette smoking.

As far as we know, there is a lack of effective interventions for high risk pregnant women on reducing or quitting cigarette smoking to improve pregnancy outcomes [3]. Lumley et al. described several interventions aiming at smoking cessation among pregnant women. However, only few studies were specifically designed for (young) pregnant women with low SES [13–17]. In these studies, no effect on smoking cessation and pregnancy outcome were reported [3,17].

In the Netherlands midwives use the minimal intervention strategies (V-MIS, “V” stands for midwife in Dutch) for smoking cessation among pregnant women which is based on the Integrated Change model [18]. In brief, the V-MIS is a smoking cessation counselling strategy in which the information is tailored to the motivational stage of the pregnant women. A Randomised Controlled Trial (RCT) by de Vries et al. (2006) showed that the V-MIS was effective on reducing cigarette smoking during pregnancy and six weeks after birth [19]. The effect of the V-MIS among high risk pregnant women was not assessed. We hypothesise that the home visitation programme conducted by specialised nurses will strengthen the effect of the V-MIS to stop or decrease cigarette smoking among high risk pregnant women.

Breastfeeding is also promoted in the VoorZorg programme because of the proven health advantages. Breastfeeding is, among others, associated with better cognitive outcomes of the child and protective against several diseases [20]. And breastfeeding is important for the relationship between mother and child [21]. The aim of our study is to assess whether the VoorZorg programme, compared to usual care, is effective in reducing cigarette smoking among young high risk pregnant women. Furthermore, the effect of VoorZorg on pregnancy outcomes such as infant birth weight and gestational age plus breastfeeding will be described.

Methods

This study is designed as a single blind, parallel-group, randomised controlled study. The interviewers were blinded from allocation. More detailed descriptions of the design are published elsewhere [22]. This study was approved by the Committee of Ethics on Human Research of the VU University Medical Center (Amsterdam, the Netherlands). All participants signed a written informed consent form.

Participants

Women were actively recruited in 20 municipalities in the Netherlands. A two-stage selection procedure was performed to include all eligible participants [23]. During the first stage, women were selected by general practitioners, midwives and other professionals on the following criteria: (1) maximum age of 25 years, (2) low educational level (primary school or prevocational secondary school), (3) maximum 28 weeks of gestation, (4) no previous live births and (5) understanding of the Dutch language. During the second stage women were interviewed by VoorZorg nurses, and an inclusion criterion was that women reported at least one of the following additional risk factors: no social support, previously or currently experiencing domestic violence, psychosocial symptoms, unwanted and/or unplanned pregnancy, financial problems, housing difficulties, no education and/or employment and alcohol and/or drug use. Out of prior evaluation, it is known that about 50% of the women that were recruited in the first stage were excluded after the interview by the VoorZorg nurses in the second stage because they did not meet the second stage criteria [23].

A total of 460 participants were eligible and randomly assigned into the control or the intervention group after being stratified by region and ethnicity by use of a computer-generated list of random numbers. 223 women were assigned to the control group and received usual care and 237 women were assigned to the intervention group and received the VoorZorg programme. The independent randomisation procedure was performed by a researcher of the VU University Medical Center.

Data collection

In the analyses of this study four data collection moments were included between 16 and 28 weeks and at 32 weeks of pregnancy, at two and six months post birth. Trained female interviewers were available in each region and women were interviewed at home. The interviewers were independent from the VoorZorg nurses. Women were usually interviewed by the same interviewers at each data collecting moment.

We expected a chance that participants could produce socially desirable answers in the presence of others, therefore, the interviews were conducted in private if possible [24]. Data concerning pregnancy outcomes were extracted from data-bases of Youth Health Care Organizations.

Intervention

All women received usual care provided by the Dutch Youth Health Care Organizations [25]. Every pregnant woman in the Netherlands receives maternal health care by a midwife. The caregiver (midwife or obstetrician) offers health education, performs physical examinations and monitors the development of the fetus. In the Netherlands, every newborn will automatically be registered in a Youth Health Care organization (ambulatory well-baby clinic) to monitor the health and development of the child, and

parents are supported in their parenthood. From 2002 onwards the V-MIS was disseminated among all midwives in the Netherlands [18]. The V-MIS aimed at smoking cessation and is based on the '5A'-model and is adjusted for pregnant women. It consists of seven steps (figure 1) described by de Vries et al.[26] Women in the intervention group were offered, in addition to usual care, approximately 10 home visits during pregnancy, 20 during the first year and 20 during the second life year of the child by trained, specialised VoorZorg nurses. In the period that we collected data for the present study (from pregnancy until six months post partum) women received approximately 20 home visits.

