

EFFICACY AND EFFECTIVENESS OF THE SMOKING CESSATION PROGRAM FOR PREGNANT WOMEN

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Abstract.

Objectives: The aim of randomized trial was to evaluate the effectiveness of anti-smoking counseling in the population of pregnant women from the maternity centers in Łódź, central Poland. **Materials and Methods:** One hundred and forty nine current smokers and 56 spontaneous quitters were randomized into the smoking cessation intervention and 144 current smokers and 37 spontaneous quitters were included in the control group. The intervention program covered four midwife visits during pregnancy and one after delivery. The control units received standard written information about the health risk from maternal smoking to the fetus. **Results:** The chance of quitting smoking by the women was significantly higher in the intervention group than in the control group (OR = 2.5; 95% CI 1.8–3.7). The difference in the mean infant birthweight between the quitters and non-quitters was 203.8 g ($p = 0.01$) in the intervention group and 198.2 g in the control group ($p = 0.08$). After controlling for socio-demographic characteristics that could affect the birthweight, the differences remained significant in the intervention group – 182.8 g ($p = 0.02$), whereas in the control group it was 92.4 g ($p = 0.4$). **Conclusions:** The midwife-assisted smoking cessation intervention seems to be an effective tool to help pregnant smokers make a decision to quit smoking.

Key words:

Intervention, Pregnancy, Smoking cessation, Birthweight

INTRODUCTION

Many studies have indicated that smoking during pregnancy increases the risk of small-for-gestational-age (SGA) infants, preterm delivery (PD) and, consequently, perinatal mortality [1–3]. A strong dose-response relationship has been found between the rate of smoking among pregnant women and the birthweight of their new born [4,5]. The risk of having a low birthweight (LBW) infant is almost doubled by maternal smoking. However, by quitting smoking early in the pregnancy, the risk of

LBW may be reduced to the level similar to that for the non-smokers [3].

The effectiveness of smoking cessation interventions depends not only on the type of activities undertaken but also on the social characteristics of pregnant women covered by such programs. One may presume that for some groups of women it will be more difficult to quit smoking during pregnancy. There are only a few reports on the results of smoking cessation programs that have considered the social characteristics of smoking pregnant

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women [6,7]. The present paper discusses the findings of a randomized controlled trial measuring the effect of intensive individual anti-smoking counseling in a population of Polish women from an urban community, which covered a large representation of socially underprivileged women.

The null hypothesis being tested was that the smoking cessation program conducted by midwives in the homes of pregnant women does not affect the quitting rate.

MATERIALS AND METHODS

Study design

A randomized trial was conducted between December 1, 2000, and December 31, 2001, in public maternity centers in Łódź, Poland.

We chose a random allocation of maternity units rather than random allocation of pregnant women because the social interaction of women who participate in the clinics could cause contamination between the two groups.

Sample size

Based on data for 1999, we found that the 33 maternity units in the Lodz district provided prenatal care for about 2960 pregnant women annually. Eleven of them provide prenatal care for 60 women, fourteen between 60–100 women, and eight for more than 100 women. As it resulted from our calculations, to find a significant difference between the quitting rates of 35% and 20%, assuming $\alpha = 0.05$ and 80% power, the compared populations should consist of at least 137 subjects. It was estimated from previous surveys [8] that the smoking rate in the 1st trimester of pregnancy is about 30%. We found that to accumulate populations of sufficient size, one small, two medium and two big maternity units should be allocated into the control procedures. Two small, four medium and four big maternity units were allocated into intervention group. We allocated more maternity units into the intervention group than to the control group because we expected that more women could refuse to participate in the intervention rather than in control activities.

Intervention group

On her first visit to a public maternity unit participating in the project, each pregnant woman who admitted smoking (current smokers – 211) or quitting smoking no later than one month before the visit (spontaneous quitters – 64) was informed by her physician about the smoking cessation program (Table 1). Of the women approached, 216 (78.5%) agreed to participate. In this group, 158 women reported smoking at least one cigarette per day and 58 declared that they had quit smoking spontaneously before their prenatal visit. In the course of the study, 11 (5.1%) women were excluded from the analysis due to miscarriage, 3 (1.4%) were lost to follow-up and were considered as smokers in the analysis. The final population covered by the smoking cessation intervention consisted of 149 current smokers and 56 spontaneous quitters.

