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The effectiveness of PROMISE minimal smoking cessation intervention strategy to improve the adherence to smoking cessation counselling during pregnancy: A stepped-wedge cluster randomized controlled trial

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Background

Smoking tobacco during and after pregnancy is a major preventable cause of perinatal death and serious foetal health problems (Pineles et al., 2016). Babies of mothers who smoke tend to have a lower birth weight, have a stunted growth and are more likely to be born with congenital heart defects (Veisani et al., 2019; Quelhas et al., 2018; Zhang et al., 2017). Children of smoking mothers are at higher risk of developing physical and mental problems, such as obesity and ADHD, and tend to receive lower grades in school (Albers et al., 2018; Huang et al., 2018; Kristjansson et al., 2017).

While many prospective parents quit smoking before or during pregnancy, smoking remains prevalent among pregnant women globally (World Health Organization 2010). Smoking during pregnancy is particularly prevalent among women with a lower education (Scheffers-van Schayck et al., 2019). Recent statistics showed that in the Netherlands, 16% of lower educated women smoked during pregnancy, while 12% of women with a medium level of education and 3% of women with higher education smoked in 2018 (Scheffers-van Schayck et al., 2018). In addition to that, about 12% of Dutch adults have poor functional health literacy skills, and interpreting health-related information and communicating with health professionals may be a challenge for them (Bijlsma et al., 2016). It is therefore imperative that smoking cessation protocols are adapted for those people with either lower education or poor functional health literacy skills.

Midwives and OB-GYNs play an important role in providing care for pregnant women in the Netherlands. The vast majority of pregnant women regularly visit either a midwife or an OB-GYN during pregnancy (van den Berg et al., 2014). Midwives are trained in educating prospective parents about pregnancies. They also support women during their pregnancy, during delivery and in the postnatal period. Midwives refer clients to OB-GYNs in hospitals when health problems arise or are likely to arise during pregnancy or birth. OB-GYNs are medical doctors specialized in both gynecology and obstetrics. Both midwives and OB-GYNs are completely covered under the national medical insurance system. Since nearly all pregnant women visit either a midwife or an OB-GYN, Dutch evidence-based clinical guidelines stress the importance of obstetric care professionals' role in providing smoking cessation care to pregnant smoking women (Trimbos Institute 2017).

Dutch midwives are required to use the 'V-MIS' smoking cessation protocol (Minimal Intervention Strategy for Midwives) (Hopman et al., 2019). This protocol is optional for OB-GYNs. The V-MIS is an effective minimal intervention protocol for helping pregnant women stop smoking. A randomized controlled trial conducted in 1996 has shown that 12% of smoking pregnant women counselled with V-MIS remain continuously abstinent during pregnancy, versus 3% in the usual care group (de Vries et al., 2006). Despite its efficacy, the V-MIS protocol has not been implemented well in daily practice (Hopman et al., 2019; Oude Wesselink et al., 2015). Midwives tend to initiate smoking cessation counselling

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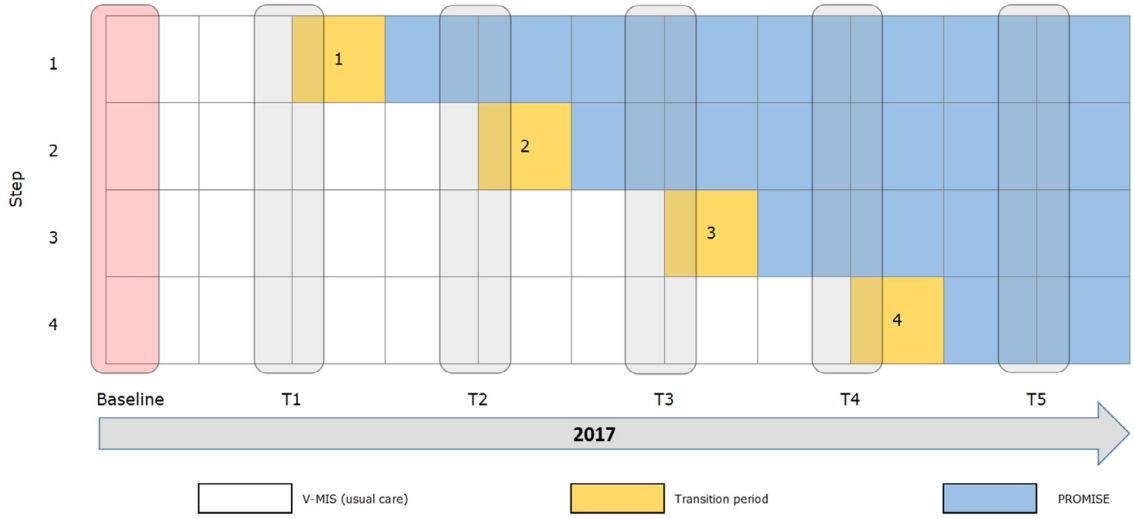

