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The effects of smoking cessation counseling by midwives on Dutch pregnant women and their partners

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Abstract

Objective: Smoking during pregnancy is an important problem in the Netherlands. We tested the effectiveness of a health counseling method by midwives using a RCT.
Methods: Four provinces with 42 practices including 118 midwives were randomly assigned to the experimental or control condition. Midwives in the experimental group provided brief health counseling, self-help materials on smoking cessation during pregnancy and early postpartum, and a partner booklet. Controls received routine care. The main outcome measures were 7-day abstinence, continuous abstinence, and partner smoking at 6 weeks post-intervention (T1) and 6 weeks postpartum (T2).
Results: Multi-level analysis revealed significant differences between both conditions at T1 and T2 using intention-to-treat analysis. Nineteen percent of the experimental group reported 7-day abstinence compared to 7% of the control group at T1, and 21 and 12%, respectively, at T2. For continuous abstinence these percentages were 12% in the experimental group and 3% in the control group. The partner intervention was not successful.
Conclusion: The intervention resulted in significant effects on smoking behavior for pregnant women, but not for partner smoking.
Practice implications: The program realized short-term effects. An important precondition is that midwives need a proper training.

Keywords: Smoking cessation; Counseling; Pregnancy; Spouses

1. Introduction

Smoking cessation during pregnancy significantly reduces the risks of growth retardation, fetal death, Sudden Infant Death Syndrome, and other problems [1–5]. Continued abstinence postpartum also reduces children's exposure to environmental tobacco smoke and its associated health risks [6,7]. Moreover, sustained abstinence postpartum reduces women's lifetime risk for smoking related-diseases [8]. It is therefore essential to develop programs that enable women to effectively quit smoking early in their pregnancy and to reduce the high relapse rates that are known to occur in the first few months post-delivery [9–11].

Studies on smoking cessation among pregnant women show mixed results, with effects ranging between 2 and 20% [12]. A few prenatal smoking cessation trials have delivered interventions through the usual prenatal care practitioners [10,13,14]. Favorable results have been found for interventions delivered by specifically trained health care professionals. Delivery in routine care has been less successful [15–19]. However, interventions are not always effective when implemented in routine antenatal care, due to difficulties that midwives experience in implementing the interventions as they are intended [15,18]. Hence, effectiveness studies are needed to test whether programs can results in significant effects when tested in a real-life

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context; these programs can be used to realize public health changes.

A Dutch pilot study suggested that pregnant women who still smoke during pregnancy need information about the advantages of non-smoking for themselves as well as for the baby, information to increase self-efficacy towards quitting, and a need for partner support [20]. A second study revealed that the implementation of such a program would be feasible [21]. Reviews on smoking and pregnant women also suggest to include partner smoking in programs since smoking status of the partner is a chief predictor of postpartum relapse [10,13].

Previous studies in the Netherlands tested the effectiveness of a health counseling protocol for other groups of smokers [22–24], a strategy referred to as the minimal intervention strategy (MIS). The MIS is based on the I-Change Model (previously referred to as the Attitude-Social influences-Self-Efficacy model [25–27]) that integrates insights from several social cognitive models [28–30]. The model distinguishes three motivational change phases. In the pre-motivational phase, people need to become aware of a health problem. In this phase, knowledge, risk perceptions and cues that prompt people to become aware are important determinants. In the motivational phase people need to become motivated to change their behavior; in this phase attitudes, social influence perceptions and self-efficacy expectations are important. In the post-motivational phase, people need to translate intentions into actions. Hence, several preparatory action plans are needed.

The aim of the study was to adapt and evaluate the MIS smoking cessation protocol for pregnant women and their partners. We hypothesize, first, that women in the experimental condition will be more likely to quit smoking during pregnancy and to remain smoke-free after delivery by stimulating awareness, a positive attitude, self-efficacy and the development of action plans towards quitting as well as by providing information on smoking cessation to the partners. Second, we hypothesize that significantly more partners in the experimental condition than in the control condition will give up smoking.

2. Methods

2.1. Study design

The study used a pre-test–post-test randomized control group design with one pre-test and two post-tests 6 weeks post-intervention (T1) and 6 weeks postpartum (T2).

Women were nested within midwife practice; practices were nested within four provinces. Provinces were used as the unit of randomization to the experimental and control conditions. Randomization of practices was planned, but turned out to be impossible since practices within a province shared personnel.

The women in the experimental condition received an intervention consisting of a video, a self-help manual, a partner booklet on non-smoking and health counseling by midwives. Women in the control condition received usual care and a general folder from the Dutch Smoking and Health Foundation. No specific counseling was given to them.