Control group

One hundred ninety four smoking pregnant women (100% of those approached) who booked for maternity care in five control units agreed to respond to further inquiry about their smoking status (Table 1). In this group, 156 were current smokers and 38 spontaneous quitters. Of all the women classified into the control group, 12 (6.2%) women who had a miscarriage were not considered in the final analysis, 6 (3.1%) were lost to follow-up and were considered as smokers. The final control group consisted of 144 current smokers and 37 spontaneous quitters.

Table 1. Examined populations at the onset and the end of the trial

	At the onset	Miscarriages	Lost to follow-up	At the end
Intervention				
Smokers	158	9	1	149
Spontaneous quitters	58	2	2	56
Refusals	59	3	14	56
Total	275	14	17	261
Control				
Smokers	156	12	6	144
Spontaneous quitters	38	1	0	37
Refusals	0	0	0	0
Total	194	13	6	181

Description of the intervention and control activities

The smoking cessation program consisted of four visits of the midwife to the home of the smoking pregnant woman. During these visits the subjects received written materials prepared by the Community Health Research Unit in Ottawa, which were translated and adapted to the Polish conditions [9].

The first visit started with a diagnosis of the level of smoking addiction, using the Fagerström method, which measures physical dependence on nicotine [10]. The visit continued with a discussion on the benefits of smoking cessation. During the second visit, about 1–2 weeks later, the pregnant woman who decided to give up smoking determined when this was to be done and signed the “Declaration to quit smoking.” On the third visit, scheduled 1–2 days after the designated quitting day, the midwife inquired whether the woman had actually quit smoking as she promised. On the fourth visit, one month after the quitting day, the midwife informed the woman how to avoid smoking and maintain smoking abstinence.

When a woman in the intervention group did not manage to quit smoking during the four midwife’s visits, she was offered a possibility to continue the intervention activities during another five visits.

The women who had stopped smoking spontaneously before their participation in the program were informed by the midwife during the home visits how to avoid smoking and keep smoking abstinence.

Women in the control group, both smokers and spontaneous quitters, received standard written information about the health risk to the fetus from maternal smoking and the benefits of smoking abstinence.

During the initial contact with the maternity unit, all subjects filled in a questionnaire that contained information about their smoking profile (number of cigarettes smoked, years of smoking, partner’s smoking, other household members’ smoking, smoking in any previous pregnancies if any, previous smoking cessation attempts). In the control group, the data on smoking habits were updated in the 20th week of pregnancy, whereas in the intervention group any changes in the smoking profile were recorded during each midwife visit. Shortly after delivery, the midwives visited

the women from the intervention and control groups in their homes. They inquired whether anything had changed in subjects’ smoking status e.g., maintaining abstinence, smoking relapses, quitting after the period of intervention. During this visit, the midwife recorded information including the infant’s gender, birthweight and length.

Statistic

We used analytic methods appropriate for clustered data because the midwives, not the women, had been randomly assigned to intervention and control groups. We used logistic regression with random-effects models to determine whether the intervention resulted in a reduction in smoking. We included midwives in the models as a random effect to account for clustering in the design. To determine possible effect modification we used models with interaction of intervention and some factors (education of women, number of cigarettes smoked at enrollment, smoking in previous pregnancies, smoking husband). Separate odds ratio (OR) for each strata of modifying variable was reported.

The level of significance for accepting the relationship between the variables was the conventional 0.05. The data were analyzed with the use of the STATA package.

RESULTS

Comparison of the social characteristics of the study groups

The women from the intervention and control groups had comparable demographic profiles (Table 2). The mean age was 25.5 ± 6.2 in the intervention group and 25.9 ± 5.9 ($p = 0.5$) in the control group. The women from the intervention group were more frequently unmarried (52.5 vs. 39.2; $p = 0.006$) and had fewer children than the controls ($p = 0.03$). No statistically significant differences were noted between the two groups with respect to the level of education and employment status. The mean week of pregnancy at booking was 19.9 ± 8.4 in the intervention group and 19.0 ± 7.5 ($p = 0.5$) in the control one.