Fig. 1. Stepped-wedge design of the study.
Note: Midwifery practices and hospital departments were randomly allocated to one of four steps. At each step, midwives and OB-GYNs from those practices received a face-to-face training and crossed over from the control phase (V-MIS) to the experimental phase (PROMISE).

with less than half of all smoking clients and tend to use only a few of the seven steps of the protocol. Reasons for this are a lack of appealing education materials such as storyboards and the absence of communication skills training to accompany the V-MIS.

The 'PROtocol for growing up smoke free, using a Minimal smoking cessation Intervention Strategy in the Early stages of life' (PROMISE) aims to address some of the limitations of the V-MIS protocol. It adds a number of elements to the existing V-MIS protocol, including the use of carbon monoxide meters and storyboard leaflets, an advanced protocol for referral to smoking cessation support, and an advanced protocol for relapse prevention. This enhanced protocol aims to improve communication with pregnant women.

In this paper, we present the results of a stepped-wedge cluster randomised controlled trial (SW-CRT) in which we evaluated the implementation of PROMISE. More specifically, we tested whether the PROMISE protocol improved the provision of smoking cessation support by midwives / OB GYNs. We hypothesize that the proportion of pregnant women with whom midwives / OB-GYNs discuss these individual strategies increases after midwives / OB-GYNs have been trained to use PROMISE.

Methods

Trial design

We conducted a stepped-wedge cluster randomized controlled trial to implement and evaluate PROMISE in 20 midwifery practices and 3 obstetrics hospital departments across three regions in the Netherlands (Amsterdam-North, Heerenveen, Zaanstreek-Waterland). In a stepped-wedge cluster randomised trial, a program or protocol is gradually implemented among clusters of respondents (see Fig. 1) (Hemming et al., 2015; Hemming et al., 2018). In this study, clusters of midwives / OB-GYNs in midwifery practices or hospitals continued to use the existing V-MIS protocol at first (usual care, control phase). At a specific, randomly allocated moment in time they received an extensive face-to-face training and switched to using the PROMISE protocol (experimental phase). We trained clusters of midwives / OB-GYNs, subsequently, at four of these specific moments ('steps'). At each step, practices that received training crossed over from the control phase to the experimental phase. We measured all outcomes at baseline, at each of the four steps (two months apart, step 1 starting two months after baseline) and a final time two months after the last step. Outcomes were measured and analysed at the level of individual midwives / OB-GYNs.

This study has been registered in the Dutch Trial Registry (NTR 6305) and was exempted from extensive medical ethics review by the Ethics Committee of the Erasmus Medical centre in Rotterdam (MEC-2016–605). Details of the study design have been described earlier in a protocol article (Bommelé et al., 2019).