The VoorZorg nurses were certified nurses working in Youth Health Care organizations and received specialised training (according to the NFP) in becoming a VoorZorg nurse. The VoorZorg trainings also included training on how to reduce smoking with the V-MIS a nationwide smoking cessation programme, and how to promote breastfeeding. According to the protocol, six domains were discussed during the home visits: (1) the health status of the mother, (2) the child's health and safety, (3) the personal development of the mother, (4) the role of the mother, (5) the mother's relation with her partner, family and friends and (6) the use of (health) care organizations. Furthermore, the VoorZorg nurse inquired about participants' smoking behaviour at each home visit. Participants who declared to smoke were systematically offered the V-MIS. The VoorZorg nurses also discussed whether women were exposed to passive cigarette smoking. After birth, the VoorZorg nurses focused on the negative health effects for the baby and to refrain from smoking in the presence of the baby, as recommended by [27].

Women receiving the VoorZorg intervention were encouraged, already during pregnancy, to initiate and continue breastfeeding after childbirth. The VoorZorg nurse also discussed the problems women encountered when breastfeeding their child and worked together with the mother to seek solutions to continue breastfeeding. It is for example known that when babies cry more often, the mother thinks the breastfeeding was not enough to satisfy the baby. Thus, when the baby cries less, chances of breastfeeding might be higher [28].

Outcomes

Primary outcome measures

The first outcome measure was the prevalence of cigarette smoking (percentage of smokers and average number of cigarettes smoked a day). Group differences were assessed at baseline, 32 weeks of pregnancy and two months post birth. Also, average numbers of cigarettes smoked a day near the baby were assessed.

Prevalence of cigarette smoking was assessed by asking at baseline whether participants had smoked during their pregnancy. Participants were able to choose from three categories: 'Yes', 'Yes, until I was aware of my pregnancy' and 'No'. The second question was whether they were a current smoker. If participants answered this question positively they were asked about the quantity of cigarettes smoked per day. At 32 weeks of pregnancy participants were asked: 'How many cigarettes do you smoke daily?' The next question was: 'How many cigarettes did you smoke over the past 48 hours?' If a participant answered both questions with '0 cigarettes', she was categorised as a non-smoker. Participants were also asked whether they had smoked during pregnancy before they were aware of their pregnancy.

At two months post birth, these questions were repeated and an additional question was asked regarding the quantity of cigarettes smoked near the baby. Other primary outcome measures were birth weight, weeks of gestation, adverse pregnancy outcomes (low birth weight (< 2500 g), prematurity (< 37 weeks) and small for gestational age), and breastfeeding. Small for gestational age was defined as a neonate with birth weight below the tenth percentile on the new Dutch reference curves for birth weight by gestational age [29].

In addition, breastfeeding initiation and duration were assessed at six months post birth by asking participants whether they had initiated breastfeeding. When participants answered this question positively, they were asked whether they were still breastfeeding their child. Participants who answered this question negatively were asked more detailed questions about when they quit breast feeding.

Data analyses

We used SPSS 15.0 for regression analyses and MLwiN 2.22 for multi-level analysis (with 95% confidence interval) [30]. Linear regression analyses were used to analyse the number of cigarettes smoked per day, birth weight, weeks of gestation, and duration of breastfeeding. Logistic analyses were used to study cigarette smoking, low birth weight, prematurity and small for gestational age, and breastfeeding. Mean differences (β) and Odds ratios were calculated to measure effect sizes. Last observation carried forward (LOCF) approach was conducted afterwards to replace missing data for dichotomous variables of smoking. Subgroup analyses were conducted to examine the association between smoking and pregnancy outcomes. Multilevel analyses were used to study changes in smoking behaviour in time (base-line assessment, 32 weeks of pregnancy and two months post birth) and to study differences between control and intervention group. It accounts for the hierarchical nature of the longitudinal data, where level 1 was the measurement in time and level 2 was the individual. Multilevel logistic modelling was performed for dichotomous data (prevalence of smokers) and multilevel linear modelling for continuous data (average number of cigarettes smoked a day). Wald statistics were used to determine significance of the effect. We tested for possible confounders and effect modifiers (age, birth weight, weeks of gestation, gender of newborn, ethnicity and number of risk factors present at baseline).