The intervention group reported smoking on average 7.3 ± 5.4 years 11.8 ± 6.0 cigarettes per day and controls 6.9

Table 2. Social characteristics of the intervention and control groups

Variable	Intervention (participants + spontaneous quitters + refusals + lost to follow-up)		Control (participants + spontaneous quitters + lost to follow-up)	
	N	%	N	%
Age (M ±SD)	25.5	6.2	25.9	5.9
Week of pregnancy at booking (M ±SD)	19.9	8.2	19	7.5
Education				
Primary or vocational (8 or 11 years of education)	194	74.3	138	76.2
College or university (12 or 17 years of education)	67	25.7	43	23.8
Marital status				
Married	124	47.5*	110	60.8
Unmarried	137	52.5	71	39.2
Number of children				
0	145	55.6*	78	43.1
1	65	24.9	54	29.8
≥2	51	19.5	49	27.1
Employment status				
Employed	102	39.1	82	45.3
Unemployed	159	60.9	99	54.7
Years of smoking				
<5	94	36.0	61	33.7
5–10	119	45.6	94	51.9
>10	48	18.4	26	14.4
No. of cigarettes smoked/day				
<5	27	10.3	16	8.8
5–10	120	46.0	99	54.7
>10	114	43.7	66	36.5
Fagerström test				
0–6	241	92.3*	179	98.9
7–9	20	7.7	2	1.1
Husband or other household member smoking				
Yes	231	88.5	151	83.4
No	30	11.5	30	16.6
Smoking in previous pregnancies				
Primigravidas	135	–	75	–
Yes	98	77.8	79	73.8
No	28	22.2	27	26.2

* $p < 0.05$

± 4.9 years 11.2 ± 5.9 ($p > 0.05$). However, the Fagerström test measuring the level of smoking addiction revealed significantly higher values in the intervention group (7.7% vs. 1.1%; $p = 0.002$).

No statistically significant differences were noted between the two groups with respect to the smoking in previous pregnancies if any and husband or other household member smoking.

When refusals and spontaneous quitters were excluded from both the groups, some differences were found in the number of children and level of smoking addiction (Table 3).

Efficacy of smoking cessation intervention

After excluding from the analysis spontaneous quitters and women who refused to participate in the study the proportion of women who quit smoking was 44.3% in the

Table 3. Social characteristics of the intervention and control groups

Variable	Intervention (participants + lost to follow-up)		Control (participants + lost to follow-up)	
	N	%	N	%
Age (M ±SD)	25.7	6.1	26.19	6.2
Week of pregnancy at booking (M ±SD)	18.9	8.2	19.1	7.8
Education				
Primary or vocational (8 or 11 years of education)	120	80.5	117	81.3
College or university (12 or 17 years of education)	29	19.5	27	18.7
Marital status				
Married	71	47.7	80	55.6
Unmarried	78	52.3	64	44.4
Number of children				
0	82	55.0*	57	39.6
1	33	22.2	43	29.9
≥2	34	22.8	44	30.5
Employment status				
Employed	56	37.6	63	43.8
Unemployed	93	62.4	81	56.2
Years of smoking				
<5	47	31.6	41	28.5
5–10	72	48.3	79	54.8
>10	30	20.1	24	16.7
No. of cigarettes smoked/day				
<5	11	7.4	9	6.3
5–10	64	43.0	74	51.4
>10	74	49.6	61	42.3
Fagerström test				
0–6	138	92.6*	142	98.6
7–9	11	7.4	2	1.4
Husband or other household member smoking				
Yes	136	91.3	122	84.7
No	13	8.7	22	15.3
Smoking in previous pregnancies				
Primigravidas	78	–	55	–
Yes	63	88.7	73	82.0
No	8	11.3	16	18.0

*p < 0.05

intervention group and 16.7 in controls ($p < 0.001$). The chance of quitting smoking was almost four times higher in the intervention than in the control group (OR = 3.8; 95% CI 3.3–4.4) (Table 4). When adjusted for the number of children and level of smoking addiction, the odds ratio was 6.0; 95% CI 4.6–7.7. The efficacy of the intervention was significantly higher among unmarried women as well as in women whose spouses were smokers than in the women whose spouses did not smoke (7.3 vs. 6.9 vs. 2.3;

interaction $p < 0.001$). No statistically significant differences could be found in the efficacy of the intervention with regard to the level of education, employment status, number of children, level of smoking addiction, (interaction $p > 0.05$).