2.2. Participants

A power analysis was run to identify how many respondents were needed for the study to find a significant difference of 15% in smoking cessation rates between the two conditions. This analysis (power 0.80; $\alpha = 0.05$ (two-tailed); based on an estimated quit rate of 20% in the experimental condition versus 5% in the control condition) revealed that 38 practices of 8 patients in each condition were needed, resulting in a total of 304 respondents [31]. Hence, our sample consisted of 318 patients within 42 practices (21 per condition).[2]

2.3. Procedure

We approached 62 chairs of provincial networks of midwife practices who received a letter and information brochure about the project; 15 chairs (24.2%) of provincial networks agreed to participate representing 60 practices (157 midwives). Reasons for refusal included time constraints, already participating in another study, the midwife was a smoker and the midwife was pregnant. Forty-two practices (118 midwives) were randomly selected and were representative of the Netherlands with regard to geographic distribution (east–west) and level of urbanization. Provinces were matched by location and level of urbanization, and one province in each of the resulting pairs was assigned to the experimental or control group condition by throwing a dice (see Fig. 1).

2.4. Identification of pregnant smokers

Women were eligible for the study if they had not been pregnant more than twice (because we assumed that women who smoked during several pregnancies would be very unlikely to change their smoking behavior), were able to speak and understand Dutch and indicated that they smoked at least one cigarette a day at the time of recruitment (approximately 12 weeks gestation). Women were included in the study from February 1996 to December 1996. Participating midwives asked their clients whether they smoked at the first consultation. Clients who reported smoking were asked to participate in a study about smoking and health. They were informed about the study requirements,

[2] In this analysis we took into account the nesting of patients within practices—assuming randomization of practices and a cluster variance of 0.37 (which implies an intraclass correlation of 0.10).