Participants

In the Netherlands, perinatal care is organized regionally by obstetric partnerships. These partnerships are coordinated by a regional hospital and include all midwifery practices in its region. We collaborated with three obstetric departments of hospitals in Amsterdam-North, Heerenveen and Zaanstreek-Waterland to implement the PROMISE protocol. These obstetric departments (1) treated at least 250 smoking pregnant women with lower education in the past year and (2) were willing and able to implement PROMISE within their partnership. Other inclusion criteria were (3) having a well-organized level of cooperation between midwives, OB-GYNs, and other perinatal care professionals, and (4) not participating in other tobacco-related research projects at project start. To increase the generalizability of our results, we selected one densely populated region (Amsterdam-North), one medium-sized, slightly less densely populated region (Zaanstreek-Waterland), and one rural region with low population density (Heerenveen). All regions were in the Netherlands.

Within each of the participating regions, all midwifery practices and obstetrics hospital departments were invited to participate in this study. Of those practices and departments who wanted to participate, we obtained a list of participating midwives / OB-GYNs. We had no inclusion or exclusion criteria for midwives / OB-GYNs, other than being employed at one of the practices enrolled in our study.

Interventions

Control phase: V-MIS. All participating midwifery practices and hospitals started as controls and used the V-MIS protocol (usual care). The V-MIS protocol consisted of seven counselling steps in

which midwives / OB-GYNs and their clients discuss smoking cessation. The steps are 1) Determine smoking behavior and underlying motivations; 2) Increase motivation to quit; 3) Discuss barriers of quitting and ways of mobilizing support; 4) Set a quit date; 5) Provide and discuss self-help materials; 6) Provide after care, if needed; and 7) Provide support and help preventing relapse after delivery. The number of sessions depended on the client's motivation to quit smoking. The steps were supposed to be conducted in consecutive order. A more extensive description of the V-MIS protocol can be found elsewhere (de Vries et al., 2006).

Experimental phase: PROMISE. PROMISE complements the original V-MIS protocol by adding the use of a carbon monoxide meter, storyboard leaflets, and more extensive referral options.

A carbon monoxide meter measures the CO level in expired air and can be used to determine smoking status during pregnancy (Bailey, 2013). As CO levels continue to be elevated for at least 24 h after smoking a cigarette, CO meters are able to determine positive smoking status even if someone abstained from smoking multiple hours prior to measurement. CO measurements are a non-invasive way to inform pregnant women how much CO potentially reaches their unborn child. CO measurements are mandatory in smoking cessation care for pregnant women in some countries (National Institute for Health and Care Excellence (NICE) 2018), but they are rarely used in Dutch midwifery practices. This study is the first to evaluate the use of CO measurements among pregnant women in the Netherlands. In this study, we used CO meters as tool for starting a conversation about smoking. This could help midwives / OB-GYNs motivate pregnant women to quit smoking and stay smoke-free. We advised midwives / OB-GYNs to use the CO meters as a conversation starter only and to avoid using the measurement outcomes in a disapproving or criticizing manner.

Storyboard leaflets are visual stories, accompanied by a small text. By using simple texts and illustrations, information can be made accessible and comprehensible to both people with either poor or good literacy skills. By using simple texts and illustrations, information can be made accessible and comprehensible to people with poor as well as with good literacy skills (Meppelink, 2016). Storyboard leaflets stimulate doctor-client communication and have proven useful in other health-related domains, such as diabetes and obesity (Koops van 't Jagt et al., 2018; Koops van 't Jagt et al., 2016). In this study, we developed the storyboard leaflets together with members of the target group. We interviewed 23 pregnant women (all of whom had a low SES) and asked them to provide feedback on the draft versions. Their feedback made the texts and illustrations more suitable for women with poor functional health literacy skills.

In addition to the CO meters and the storyboard leaflets, we developed a training for midwives and OB-GYNs. The midwives / OB-GYNs who switched to the experimental condition (i.e., PROMISE protocol) received this 4-hour face-to-face training from an experienced smoking cessation counsellor. During this training session, they learned about the dangers of smoking, discussed ways of identifying clients with poor functional health literacy skills and practiced communication techniques for counselling smoking clients. They also learned how to use the carbon monoxide meter and the storyboard leaflets during consults. These elements were designed to reduce consultation time and increase counselling effectiveness. More details of the PROMISE protocol have been described elsewhere (Bommelé et al., 2019).