Findings

Attrition

After randomisation, 20 (8%) of the 237 participants in the intervention group and 35 (16%) of the 223 participants in the control group were excluded from the study (figure 2). Three women in the control group and five women in the intervention group miscarried before receiving any treatment (< 28 weeks of pregnancy). One mother in the control group and four mothers in the intervention group experienced a perinatal death. The difference between both groups, in the prevalence of perinatal deaths, was not significant. The cause of death in the control group was that the baby had a hydrocephalus and in the intervention group that two babies were born premature, one twin died after 29 weeks of pregnancy and one baby died because of a knot of the umbilical cord.

The baseline characteristics of women who were lost to follow up in each measurement were similar to women who remained in the study. Table 1 summarises the base-

line characteristics of the participants. At inclusion, participants were on average 19.4 years old and were included on average at 19.8 weeks pregnancy. The difference between control and intervention group was not significant for any of the variables.

Cigarette smoking

Table 2 shows that at 16-28 weeks of pregnancy, an average of 45% of the participants in both conditions are current smokers, smoking on average 7–8 cigarettes per day. At 32 weeks of pregnancy a decrease of the percentage of smokers was measured in both conditions: in the control group, 35% of the women and in the intervention group 33% are currently smoking (OR 0.9; 95% confidence interval (CI) 0.5-1.5, n.s.). After applying the LOCF approach, group differences became significant ($p=0.03$; OR 0.5; 95% CI 0.3-0.9). At two months post birth, the percentage of smokers was respectively 62% and 49%. LOCF analyses showed a significant difference between control and intervention group ($p=0.02$; OR 0.5; 95% CI 0.3-0.9).

At two months post birth, the number of cigarettes smoked per day was significantly higher in the control group; in the control group 8 (SD \pm 10) cigarettes were smoked per day, while in the intervention group 4 (SD \pm 7) cigarettes were smoked per day (mean difference (β) 4; 95% CI 1.0-7.9). The number of cigarettes (cig.) smoked near the baby was also significantly higher in the control group (2 (SD \pm 5) cig. per day) compared to the intervention group (0 (SD \pm 0) cig. per day) (β 1.6; 95% CI 0.2-0.1).

Multilevel analysis showed that over time, cigarette smoking decreased significantly in the intervention group (β 1.7; 95% CI (2.8 to 0.5)). Furthermore, the number of women who smoked was significantly lower in the intervention group (OR 0.5; 95% CI (1.0 to 0.05)).

Pregnancy outcomes

As illustrated in table 3, mean birth weight was similar in both groups (C: 3147; 519 versus. I: 3144; 577 (mean; standard deviation (SD))). No significant difference in mean gestational age was measured (C: 40; 2.1 vs. I: 39; 2 (mean; SD)). The prevalence of babies with low birth weight, being premature or being small for gestational age, was similar in both groups. Subgroup analyses on smoking status (yes, no) showed also no effect on pregnancy outcomes.

Breastfeeding

As table 4 shows, the percentage of women who initiated breastfeeding was similar in both groups (OR 1.3; 95% CI (0.7-2.4) n.s.). Women who quit breastfeeding (> 1 week), quit at on average 10 \pm 8 weeks after birth in the control group and 9 \pm 7 weeks in the intervention group (β 0.1; 95% CI (3.0-1.5)). At 6 months post birth, significantly more women in the intervention group were still breastfeeding their child (OR 2.6; 95% CI (1.0-6.8)).

Discussion

VoorZorg is a nurse home visiting programme and is the Dutch equivalent of the Nurse Family Partnership in the US. The main focus of VoorZorg is primary prevention of child abuse. Results of VoorZorg on child abuse will be presented elsewhere. In the present study we investigated whether the VoorZorg programme was effective in reducing cigarette smoking, improving pregnancy outcomes and breastfeeding duration among

high risk pregnant women. After applying LOCF analyses VoorZorg seemed to be effective in reducing the percentage of smokers during pregnancy and after birth. Women that followed VoorZorg also smoked fewer cigarettes per day after birth and fewer cigarettes in the presence of the baby. Furthermore, a higher prevalence of VoorZorg women breast fed their child at six months. No effect was measured on pregnancy outcomes.