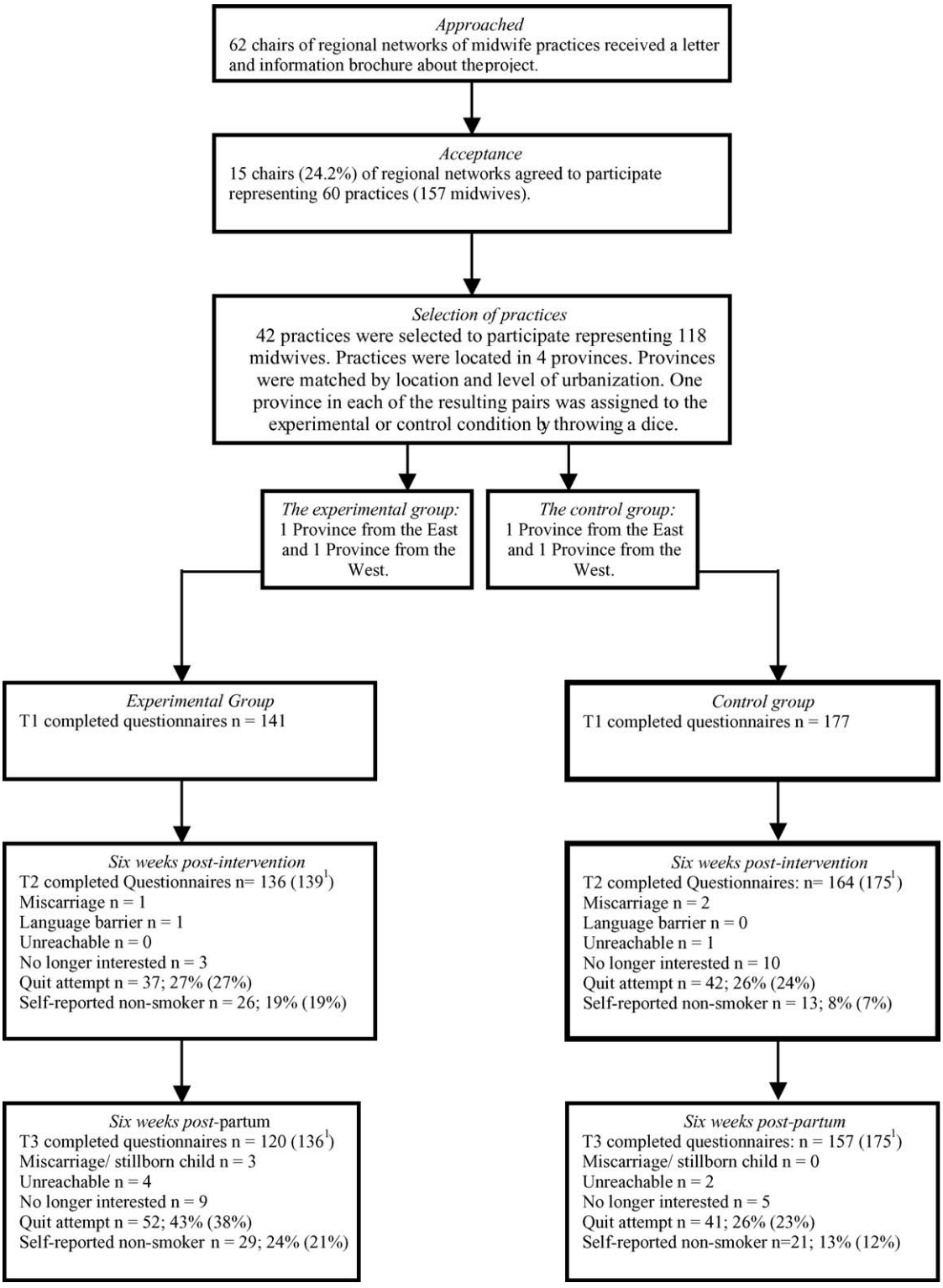

Fig. 1. Flow of participants, dropout rates and reasons for dropout ([1]*n* when dropouts either unreachable or expressing no further interest were counted as smokers).

including the possibility of having their urine tested for cotinine, a by-product of nicotine, which is recommended to be collected [13]. If the woman consented to the study, she completed the baseline questionnaire.

2.5. Intervention

The development of the intervention was guided by a program matrix based on McGuire's [32,33] persuasion

communication model. For every step in the information process, corresponding strategies for the message, the source and the method were developed (see Fig. 2 for more details). Consequently, a video, self-help guide and post-delivery booklet were developed for women.

The video was directed at raising awareness about the consequences of smoking during pregnancy, which was important for many women since our previous study revealed that many of them were not yet motivated to quit [20]. Pilot testing showed that the video was attractive for women contemplating and not contemplating to quit.

The self-help guide was stage-matched and based on a self-help smoking cessation guide used by general practitioners [23,24]. The guide was adapted for pregnant women through the addition of pregnancy related specific information illustrations. To increase women's awareness of the danger of relapse after delivery, a booklet was written on the positive effects of remaining smoke-free post-delivery and the consequences of environmental tobacco smoke for young children.

Because pregnant women motivated to stop smoking encounter difficulties to quit in the presence of a smoking partner [34], a booklet was made for smoking partners. The booklet outlined the importance of the commitment of the father to the pregnancy, it explained that quitting together would make a substantial difference to the health of the baby, as well as to the health of the father and mother, and it provided suggestions on how to quit smoking.

2.6. The Health Counseling MIS protocol for the experimental condition

The Health Counseling MIS protocol was based on protocols used in earlier studies [22,24] and consisted of seven steps. In step 1, midwives identified smoking behavior by the woman and her partner. The number of cigarettes smoked per day and the motivation to quit were also assessed in order to classify her stage of change [30]. Women who indicated that they wanted to quit smoking in the next 30 days were identified as in preparation, women who indicated that they wanted to quit smoking during this pregnancy but not within the next 30 days were identified as contemplators and women who indicated that they did not want to quit smoking were identified as precontemplators. In step 2, the midwife attempted to enhance the motivation to quit for precontemplators and contemplators by providing

	Health Communication Factors			
	TARGET GROUP	**MESSAGE**	**CHANNEL**	**SOURCE**
Attention ↓	- low/ moderate motivation to quit: other issues than smoking are important - more LSES	- worthwhile quitting for baby's health - it is possible to quit - both parents are responsible for the health of the baby	- personal communications - video - cover self-help guide	- pregnant women and partners - gynecologist - midwife
Comprehension ↓	- low/ moderate educational level	- brief easy messages	- video	- pregnant women from same SES-group
Attitude ↓	- not convinced of advantages of NS - not convinced of disadvantages of S for fetus and themselves - unaware of risks of passive smoking	- pros NS for baby - pros NS for mother - risks of passive smoking for young children	- personal communications - video messages - self-help guide for pregnant women	- pregnant women and partners - gynecologist - midwife
Social influences ↓	- smoking behavior of partner - support of partner, midwife and social environment	- S-partner should quit - NS-partner can help pregnant smoker - social environment should help	- personal communications - self-help guide for pregnant women - partner booklet - video	- pregnant women - partners who have quit smoking and support their wife - midwife
Self-efficacy & Action plans ↓	- low levels of SE towards quitting - lower levels of SE to maintain quitting postpartum	- you can cope with barriers: (social/ personal) discuss and show ways of coping - setting specific action plans	- video - self-help guide for pregnant women - personal communications	- pregnant women who have quit smoking - partners who have quit smoking - midwife
Behavior change ↓	- need skills to refrain from smoking - need alternatives for smoking	- practice skills to cope with barriers	- self-help guide for pregnant women - personal communication	- pregnant women and partners - midwife
Maintenance	- need skills to resist pressure to start again - need skills to motivate partner to remain non-smoker - feedback	- continuation of cessation is important: passive smoking, health of young children and parents	- relapse prevention booklet - self-help guide for pregnant women - personal communications	- women and partners with young children - midwife - gynecologist