Outcomes

Midwives / OB-GYNs individually filled out six questionnaires: one at baseline, four immediately after each step (i.e., after each two-month interval of the stepped-wedge design) and a sixth questionnaire two months after the final training step.

Primary outcome

Discussing detailed smoking cessation strategies. Our primary outcome measure was the percentage of smoking pregnant clients with whom midwives / OB-GYNs discussed detailed smoking cessation strategies. We asked: a. 'How many pregnant clients have you seen in the last month?'; b. 'How many of those clients smoked?'; c. 'With how many smoking pregnant clients have you discussed smoking?; and d. 'With how many smoking pregnant clients have you discussed detailed smoking cessation strategies?'. Examples of detailed strategies were setting a quit date, discussing ways of quitting smoking, and discussing strategies for coping with barriers to quit smoking. The primary outcome was the proportion of smoking pregnant clients with whom the professional discussed detailed smoking cessation strategies.

Secondary outcomes

Discussing smoking in general. We divided the number of clients with whom midwives / OB-GYNs discussed smoking cessation (c.) by the total number of smoking clients seen by the professional (b.). When midwives / OB-GYNs and clients discussed smoking in general, they did not always discuss detailed smoking cessation strategies. This outcome is therefore a more distal outcome measure than our primary outcome.

Time spent on discussing smoking in intake interviews. We asked how many minutes of an average intake interview midwives / OB-GYNs spend on discussing smoking with clients. Intake interviews are held once at 8 weeks of pregnancy and last about 45 min.

Time spent on discussing smoking in consultations. We asked how many minutes of an average follow-up consultation midwives / OB-GYNs spend on discussing smoking. Clients have 10 to 15 of such consultations throughout their pregnancy and they usually last about 15 min.

Sample size

We used the *SWSamp* package in R 3.0 to calculate the power and required sample size for the four-step stepped-wedge randomised trial (Baio et al., 2015; Baio, 2019). We calculated the sample size necessary for a power of 0.80. Assuming a differential effect on our primary outcome of 35% (control phase / V-MIS) vs. 60% (PROMISE phase) (Oude Wesselink et al., 2015; Hopman et al., 2017), and taking into account α=0.05 (2-sided) and a coefficient of variation between clusters of 0.3, 18 midwives / OB-GYNs in each region were required; since there are three regions, a total of 54 midwives / OB-GYNs had to be included in the study for sufficient power.

Randomization and blinding

We used the *random* package in the R 3.0 programming language to randomize the sequences, i.e. the order in which clusters of midwife-practices and hospitals will be trained – this was a computerised process. At times of the randomization, all participating practices and hospitals were known, and hence the randomization and allocation took place at a fixed time point, before the inclusion phase of the study. randomization was stratified for the region in which the practise or hospital was located. Neither midwives, OB-GYNs, pregnant women nor the researchers were blinded to the randomly allocated sequences.

Procedures

After receiving informed consent from midwives and OB-GYNs, we randomly assigned their practices to one of four steps. Randomization was stratified at the region-level: we assigned an equal number of practices within a region to each step. At baseline, all

practices used the existing V-MIS protocol (i.e., control group). Two months after baseline, we trained the first cluster of practices (i.e., step 1) and provided them with the PROMISE materials. At this point, they crossed over to the experimental phase and started using the PROMISE protocol. We trained clusters in steps 2, 3 and 4 subsequently, each at a two-month interval. Participating midwives / OB-GYNs received no incentive for filling out the questionnaires, but those who completed the training received continuing education credits. This study was conducted from January 2017 until December 2017. The first training session took place in March 2017.