Effectiveness of smoking cessation intervention

We decided to add a population of women who refused to participate in the project, and those who were lost to

Table 4. Efficacy of anti-smoking intervention among women with different socio-demographics characteristic (participants + lost to follow-up)

Variable	OR	95% CI	Interaction P
Crude	3.8	3.3–4.4	
Adjusted	6.0	4.6–7.7	
Education			
Primary or vocational	6.2	5.0–7.7	0.9
College or university	5.8	3.0–11.4	
Employment status			
Employed	4.9	3.4–7.0	0.3
Unemployed	7.4	5.7–9.6	
Marital status			
Married with non-smoking husband	2.3	0.5–11.1	<0.001
Married with smoking husband	6.9	5.4–8.8	
Unmarried	7.3	5.2–10.2	
Number of children			
0	5.8	4.3–7.7	0.6
1	7.3	5.6–9.5	
≥2	5.9	2.3–15.2	
Fagerström test			
<5	5.2	4.2–6.3	0.7
≥5	3.1	0.8–12.5	

Table 5. Effectiveness of anti-smoking intervention among women with different socio-demographics characteristic (participants + spontaneous quitters + refusals + lost to follow-up)

Variable	OR	95% CI	Interaction P
Crude	2.2	1.6–2.9	
Adjusted	2.5	1.8–3.7	
Education			
Primary or vocational	2.6	1.8–3.9	0.8
College or university	2.5	1.4–4.4	
Employment status			
Employed	2.1	1.3–3.2	0.04
Unemployed	3.0	2.0–4.6	
Marital status			
Married with non-smoking husband	1.4	0.6–3.8	0.01
Married with smoking husband	2.0	1.2–3.3	
Unmarried	3.8	2.5–5.8	
Number of children			
0	2.2	1.3–3.6	0.2
1	3.5	2.3–5.1	
≥2	2.7	1.3–6.0	
Fagerström test			
<5	2.2	1.5–3.2	0.1
≥5	3.7	0.9–14.7	

follow-up into the analysis and considered them as smokers throughout their pregnancies. We also added spontaneous quitters and all of them confirmed smoking abstinence to the end of pregnancy.

Proportion of women who quit smoking in pregnancy was 48.3% in the intervention group and 33.7% in the control one ($p = 0.002$). The chance of quitting smoking was two times higher in the intervention group than in controls (OR = 2.2; 95% CI 1.6–2.9) (Table 5). When adjusted for marital status, number of children and level of smoking addiction, the odds ratio was 2.5; 95% CI 1.8–3.7. The effectiveness of the intervention was significantly higher among unmarried women as well as in women whose

spouses were smokers than in the women whose spouses did not smoke (3.8 vs. 2.0 vs. 1.4; interaction $p = 0.01$); and it was 3.0 95% CI 2.0–4.6 among unemployed women and 2.1 95% CI 1.3–3.2 among the employed (interaction $p = 0.04$). No statistically significant differences could be found in the effectiveness of the intervention with regard to the level of education, number of children, level of smoking addiction (interaction $p > 0.05$).

Infant birthweight

The difference in the mean infant birthweight between the quitters and the smokers was 203.8 g ($p = 0.01$) in the intervention group and 198.2 g in the control group ($p = 0.08$)

Table 6. Mean infant birthweight in the intervention and control groups

Group	Mean infant birthweight (g) (\pm SD)			Differences between quitters and smokers		Differences between spontaneous quitters and smokers	
	Spontaneous quitters	Quitters	Smokers	Crude	Adjusted*	Crude	Adjusted*
Intervention	3279 \pm 449	3217 \pm 334	3014 \pm 573	203.8**	182.8**	265.5**	260.7**
Control	3263 \pm 455	3303 \pm 612	3105 \pm 550	198.2	92.4	157.5	50.3

* Adjusted for age, level of education, number of cigarettes smoked before enrolment, smoking husband.

** $p < 0.05$.

(Table 6). After controlling for the socio-demographic characteristics that could affect birthweight (age, level of education, number of cigarettes per day smoked before the first prenatal visit, smoking husband), the difference remained significant in the intervention group (182.8 g, $p = 0.02$), whereas in the control group it was at the level of 92.4 g, $p = 0.4$ (Table 5). Although the quitters had a significantly higher mean infant birthweight than the smokers (crude difference 203.8, $p = 0.01$; adjusted 182.8, $p = 0.02$), the relative gain was still lower compared to the difference between spontaneous quitters and smokers (crude 265.5, $p = 0.002$; adjusted 260.7, $p = 0.003$).

DISCUSSION

We found that the midwife-assisted smoking cessation intervention was effective when compared with the routine procedures used for the control group.