Fig. 2. The health communication persuasion matrix.

information on mainly the short-term advantages of not smoking. During step 3, which was relevant for women in the preparation stage, the midwife discussed barriers for successful quitting, and how to mobilize social support for quitting. Step 4 addressed goal setting and setting action plans. Women in preparation agreed on a quit date that was registered by the midwife. All women were invited for a second contact at 8 months pregnancy in order to discuss either their motivation to quit smoking (for women who did not indicate that they wished to quit) or relapse prevention (for women who had set a quit-date). In step 5, additional self-help materials, tailored to their motivational stage, were provided to women stimulating the women to read more about the advantages of quitting (for women unmotivated to immediately quit smoking) and to develop action plans for quitting and how to cope with potential problems (for women motivated to quit smoking). Midwives were requested to invite women to read the booklet and watch the video. Step 6 addressed women's preferences for aftercare (e.g. telephone contacts, during the next consultation, or on initiative by the woman herself). In step 7, at about 8 months gestation, the midwife handed out a booklet on smoking post-delivery to all who had been smokers, regardless of quit status. The consequences of passive smoking for young children were discussed. Quitters were invited to make a commitment to remain non-smokers.

2.7. Materials and training for midwives

All pregnant women who receive prenatal care from a Dutch midwife visit their midwife on a regular basis from approximately 12 weeks gestation until 6 weeks after delivery. Midwives see their clients once every 4 weeks, but more often during the last month of the pregnancy. In the experimental group midwives talked twice to their clients about smoking: (a) during their first scheduled contact when they were approximately 3 months pregnant and (b) at about 8 months during their regularly scheduled consultations. A brief manual and intervention card, using the seven-step protocol to facilitate effective counseling was developed for midwives of the experimental condition. The intervention card was designed for midwives to record the progress and commitments of their clients. Midwives dedicated approximately 10 min of their consultation to cessation counseling [21,35]. We also offered 3 h of training on how to address the topic of smoking and smoking cessation with their clients [21]. The training was based on earlier work with the MIS-protocol [22–24].

2.8. Questionnaires

The questionnaire was based on previous work on smoking cessation in pregnant women [20]. Data presented in this paper are derived from three measurements: a written questionnaire completed at intake (T0) and two telephonic interviews conducted by trained interviewers 6 weeks (T1) after the intervention and 6 weeks postpartum (T2).

2.8.1. Pre-test questionnaire

The pre-test questionnaire assessed socio-demographic characteristics (age in years, educational level, having a regular partner, and having a paid job), pregnancy (parity and number of weeks gestation at entry into care), and smoking items (number of cigarettes per day before pregnancy and at entry into care, number of minutes to first cigarette since waking up, age when they became a regular smoker, and whether they anticipated help from their partner for quitting). Weekly alcohol consumption per week (in glasses) was measured at all time points.

2.8.2. Post-test questionnaire

Three outcomes were assessed. First, point prevalence abstinence was assessed by asking whether respondents had smoked a cigarette (even if it was just one puff) in the past 7 days at T1 and T2. Second, continuous abstinence (defined as reporting 7-day abstinence at both time points) was assessed at T2. Third, partner smoking was measured by women's report on partner smoking and his daily amount of cigarettes. Additionally, quit attempts were assessed by asking women whether they had one or more quit attempts of at least 24-h since the last measurement contact. To increase self-report reliability, a bogus-pipeline procedure was used for all women by asking them participate in cotinine assessments to validate women's self-reported smoking behavior [36]. A random sample of 30% of participating midwives was asked to collect urine samples. Urine-cotinine was measured by gas chromatography/mass spectrometry. The cut off point was set at 25 mg/l [37].

Program evaluation questions assessing satisfaction with the content and appearance of the material were asked in the first post-test using questions from earlier studies [34,38,39]. Women were asked to indicate whether they had received the video (yes/no) and watched it (yes/no), whether they had received the self-help guide (yes/no), had read it (yes/no) and if yes, to what extent (0 = nothing; 4 = everything). Those who watched the video and/or self-help guide rated its credibility, understanding, interest, attractiveness and length on a scale from 1 (low) to 7 (high). Finally, two overall ratings for the video and guide were given ranging from 1 (very bad) to 10 (excellent).