Statistical methods

We used generalized linear mixed modeling analysis in R 3.0 to analyze effects on our outcome variables over time. In line with previous literature on stepped-wedge trials (Hemming et al., 2015), we interpreted data at the sample-wide level. This means that not individual changes, but sample-wide changes over time were used to test the effectiveness of PROMISE. For the analysis of the effects of the stepped-wedge trial, we used the model specifications suggested by Hussey and Hughes (Hussey and Hughes, 2007): A random effect for cluster and a fixed effect for each step, and an additional random effect for individuals in the study to account for the dependence between individual measurements over time. Our models therefore consisted of the following variables: *Outcome* was the outcome variable of interest, *Switch* was a dichotomous variable which indicates whether the participant has switched/crossed over from the untrained control/V-MIS condition to the PROMISE trained condition - similar to the condition variable in traditional RCT terms. *Step* indicated the steps of the trial – similar to a time variable in a traditional RCT. One of the two random effects in the model was *Sequence*, which indicated the cluster to which the participant was randomised. The cluster determined at which time point the participant was trained and had switched from the old to the new/trained condition. The second random effect variable was *Participant*, and indicated which data belonged to which study participant. The mixed modeling analyses were performed using the *lme4* package, and robust mixed modeling analyses were performed using the *robustlmm* package.

In the tables and figures we used *c* to indicate the number of clusters and *n* to indicate the number of midwives / OB-GYNs.

Results

Fig. 2 displays the flow of participants during recruitment, training and data collection. A summary of this flow diagram can be found in Supplement 1. We allocated 30 clusters (27 midwifery practices and 3 obstetrics hospital departments; in total 151 midwives / OB-GYNs), all initially to the control intervention. Four midwifery practices withdrew before baseline and three midwifery practices withdrew during the study, leaving 20 midwifery practices and 3 obstetrics hospital departments in the study. All those 23 clusters completed the control condition and switched over to the experimental condition at one of the consecutive steps. We were unable to contact 28 of 138 midwives / OB-GYNs (20.3%) within the allocated clusters, while another 25 (18.1%) were unable to participate in the PROMISE training. Hence we trained 85 midwives / OB-GYNs of whom 81 completed both experimental phases and filled out at least one outcome questionnaire. Table 1 presents the available baseline characteristics of all midwives / OB-GYNs who participated in the study (n = 106 – Intention to treat (ITT) sample) and the trained midwives / OB-GYNs only (n = 81 – per protocol sample). Table 2 presents the outcome means in both the control phase and the experimental phase. The results below describe the results for the ITT sample (n = 106) unless indicated otherwise.

Primary outcome

Discussing detailed smoking cessation strategies. The percentage of smoking clients with whom midwives / OB-GYNs discussed detailed smoking cessation strategies increased from 51.7% in the control phase to 56.8% after switching to the PROMISE protocol. The linear mixed modeling analysis revealed that the main effect of Switch was significant ($B = -0.43$, $SE = 0.20$, $t(203.7) = 2.16$, $p = 0.031$), indicating that the PROMISE protocol significantly increased the proportion of smoking clients with whom cessation strategies were discussed. Supplement 2 presents these results in more detail. This finding was corroborated using a robust mixed modeling approach ($B = -0.44$, $SE = 0.21$, $t = 2.12$). In the per protocol sample ($n = 81$), we found a similar positive effect of introducing the PROMISE protocol using linear mixed modeling analysis, $B = -0.44$, $SE = 0.21$, $t(164.6) = 2.06$, $p = 0.041$.

Secondary outcomes

Discussing smoking in general. The percentage of smoking clients with whom midwives / OB-GYNs discussed smoking in general increased from 66.0% in the control phase to 72.0% after implementing the PROMISE protocol. The linear mixed modeling analysis revealed that the main effect of Switch was significant ($B = -0.45$, $SE = 0.16$, $t(227.8) = 2.75$, $p = 0.006$), indicating that the PROMISE protocol significantly increased the proportion of smoking clients with whom smoking was discussed in general. This finding was corroborated using a robust mixed modeling approach ($B = -0.45$, $SE = 0.16$, $t = 2.88$). In the per protocol sample (n = 81), the direction of the effect of introducing the PROMISE protocol on discussing smoking in general was similar but the effect did not meet statistical significance, $B = -0.33$, $SE = 0.19$, $t(185.3) = 1.74$, $p = 0.084$.