Significantly fewer women in the intervention group started smoking after the child was born compared to women in the control group. Tappin et al. discussed the difficulty of changing smoking behaviour among women with multiple risk factors [31]. An RCT of nurse home visiting in Australia (Kemp et al. 2011) similar to VoorZorg did not find any difference in smoking between the control and intervention group [17]. The difference in the RCT by Kemp et al. was that women of any age and women who already had children as well as first time mothers were enrolled. Because of the result on cessation of smoking, VoorZorg is expected to have a positive effect in this difficult high risk group on other risk behaviours, like drug and/or alcohol abuse and sexual risk behaviour.

The results found in the present study, concerning the similar reduction of the average numbers of cigarettes smoked per day during pregnancy in both groups, were comparable to findings in other studies conducted among low income pregnant women [15,31,32]. However, Olds et al. (1986) showed a positive intervention effect on the numbers of cigarettes smoked per day [1]. We expected the same results in the Netherlands. But we hypothesise that women in our study population had other priorities during pregnancy and VoorZorg nurses possibly gave more attention to these problems. Furthermore, there is already a national intervention programme for smoking cessation offered by midwives to all pregnant women in the Netherlands (the V-MIS) [19]. In the US, the control group received no such intervention during pregnancy. In the present study, after childbirth the message was continued in the VoorZorg intervention that mothers should not smoke in the presence of the child, whereas the control group received no such intervention.

In this study, no significant differences in pregnancy outcomes were found between both groups. These results are consistent with other studies conducted among socially disadvantaged women aiming at improving pregnancy outcomes by reducing smoking [33,34]. However, Olds et al. (1986) found a significant effect in pregnancy outcome in a subgroup of women between 14 and 16 years of age. In the present study the proportion of women in this age group was very low (10 %); we also conducted several subgroup analyses but no effects were measured, probably due to the small sample size in this subgroup. This is in line with the low number of teen pregnancies of this age group in the Netherlands. An unexpected finding regarding pregnancy outcome was that mean birth weight was approximately 3140 g. in both treatment groups. This is low compared to the common Dutch population, where birth weight is on average 3500 g. [35] and also compared to Dutch women with a very low education level where the average birth weight is approximately 3375 g. [36]. Olds et al. (1986) reported on average higher birth weight rates (C: 3262 g. vs. I: 3285g.) [1]. This suggests that in the Netherlands we are dealing with a subgroup of young women with many risk factors associated with adverse pregnancy outcomes.

In the present study significantly more women in the intervention group continued breastfeeding for at least 6 months. According to Milligan et al. (2000), only a few studies found an effect on breastfeeding duration among low income women [37].

In our study the rates of women initiating breastfeeding were comparable to rates in the general female population of the Netherlands (81%). Midwives in the Netherlands promote breastfeeding to all pregnant women. The rates of women in the intervention group continuing breastfeeding for 6 months were comparable to the general female population (13%) and two times higher than in the control group [38]. It is important to encourage breastfeeding for 6 months in young women with low SES. These women experience several barriers associated with breastfeeding duration, like being anxious or depressed or lacking social support [37]. The VoorZorg programme addresses these barriers to support longer breastfeeding duration. VoorZorg builds on the well-established relationship between the mother (to-be) and nurse. Although important improvements are achieved the programme can also be improved in this respect.

A limitation of this study is that self-report questionnaires were used to measure participants' cigarette smoking behaviour instead of biochemical assessments. We chose this method because of financial- and time constraints in our study. Using self-report questionnaires can be done quickly, saving time both for the participants and the researchers. And to increase adherence, it is important to use non-time consuming measurements. In addition, by using cotinine (metabolite of nicotine) measured in blood samples passive smoking is also measured [39]. This could lead to false positive results, especially among this study population who are more likely to be surrounded by smokers [40]. Furthermore a limitation is that we did not report exclusive, full and partial breastfeeding rates because we did not assess these data. Thirdly, a limitation in our study was the relatively high non-response rate in the control group. Because these women did not receive an intervention, they were probably not motivated to participate in the measurements [41]. Furthermore, these women were less traceable for the interviewers than women in the intervention group. Because women in the intervention group had several contact moments with the VoorZorg nurse, they could be easily localised by youth health care organizations. A high non-response rate could bias the results reported in this study, especially when women who are smokers or experience more difficulties were untraceable, but it is likely that we underestimate rather than exaggerate intervention-effects. A recommendation for other researchers is to study how to achieve a higher follow-up rate among young women with low SES.