2.9. Analysis

Multilevel logistic regression analyses with patients nested within practices were run to test for differential attrition at post-test 1 and post-test 2, as well as to test the effects of the intervention using MlwiN [40]. Outcome analyses were conducted with dropouts (except for women who miscarried or could not participate due to language difficulties) treated as smokers as well as without dropouts.

Table 1
Baseline characteristics in percentages or mean (S.D.) by study group (socio-demographic, pregnancy, smoking history and smoking networks)

	Experimental (n = 141)	Missing	Control (n = 177)	Missing
Age (M, S.D.)	28.6 (4.32)	9	28.4 (4.39)	5
Level of education		5		13
Low (%)	47.1		61.6	
Medium (%)	38.2		23.8	
High (%)	14.7		14.6	
Steady partner (yes)	99.3%	2	97.2%	1
Paid job woman (yes)	68.4%	5	65.2%	13
Number of prior pregnancies		5		13
0 (%)	55.1		51.8	
1 (%)	29.4		30.5	
2 (%)	15.4		17.7	
Number of weeks pregnant at intake (M, S.D.)	12.4 (1.91)	1	13.4 (3.67)	3
Number of cigarettes a day before pregnancy (M, S.D.)	17.4 (8.46)	1	18.4 (8.51)	0
Number of cigarettes a day at first visit with midwife (M, S.D.)	9.1 (6.83)	0	7.7 (5.01)	0
Age began smoking (M, S.D.)	14.9 (2.28)	5	15.4 (2.51)	13
Minutes to first cigarette		6		16
<5 (%)	8.9		6.8	
6–30 (%)	18.5		22.4	
31–60 (%)	20.0		13.7	
>60 (%)	52.6		57.1	
Drinks alcohol	14%	5	11%	13
Partner smoking (yes)	71.2%	10	72.5%	18
Anticipated help in effort to quit from partner		6		12
A lot (%)	31.1		28.5	
Average (%)	32.6		32.1	
Little (%)	14.1		16.4	
None (%)	22.2		23.0	

The PQL2-RIGLS estimation method was used to assess intervention effects [31]. Predictors were all baseline variables listed in Table 1 (except for having a steady partner as this variable had almost no variance). Interactions between treatment and those covariates that were predictive of post-test smoking were also tested. Province was included into all models as a fixed effect.

Multilevel logistic regression of all outcomes at both post-tests was conducted using two methods. Method 1 included all baseline predictors with a $p < 0.10$ for either quit attempts or point prevalence in at least one analysis ($N_{T1} = 289$; $N_{T2} = 286$). Because this method resulted in a reduction of the sample size due to missing values on several predictors, all analyses were rerun with only those predictors that were significant ($p < 0.05$) for both quit attempt and abstinence at both post-tests ($N_{T1} = 313$; $N_{T2} = 310$). This will be referred to as Method 2. No collinearity between predictors was found (all VIF < 1.5, see [41]).

2.10. Ethical approval

The Medical Ethical Board of Maastricht University granted ethical approval for the study.

3. Results

3.1. Recruitment results

Although midwives were instructed to invite every pregnant woman who smoked, they invited only 80% of the eligible women. Minutes of meetings and process evaluations revealed that they sometimes could not comply with the study recommendation when they were too busy.

Of the women that were invited, 72% agreed to participate. Reasons for refusal were that women did not want to quit smoking, feared the confrontation with their smoking status as young mothers, regarded the study as an intrusion of privacy, anticipated feelings of guilt and shame and did not want to be burdened by participating in a research study.

Consequently, a total of 318 smokers were included into the study, 141 were in the experimental condition and 177 in the control condition. At the second post-test 85.1 and 88.7% of the two groups, respectively, were eligible for the study (Fig. 1). Multilevel logistic regression of dropout (1 = yes; 0 = no) at first and/or second post-test, using treatment group, province and number of cigarettes smoked as predictors (all other baseline variables were missing for many dropouts) showed that dropout varied between practices (intraclass correlation = 0.35, $p < 0.05$). However, none of the predictors were significantly related to dropout at any point in time (all ps > 0.10).

3.2. Characteristics of the respondents

Baseline characteristics of both study groups are presented in Table 1. The majority of women were lower educated, had a steady partner, had a paid job, were pregnant for the first or second time, reduced the number of cigarettes they smoked since the onset of pregnancy, did not drink alcohol and had a smoking partner.