Time spent on discussing smoking in intake interviews. Although the number of minutes spend in intake interviews on discussing smoking increased on average from 6.0 ($SD = 3.9$) minutes in the control phase to 7.2 ($SD = 3.3$) minutes after implementing the PROMISE protocol, the linear mixed modeling analysis ($B = -2.55$, $SE = 1.75$, $t(180.0) = 1.452$, $p = 0.148$) did not show a significant effect. The robust mixed modeling analysis showed a similar, non-significant result ($B = -2.64$, $SE = 1.44$, $t = 1.84$). The results in the per protocol sample were also similar and non-significant, $B = -1.97$, $SE = 1.80$, $t(151.3) = 1.095$, $p = 0.275$.

Time spent on discussing smoking in consultations. Although the number of minutes spend in intake interviews on discussing smoking increased on average from 3.3 ($SD = 2.8$) minutes in the control phase to 3.8 ($SD = 1.9$) minutes after implementing the PROMISE protocol the linear mixed modeling analysis ($B = -0.36$, $SE = 0.91$, $t(166.15) = 0.40$, $p = 0.690$) did not show a significant effect. The results of the robust mixed modeling analysis ($B = -0.38$, SE = 0.65, $t = 0.59$) and the per protocol sample analysis ($B = -0.051$, SE = 0.93, $t(148) = 0.055$, $p = 0.96$) were similar and non-significant.

Discussion

In this study, we evaluated the impact of the introduction of the PROMISE protocol on providing smoking counselling to pregnant women. We found that the PROMISE protocol effectively improved smoking cessation counselling for pregnant women. After implementation of the PROMISE protocol, midwives / OB-GYNs discussed detailed smoking cessation strategies with a higher proportion of their smoking clients. They also discussed smoking in general with

