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## Midwifery ■ (■■■) ■■■-■■■



Contents lists available at ScienceDirect

## Midwifery



journal homepage: www.elsevier.com/midw

# Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: A randomized controlled trial $^{\bigstar}$

Jamila Mejdoubi, MSc (PhD Student)<sup>a,\*</sup>, Silvia C.C.M. van den Heijkant, PhD, MD (Senior Researcher)<sup>a</sup>, Frank J.M. van Leerdam, PhD, MD (Senior Researcher)<sup>a</sup>, Matty Crone, PhD (Associate Professor)<sup>b</sup>, Alfons Crijnen, PhD, MD (Child and Adolescent Psychiatrist)<sup>c</sup>, Remy A. HiraSing, PhD, MD (Professor)<sup>a</sup>

<sup>a</sup> EMGO+ Institute for Health and Care Research, VU University Medical Center, Department of Public and Occupational Health, Van Der Boechorststraat 7, 1081 BT Amsterdam, The Netherlands

<sup>b</sup> Leiden University Medical Center, Leiden, The Netherlands

<sup>c</sup> de Waag, Center for Forensic Services, Amsterdam, the Netherlands

#### ARTICLE INFO

Article history: Received 1 February 2013 Received in revised form 2 August 2013 Accepted 6 August 2013

Keywords: Smoking cessation High-risk Breastfeeding Pregnancy outcome

## ABSTRACT

*Objective:* antenatal smoking is more prevalent among young women with low socio-economic 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,  $\le 28$  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 ± - 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 ± 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.

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Abbreviations: US, United States; NFP, nurse family partnership; RCT, randomised controlled trial; SES, socio-economic status; V-MIS, minimum intervention strategies for midwifes; ZonMw, Netherlands Organisation for Health Research and Development; C, control group; I, intervention group; OR, Odds ratio; CI, confidence interval; LOCF, last observation carried forward

\*Trial registration: Dutch Trial Register, NTR854, http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=854.

\* Corresponding author.

E-mail addresses: j.mejdoubi@vumc.nl,

jamilamejdoubi@hotmail.com (J. Mejdoubi), s.vandenheijkant@vumc.nl (S.C.C.M. van den Heijkant), f.v.leerdam@igz.nl (F.J.M. van Leerdam), m.r.crone@lumc.nl (M. Crone), crijnen@xs4all.nl (A. Crijnen), ra.hirasing@vumc.nl (R.A. HiraSing).

0266-6138/\$-see front matter © 2013 Elsevier Ltd. All rights reserved. http://dx.doi.org/10.1016/j.midw.2013.08.006

## 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 (Olds et al., 1986).

Maternal cigarette smoking is one of the most preventable causes of adverse pregnancy outcomes (Dietz et al., 2010). Women

Please cite this article as: Mejdoubi, J., et al., Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: A randomized controlled trial. Midwifery (2013), http://dx.doi.org/10.1016/j.midw.2013.08.006

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who smoke during pregnancy are at a higher risk for preterm birth, low birth weight and placental complications (Lumley et al., 2009). In addition, more babies with Sudden Infant Death Syndrome are reported among women who smoked (Rasmussen and Irgens, 2006). Complications during birth, like fetal distress or maternal infection, lead to 66% higher medical costs among smokers compared to non-smokers (Miller et al., 1999, Adams EK, 1997). 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 (Wakschlag et al., 2002; Gatzke-Kopp and Beauchaine, 2007; Roza et al., 2007). 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 (Lumley et al., 2009). In the US, 12% of pregnant women smoke, which is similar to that reported in Sweden (Cnattingius, 2004). In Australia the percentage of women who smoked during pregnancy is higher (17%) (Mohsin and Bauman, 2005). The prevalence is highest amongst women with low SES (Lumley et al., 2009; Al-Sahab et al., 2010). Mohsin et al. showed that 43% of young women (<20 years) with low SES in Australia smoked during pregnancy (Mohsin and Bauman, 2005). 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 (Lumley et al., 2009). 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 (Price et al., 1991; Donatelle et al., 2000; Solomon et al., 2000; Malchodi et al., 2003; Kemp et al., 2011). In these studies, no effect on smoking cessation and pregnancy outcome were reported (Lumley et al., 2009; Kemp et al., 2011).

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 (Bakker et al., 2003). 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 (de et al., 2006). 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. Breast feeding is, among others, associated with better cognitive outcomes of the child and protective against several diseases (Evenhouse and Reilly, 2005). And breast feeding is important for the relationship between mother and child (Gribble, 2006). 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 (Mejdoubi et al., 2011). 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 (Mejdoubi et al., 2012). 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 (Mejdoubi et al., 2012).

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 (Dolcini et al., 1996). Data concerning pregnancy outcomes were extracted from databases of Youth Health Care Organizations.

#### Intervention

All women received usual care provided by the Dutch Youth Health Care Organizations (Verbrugge, 1990). 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 (Bakker et al., 2003).

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