3.3. Implementation

At least one midwife in every experimental practice was trained in using the MIS, resulting in 71% of all midwives trained. In total 96% of women in the experimental group reported having received the video while 91% reported having received the self-help guide. Of those women who

Table 2
Evaluation of video, self-help guide and relapse booklet by experimental intake smoking group

	Video ($n = 92$), mean (S.D.)	Self-help guide ($n = 112$), mean (S.D.)
Credible[a]	5.76 (1.30)	5.91 (1.03)
Understandable[a]	6.30 (0.87)	6.32 (0.54)
Interesting[a]	5.08 (1.66)	5.78 (1.10)
Attractive[a]	4.40 (1.81)	5.35 (1.41)
Length[a]	5.20 (1.59)	3.19 (1.65)
Overall[b]	6.66 (1.36)	7.39 (0.96)

[a] Scale of 1–7, 1 = lowest rating.
[b] Scale of 1–10, 1 = lowest rating.

had received the video 68% reported watching the video while 82% of those who received the guide reported having read at least part of it, with an average of 2.82 on a scale from 0 to 4 (S.D. = 1.40). In general, women rated the materials as credible, understandable, interesting, and attractive and gave them a good overall rating (Table 2). The self-help guide, however, was perceived as too long.

3.4. Results 6 weeks after the intervention

When all dropouts were included as smokers we found that 27% of the treated women reported a quit attempt 6 weeks after the intervention as opposed to 24% of the control group (for details, see Fig. 1). Additionally, 19% of the experimental group reported 7-day abstinence compared to 7% of the control group. When dropouts were excluded from the analysis these percentages for the experimental group and the control group were not markedly different.

Table 3 summarizes the results of the multilevel logistic regression analysis for quit attempt (yes/no) and 7-day abstinence, using Method 1 (i.e. including all predictors with a $p < 0.10$ for at least one outcome at one time point). The second method, with treatment, province, and the number of cigarettes a day at intake (the only covariate with a $p < 0.05$ in all analyses) produced similar results (not in the Table). Complete cases analysis (excluding dropouts) also produced similar results, which is in line with the fact that the dropout rate was modest and not significantly related to any of these predictors. We also tested the interactions treatment × province and treatment × number of cigarettes a day at intake. No significant interactions were found 6 weeks after the intervention (all ps > 0.30).

3.5. Results at 6 weeks postpartum

At T2, 6 weeks postpartum, a quit attempt was reported by 38% of the experimental group and 23% of the control group. Seven-day abstinence was reported by 21% of the experimental group versus 12% of the control group. Again, when dropouts were excluded these percentages for both groups were not noticeably different. Table 4 shows that these effects were significant when using Method 1. The second method (with treatment, province, and the number of cigarettes a day at intake as the only predictors), and complete cases analysis again produced very similar results (not in the Table). We once more tested the interactions treatment × province and treatment × number of cigarettes a day at intake. We found an interaction between treatment and the number of cigarettes smoked a day at intake with respect to both outcomes (two-tailed $p < 0.05$). The treatment effect increased with the number of cigarettes smoked a day at intake. The odds ratios in Table 4 correspond to the treatment effect for patients' smoking about six cigarettes a day at intake. This suggests that smoking status at intake is important for maintaining rather than generating a beneficial treatment effect on smoking behavior.

Table 3
Mixed logistic regression of quit attempt and 7-day abstinence on treatment and covariates 6 weeks after the intervention (dropouts included as smoker; $N = 289$)[a]

	B	S.E.	OR	95% CI	p-value
Quit attempt[a]					
Treatment group[1]	0.92	0.40	2.51	1.14–5.54	0.023
Province[b]	0.32	0.39	1.37	0.64–2.94	0.42
Cigarettes/day[c]	−0.36	0.14	0.70	0.53–0.91	0.008
Age onset smoking[c]	0.39	0.29	1.48	0.84–2.58	0.17
Smoking partner[a]	−0.18	0.31	0.84	0.46–1.53	0.57
Educational level[d]	0.58	0.28	1.79	1.02–3.12	0.041
Constant	−2.25	1.03			0.028
Cluster variance[e]	0.35	0.24			0.077
Point prevalence abstinence[a]					
Treatment group[a]	1.90	0.67	6.67	1.81–24.59	0.004
Province[b]	0.74	0.63	2.10	0.61–7.25	0.24
Cigarettes/day[c]	−0.95	0.27	0.39	0.23–0.66	0.000
Age onset smoking[c]	0.08	0.45	1.08	0.44–2.64	0.86
Smoking partner[a]	−0.72	0.43	0.49	0.21–1.12	0.091
Educational level[d]	0.13	0.43	1.14	0.49–2.66	0.77
Constant	−2.08	1.64			0.20
Cluster variance	0.82	0.55			0.069

[a] Coding: 1 = yes; 0 = no.
[b] Province: 1 = west; 0 = east.
[c] Results for age of onset and number of cigarettes a day are reported for the effects of 5 units increase, i.e. 5 years for age onset smoking and 5 cigarette.
[d] Educational level: 1 = medium or high, 0 = low; age is in years.
[e] One-tailed p-value, since the cluster variance cannot be negative.