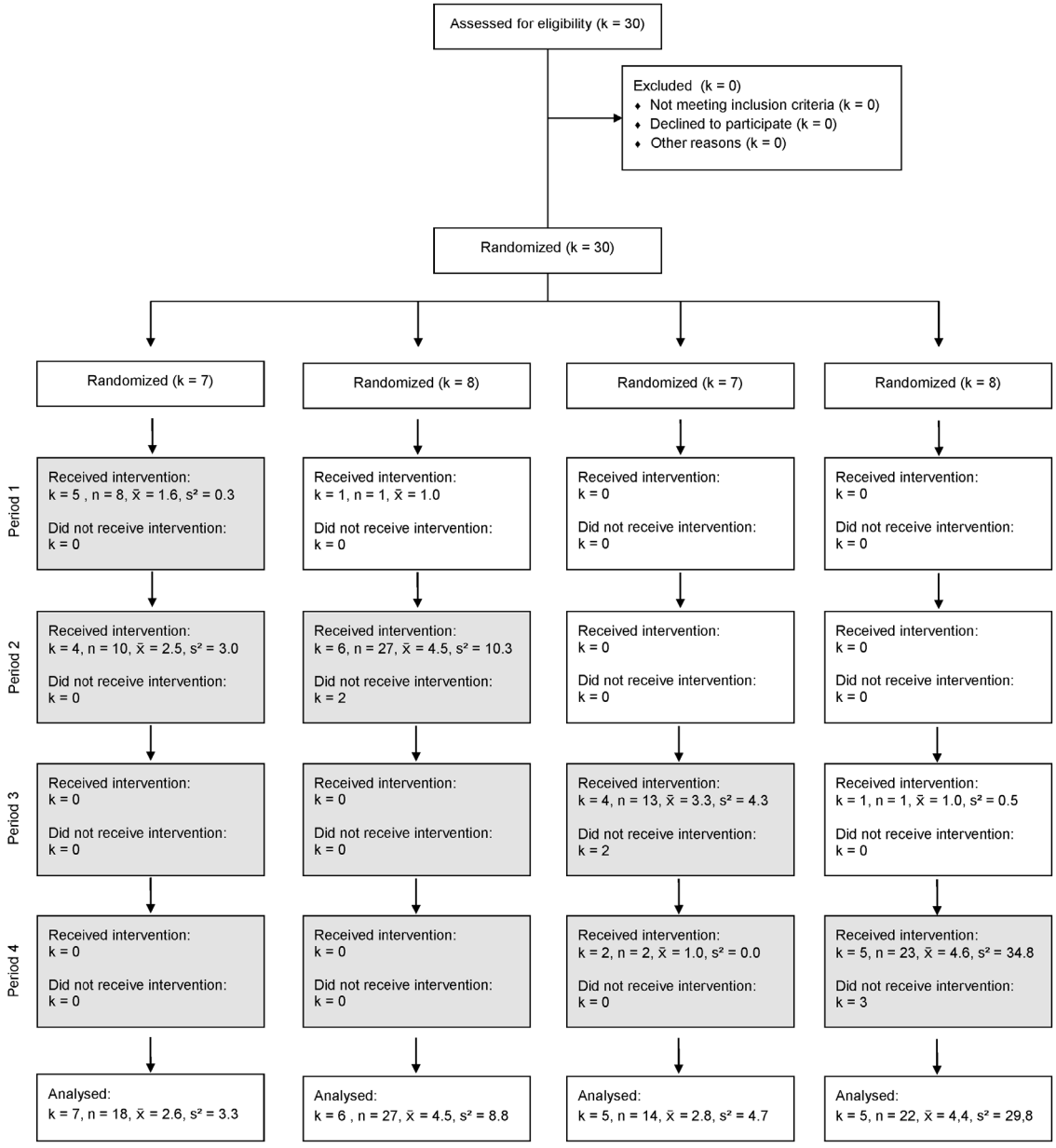

Fig. 2. Flow diagram of recruitment and data collection per step.
Note: This figure presents the number of clusters (c), the number of midwives / OB-GYNs (n), the average cluster size ($\bar{x}$) and the variance of cluster sizes (s^2).

Table 1
Background characteristics of midwives / OB-GYNs at baseline.

	All midwives / OB-GYNs (n = 106)		Trained midwives / OB-GYNs only (n = 81)	
	M	*SD*	*M*	*SD*
% Female	88.8	–	89.6	–
% Midwife	79.6	–	81.8	–
% OB-GYN	20.4	–	18.2	–
Age	39.4	10.2	40.3	10.3
Years working as midwife / OB-GYN	10.8	8.1	11.3	8.5
# clients in last month	76.1	43.1	75.8	39.6
# smoking clients	8.2	6.0	7.7	5.8
% smoking in general discussed	72.6	30.9	73.3	31.0
% individual strategies discussed	48.0	37.3	49.6	38.2
Time spend in intake interviews (min.)	5.6	3.5	5.4	3.5
Time spend in consultations (min.)	3.1	2.0	3.2	2.2

Table 2
Primary and secondary outcome means in both conditions.

	V-MIS (control)		PROMISE (experimental phase)	
	M	*SD*	*M*	*SD*
# clients in last month	69.8	52.8	55.7	40.2
# smoking clients	7.4	7.2	4.1	4.1
% smoking in general discussed	66.0	37.2	72.0	36.9
% individual strategies discussed	51.7	37.7	56.8	35.8
Time spend in intake interviews (min.)	6.0	3.9	7.2	3.3
Time spend in consultations (min.)	3.3	2.8	3.8	1.9

Note: This table presents data for all midwives / OB-GYNs (n = 106).

a higher proportion of their smoking clients. These improvements appeared to have occurred independent from time effects in our study. The introduction of the PROMISE protocol did not result in an increase of the amount of time spent on discussing smoking and cessation during intakes and other consultations.