In conclusion, the VoorZorg intervention seemed to be effective in reducing cigarette smoking during pregnancy and after birth; in the intervention group no cigarettes were smoked in the presence of the baby, which is in contrast to the control group. The VoorZorg intervention had no effect on pregnancy outcomes. Furthermore, significantly more women in the intervention group were still breastfeeding at six months.

Implications for midwives

Midwives are usually the first health care providers (after the general practitioners) to see and examine pregnant women. The women in our study population and their children are at high risk of having several health problems. It is therefore important for midwives to be aware of the problems these women have and also to provide them with information on tailored interventions that are available in their country. Midwives therefore have an ideal position for recruiting and motivating women for a programme, such as the Nurse Family Partnership. Midwives can recruit women for this programme. Furthermore, midwives have a role in counselling pregnant women who smoke on smoking cessation. The V-MIS can support them in this task.

TABLES

Table 1:
Baseline characteristics of participants

	Control (n=223)	Intervention (n=237)
Age n(sd)	19.2 (2.6)	19.5 (2.8)
Weeks of gestation n(sd)	19.5 (5.9)	20.1 (6.5)
Married/living with partner	34 (22)	47 (24)
Current education level		
Primary school	7 (4)	11 (6)
Pre-vocational education	150 (96)	179 (94)
Employed	44 (28)	56 (29)
Ethnicity		
Dutch	107 (48)	117 (49)
Moroccan	5 (2)	5 (2)
Turkish	8 (4)	8 (3)
Surinamese/Antillean	60 (27)	65 (27)
Cape Verdean	4 (2)	5 (2)
Other	37 (17)	38 (16)
Attempted to quit smoking	78 (80)	90 (82)
Stopped smoking after aware of pregnancy	25 (20)	21 (13)

Note.

In italics the number of participants for whom data were available is described. Numbers are n (%) unless described otherwise.

Table 2:

Percentage of smokers and average numbers of cigarettes smoked a day at baseline, 32 weeks of pregnancy, and at 2 months after birth in control and intervention group and effects of the intervention

	Control N=223 n(%)	Intervention N=237 n(%)	OR / β (95% CI)	Significance level
Smoking at baseline (16-28 wks of pregnancy)				
Current smoker	59 (47%)	71 (43%)	0.7(0.5-1.2) ^b	ns.
Average no. of cigarettes smoked/day	8 (7)	7 (5)	1.4 (-3.3-0.5) ^a	ns.
Smoking at 32 weeks of pregnancy				
Current smoker	34 (35%)	45 (33%)	0.9 (0.5-1.5) ²	ns.
Current smoker (LOCF)^c	69 (48%)	75 (40%)	0.5 (0.3-0.9)	p=0.03
Average no. of cigarettes smoked/day	3 (5)	2 (4)	0.5 (-0.6-1.7) ^a	ns.
Smoking at 2 months after birth				
Current smoker	32 (65%)	31 (48%)	0.5 (0.3-1.1) ^b	p=0.08
Current smoker (LOCF)	97 (62%)	96 (49%)	0.5 (0.3-0.9)	p=0.02
Average no. of cigarettes smoked/day n(sd)	8 (10)	4 (7)	4.4 (1.0-7.9) ^a	p=0.01
Average no. of cigarettes smoked/day in presence of the baby n(sd)	2 (5)	0 (0)	1.6 (0.2-0.1) ^a	p=0.03

Note. Numbers are n(%) unless described otherwise.
The control group is the reference group

^a β value (mean difference)

^b Odds Ratio

^c LOCF= Last observation Carried Forward

Table 3:

Birth weight, gestational age and adverse pregnancy outcomes for control- and intervention group and effect sizes

	Control N=223 n(%)	Intervention N=237 n(%)	Corrected β /OR (95% CI)	Significance level
Average birth weight (g) n(sd)	3147 (519)	3144 (577)	-2.4 (-111.1-106.4) ^a	ns.
Average gest. age (wks) n(sd)	40 (2.1)	39 (2)	-0.2 (-0.6-0.1) ^a	ns.
Low birth weight (< 2500g)	20(11.3)	25(12.3)	1.1 (0.5-2.5) ^b	ns.
Preterm gestation (< 37 wks)	10(7.0)	16(8.6)	0.9 (0.3-2.7) ^b	ns.
Small for gestational age	31(18)	34(16)	0.8 (0.4-1.6) ^b	ns.