Table 4 furthermore reveals a significant treatment effect for continuous abstinence, which was 12% in the experimental group and 3% in the control group. We again tested interaction of treatment with province and with the number of cigarettes a day at intake, and found no interactions (both $p > 0.30$).

Combining the results of all outcomes at both post-tests, Tables 3 and 4 show that (a) only treatment and the number of cigarettes a day at intake consistently predict smoking cessation; (b) educational level, age onset smoking and having a smoking partner are sometimes predictive; and (c) province (east versus west) is never predictive ($p > 0.20$ for all outcomes). No significant cluster variance was ever found and the estimated ICC varied from 0.06 to 0.23, depending on the outcome.

Table 4
Mixed logistic regression of quit attempt, 7-day abstinence and continuous abstinence on treatment and covariates 6 weeks postpartum (dropouts included as smoker; $N = 286$)[a]

	B	S.E.	OR	95% CI	*p*-value
Quit attempt[a]					
Treatment group[a]	1.17	0.39	3.21	1.50–6.85	0.003
Province[b]	0.13	0.38	1.14	0.55–2.38	0.73
Cigarettes/day[c]	−0.72	0.16	0.52	0.36–0.67	0.000
Age onset smoking[c]	0.57	0.31	1.76	0.97–3.20	0.064
Smoking partner[a]	−0.48	0.31	0.62	0.33–1.14	0.12
Educational level[d]	0.65	0.30	1.92	1.07–3.42	0.03
Constant	−2.08	1.08			0.05
Cluster variance[e]	0.22	0.22			0.16
Point prevalence abstinence[a]					
Treatment group[a]	1.08	0.54	2.94	1.03–8.40	0.044
Province[b]	−0.58	0.52	0.56	0.20–1.54	0.26
Cigarettes/day[c]	−0.80	0.23	0.45	0.29–0.71	0.001
Age onset smoking[c]	0.76	0.40	2.13	0.97–4.66	0.06
Smoking partner[a]	−1.22	0.39	0.29	0.14–0.64	0.002
Educational level[d]	1.17	0.41	3.21	1.42–7.22	0.005
Constant	−3.06	1.43			0.03
Cluster variance	0.60	0.44			0.09
Continuous abstinence[a]					
Treatment group	1.83	0.86	6.25	1.16–33.61	0.033
Province	−0.51	0.78	0.60	0.13–2.76	0.52
Cigarettes/day	−0.80	0.35	0.45	0.23–0.89	0.022
Age onset smoking	0.15	0.64	1.16	0.33–4.07	0.82
Smoking partner	−1.26	0.56	0.28	0.10–0.84	0.023
Educational level	0.48	0.60	1.61	0.50–5.24	0.43
Constant	−2.60	2.27			0.25
Cluster variance	0.98	0.83			0.12

[a] Coding: 1 = yes; 0 = no.
[b] Province: 1 = west; 0 = east.
[c] Results for age of onset and number of cigarettes a day are reported for the effects of 5 units increase, i.e. 5 years for age onset smoking and 5 cigarette.
[d] Educational level: 1 = medium or high, 0 = low; age is in years.
[e] One-tailed *p*-value, since the cluster variance cannot be negative.

3.6. Biochemical validation

Biochemical validation results were unusable due to problems experienced in their transportation. Only 47 samples of pre-test self-reported non-smokers were available for analysis, 17 from the experimental and 30 from the control group. These results revealed that three and five pre-test self-reported non-smokers were actually pre-test smokers in the experimental and control group respectively (17% of the urine samples). Only seven valid urine samples were available at 6 weeks postpartum. These samples all confirmed the self-reported non-smoking status.

3.7. Partner smoking

In total, 76.2% of women in the experimental condition reported handing the partner booklet to their partner. Of those who received the booklet, 48.4% had read it. At intake and both post-tests, as well as in both groups, about 72% of the patients reported their partner to be a smoker (percentages varied between 70 and 74%, depending on time point and group). The group differences were non-significant at all time points (all $ps > 0.30$). Hence, the intervention had no effect on the smoking behavior of the partner.