Time effects that occurred during the study might be explained by two initiatives that were undertaken in the same period as the one in which the PROMISE protocol was being implemented. The first one is the Smoke free Generation movement, which is a nationwide movement created by three Dutch health foundations. It campaigns for a society in which all children born from 2017 onwards grow up free from tobacco smoke exposure. Over the course of our study, the movement raised attention for smoking cessation by broadcasting several mass media campaigns and by creating smoke free places throughout the nation. The other initiative that coincide with the implementation of PROMISE was the mass media campaign set up by the Dutch Smoke Free Start Taskforce. This government funded taskforce of obstetrics care professionals set up a mass media campaign in 2017, raising awareness about ways people could support pregnant women to remain smoke free during pregnancy. Although both initiatives may have contributed to the improvement of smoking cessation support in our cohort of midwives / OB-GYNs, results also showed that the effects of the PROMISE protocol were independent from these time effects (i.e. independent from the campaigns).

Strengths and limitations

The findings of this study should be considered in the light of its strengths and limitations. A strength of this study could be that we used a stepped wedge cluster RCT design. A major advantage of a stepped wedge cluster design over classical two-arm randomized controlled trials is that it allows for a phased implementation of protocols that could not be implemented in a large number of facilities at once (Hemming et al., 2015). The PROMISE counselling protocol includes an extensive face-to-face training for which only a limited number of trainers were available. Because of this, the stepped wedge cluster randomized design was particularly suitable for this study. Another advantage of using this design was that it allowed us to train all participating hospitals and practices albeit at consecutive moments in time. This was particularly helpful in our communication towards professionals. In studies such as ours that run for several months there is a risk that professionals in control conditions lose interest in the study and will be lost at follow-up. In this study, we were able to assure midwives / OB-GYNs when they would receive a face-to-face training. We believe this helped prevent participants from dropping out of the study.

A limitation of a stepped wedge design is the relatively high burden it puts on participating professionals (Kotz et al., 2012). Although the prospect of being trained at a certain moment kept many midwives / OB-GYNs in the study, a number of professionals left the study prematurely. This may be because of the high burden the study had on their work: midwives and OB-GYNs tend to have high-pressure jobs and often find it difficult to find time for filling out multiple questionnaires or participate in training sessions. A related limitation is that in this study we relied on self-reported data from the midwives and OB-GYNs. Self-reported data may reliably provide information on health professionals' knowledge about protocol guideline, but may be susceptible to bias when assessing protocol adherence (Adams et al., 1999).

The limited number of participants in our study makes it difficult to examine in detail to what extent individual components of the promise protocol contributed to the overall improvement in smoking cessation support. PROMISE consists of a face-to-face training and a set of supporting materials, such as a carbon monoxide meter and storyboard leaflets for women with low health literacy. Although we had pre-tested these supporting materials in small settings before this study, it would have been helpful to know what effect these materials precisely had on the overall effect of this protocol. Informal interviews with participating midwives and OG-GYN's after the study suggested that both the training and the carbon monoxides meter had been perceived as very helpful. Also, throughout the study midwives and OB-GYNs provided counselling to 172 pregnant women, of which 55 had a low SES (35%). This underlines the need for materials that are suitable for pregnant women with low SES or functional illiteracy. At the same time, some midwives had been reluctant to use the storyboard leaflets due to concerns about whether they are helpful for women without functional illiteracy.

Although our outcome variables allowed us to report on the uptake of PROMISE, i.e. the number of times professionals discussed smoking cessation with the clients, we were not able to report on whether these clients actually reduced or quit smoking as a consequence of the improved counselling. Future research aimed at assessing the clinical effects of PROMISE would therefore be a welcome addition to the current study.

Conclusions

The PROMISE smoking cessation counselling protocol significantly improved the provision of smoking cessation support for pregnant women in the participating midwifery practices and obstetrics hospitals departments. Midwives and OB-GYNs are recommended to implement this protocol and its accessory materials in daily practice.

Credit author statement

All authors contributed to the design of the study and the implementation of the intervention. JB and MB analyzed the data. JB drafted the manuscript and all other authors contributed to subsequent drafts and approved the final manuscript.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.midw.2022.103364.

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