Note. Numbers are n(%) unless described otherwise.
The control group is the reference group

^a β value

^b Odds Ratio

Table 4:

Breastfeeding initiation and duration at 6 months after birth in control and intervention group

	Control N=223 n (%)	Intervention N=237 n (%)	OR (95% CI)	Significance level
Initiated breastfeeding	85(78)	130(82)	1.3 (0.7-2.4)	ns.
Ended < 1 week	6(8)	5(5)	0.6 (0.2-2.0)	ns.
Ended > 1 week*	73(92)	103(95)	1.7 (0.5-5.8)	ns.
Breastfeeding at 6 months	6(6)	21(13)	2.6 (1.0-6.8)	p=0.04

Note. No confounders or effect modifiers were found.

The control group is the reference group

* C: on average 10 ± 8 weeks

I: on average 9 ± 7 weeks

FIGURES

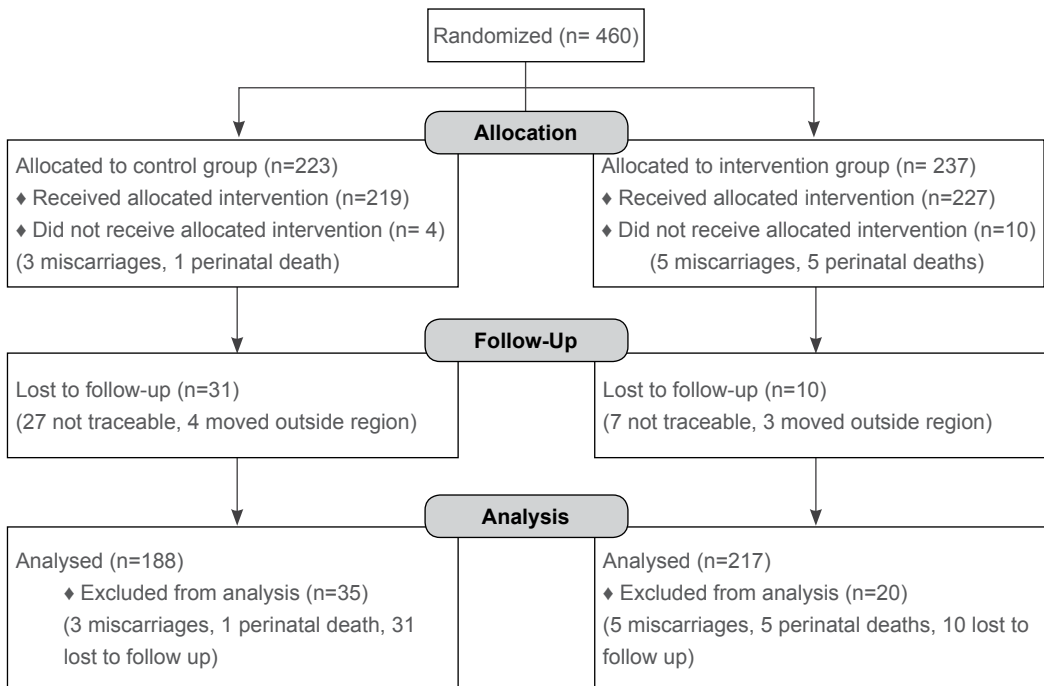
Figure 1:

Seven steps of the V-MIS (minimal intervention strategy for midwives): an instrument for smoking cessation among pregnant women.

<p>1. Smoke Profile Identifying motivation to quit and level of addiction.</p> <p>2. Motivation If necessary, increase motivation to quit.</p> <p>3. Barriers and social support Discussing and removing barriers to stop smoking and mobilizing support in the immediate environment.</p> <p>4. Stop Event Choose a date with the pregnant woman (and her partner) for smoking cessation</p> <p>5. Discuss tools Distribution of brochure and flyer of tailored advice to pregnant woman and discuss potential useful tools. (This always takes place even if there is no stop date agreed).</p> <p>6. Help after the quit date Following consultations: return to the topic (stop with) smoking.</p> <p>7. Relapse after childbirth Prevention of relapse after delivery.</p>
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Figure 2:

Flow of participants in the control and intervention group



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