4. Discussion and conclusion

4.1. Discussion

Dutch midwives are in a unique position to help pregnant women that smoke to quit. The goal of our study was to test a smoking cessation intervention for pregnant women by midwives since studies revealed that the effectiveness of programs can be hindered when implemented in routine antenatal care [15,18]. The multilevel analysis revealed that, using the 7-day abstinence criterion, the intervention resulted in a three-fold increase in the chances of quitting during pregnancy among the experimental group (19%) compared to the control group (7%). Seven-day abstinence at 6 weeks postpartum increased almost two-fold in the experimental group (21%) compared to the control group (12%). Significant effects were also found at T2 for continuous abstinence, which was 12% in the experimental group and 3% in the control group. Two European studies also showed significant results [12,42]. Our results support a review by Melvin et al. [43] suggesting that brief cessation counseling session of 5–15 min delivered by trained providers can be effective; they found an average risk ratio of 1.7. Lumley et al. reviewed 64 trials and found a significant reduction in smoking in the intervention groups with an overall relative risk (RR) of 0.94. The authors concluded that one strategy consisting of rewards plus social support resulted in significantly greater smoking reduction than the other strategies. However, five trials that also included relapse prevention did not show a statistical reduction in relapse, suggesting that effective relapse prevention strategies still need to be developed [14].

Our results from Tables 3 and 4 furthermore indicate that smoking fewer cigarettes a day at intake and having a higher education were predictive of quit attempts 6 weeks post-intervention and 6 weeks postpartum. The former factor also significantly predicted non-smoking status 6 weeks post-intervention and 6 weeks postpartum. Having a non-smoking partner and having a higher education were predictive of non-smoking status 6 weeks postpartum.

Social support is an important determinant of success for quitting smoking. The smoking status of a pregnant smoker's partner influences her chances of quitting [44]. Our intervention, consisting of only a self-help guide, did not change partner's smoking behavior. Similar results were found in a multi-component program for lower socio-economic African Americans at 6-month follow-up [45]. Park et al. [19] concluded from nine studies that no effects with a persistence of 6 months or longer could be found.

However, Stanton et al. did find a16.5% quit rate in fathers of the intervention group versus 9.3% in the control group. Their intervention group received an 18-min video, nicotine patches, an information pack and a newsletter. The authors attributed their success to the free distribution of nicotine patches [46]. More research, however, is needed to reveal effective components for motivating husbands to quit smoking.

Our study did not use pharmacotherapy since this was not allowed in the Netherlands. Conclusions about using pharmacotherapy for smoking cessation in pregnant women are still mixed; neither is the efficacy of NRT during pregnancy fully known. Although NRT in pregnancy may be safer than smoking [47], more evidence is still required [48]. Hence, the choice whether to use pharmacotherapy for smoking cessation should be made jointly by the pregnant smoker and her health care provider [49].

Our study is subject to limitations. First, one of the problems of conducting research in routine care is that standard practice should not be disrupted. Women were required to complete the pre-test at the midwife's office, during the first consultation before the start of the intervention. Our women completed the questionnaire after the first consultation was finished. Consequently, variables such as attitudes and intention towards quitting could not be used as predictors. Second, it is recommended to collect cotinine samples [13]. Our assessments failed, because of logistic problems during the transportation of the samples. Third, in order to prevent treatment contamination, provinces instead of practices were randomized. We could only include 4 out of 12 provinces in our study. The fact that the fixed effect of province was not predictive of any outcome ($p > 0.20$) suggests that provinces did not influence the results. Also, any difference between provinces with respect to baseline variables as listed in Table 1 was adjusted for by including all baseline variables as covariates into the models. Fourth, the response rate among the chairs of the regional networks of midwife practices was low which could reflect a response bias. Finally, we had to rely on women's report on partner smoking. Self-reports from partners themselves should be used in future research.

4.2. Conclusions

Our intervention was easy to use in routine prenatal midwifery care, appreciated by women and midwives, and resulted in cessation during pregnancy and at 6 weeks postpartum. We recommend further investigation of the possibilities for and requirements of implementation. Nation-wide implementation is a precondition before a public health impact can be realized. However, more research is needed to further strengthen the intervention and to improve partner interventions, and to identify which elements of the MIS protocol are the most effective and for whom. For instance, Donatelle et al. [50] suggest positive effects of social support and direct financial incentives for high-risk pregnant women. Recent findings using motivational interviewing might be useful to attract unmotivated women [51,52]. Finally, to prevent relapse long-term postpartum interventions are required.

4.3. Practice implications

Our program can be used to realize short-term effects. An important precondition is that midwives need a proper training. Currently the program is implemented nation-wide and future studies will reveal the factors facilitating or hindering national implementation, as well as national implementation levels [53]. Furthermore, additional research is needed to test the effects of this approach in combination with more recent approaches using computer tailoring [54–56], telephonic counseling [57–60] and motivational interviewing [61–63].

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