Our study was conducted in fifteen out of thirty three maternity units, which take care of 45% of pregnant women from the Łódź district. It is scientifically proved that about 20–30% of pregnant women smoke during pregnancy. In our study we found about 35% of pregnant smokers. The indicated higher percentage of smokers could be explained by the fact that we also included spontaneous quitters who quit smoking in early pregnancy. At booking we found differences between the intervention and control groups regarding the marital status, number of children and level of smoking addiction for all population (27% of variables) and the number of children and level of smoking addiction after excluding from the analysis spontaneous quitters and women who refused to participate in the study (18% of variables). We listed all variables expected to possibly influence smoking and quitting smoking. The differences mentioned above were included in the analysis. We did not include some variables that can influence birthweight such as women's weight, gain weight or nutrition because an analysis of birthweight was not primary key of this study. A positive outcome was considered when women who quit smoking in pregnancy did not smoke until delivery. We covered by our smoking cessation intervention spontaneous quitters because it was expected that they could

return into smoking habits throughout the pregnancy. At booking, spontaneous quitters made up about 20% of both intervention and control groups. All of those women confirmed smoking abstinence at the end of their pregnancy. We performed one analysis with and one without spontaneous quitters.

About 20% of pregnant women refused to participate in smoking cessation intervention and 1.4% were lost to follow-up. In the control group 3.1% were lost to follow-up. All of those women were considered as smokers in the analysis so the real quitting rate in both groups could be even higher than observed.

In our study the rates of quitting smoking were higher than those reported by other investigators [2,11–16]. Rates reported in the literature were usually at the level of 2–17% in control groups and 6–27% in intervention groups. A high percentage of quitters in our study population may be explained by the fact that in Poland, the population of smoking women includes occasional smokers who may have less problems with quitting smoking during pregnancy than those who are strongly addicted to tobacco. It is confirmed in the Fagerström test, which measures physical dependence on nicotine. The quitting rate of 33.7% in the control group is very close to the rates obtained in other Polish surveys of pregnant women [8,17].

The effectiveness and efficacy of the intervention was found to be significantly higher among unmarried women as well as in women whose spouses smoked than those who had non-smoking spouses. The former finding could be due to the fact that the unmarried women may have not had enough social support or stimulation to give up smoking. For such persons, the midwife visiting them could be more of a friend who used to provide motivation or even persuade them to give up smoking. Quitting the habit spontaneously was also more difficult for the women whose husbands smoked than for those who had non-smoking husbands, since the former group used to stay in the smoking environment almost all the time.

A significantly higher effectiveness of the intervention was found among the unemployed than the employed women. This can be explained by the fact that the employed women could stay in the smoking environment at

work and it was particularly difficult for them to quit the habit even if they were provided with support. The unemployed women who participated in the intervention were more willing to quit smoking than the women from the control group.

We did not verify the self-reported smoking status by using biomarkers of exposure to tobacco smoke. Research by Windsor et al., Gielen et al., Etzel's and Lumley et al. [12,18–21] and a comprehensive review of the literature showed that a biochemical test may not be the gold standard, especially if low levels of smoking and high amounts of environmental smoke exposure are present. As the biochemical measures have a relatively poor correlation with the number of cigarettes smoked, it is not possible to use, for example cotinine levels to assess smoking reduction. On the other hand, information about the verification of smoking status by biomarkers may influence the quitting rate. We learned from our previous investigations that about 20% of smokers may not admit that they smoke [17]. It is possible that a similar proportion of smokers may not have been identified in our study and consequently was not assigned either to the intervention or control group. We cannot predict whether the inclusion of representatives of this group would result in an increase in the quitting rate (as they are more conscious of the smoking hazard) or a decrease (for they are less willing to accept any counseling). Our position is that whatever the direction of this bias might be, it should apply to both the groups; hence the final outcomes should not be affected.

Women who discontinued smoking during pregnancy in response to the midwife intervention delivered infants with more than 203 g higher birthweight than those who smoked throughout pregnancy. A similar effect was noted in the control group, but it was not statistically significant. The small difference in the mean infant birthweight between quitters and smokers in the control group could be the consequence of a misclassification of their smoking status (some women who reported quitting smoking might not have actually done so). The effect of the intervention could be more evident if this misclassification had been considered.

CONCLUSIONS

The midwife-assisted smoking cessation intervention seems to be an effective tool to help pregnant smokers make a decision to quit smoking and avoid of the potential hazards to their pregnancies and the children to be born. However, the best results as far as the infant birthweight is concerned were observed in the group of women who spontaneously quit smoking in the beginning of pregnancy.

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