BMJ Open

Effectiveness evaluation of an organisational intervention, targeting pregnancy and addiction care professionals, among women who have just given birth in maternity wards and smoked tobacco during pregnancy (5A-QUIT-N): study protocol for a stepped-wedge cluster randomised trial

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To cite: Kervran C, Francis-Oliviero F, Kret M, *et al*. Effectiveness evaluation of an organisational intervention, targeting pregnancy and addiction care professionals, among women who have just given birth in maternity wards and smoked tobacco during pregnancy (5A-QUIT-N): study protocol for a stepped-wedge cluster randomised trial. *BMJ Open* 2024;**14**:e087541. doi:10.1136/bmjopen-2024-087541

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-087541).

Received 12 April 2024
Accepted 18 October 2024

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ABSTRACT

Introduction In 2021, among French women who smoked when they knew they were pregnant, 59% still smoked at the end of pregnancy. Support for pregnant women to stop smoking must include a structured organisational perspective. The main objective of the study is to evaluate the effectiveness of the 5A-QUIT-N organisational intervention on smoking cessation at delivery among pregnant women who smoke during pregnancy.

Methods and analysis The overarching goal of the 5A-QUIT-N intervention, which aims to organise the healthcare professionals monitoring pregnancy, specialists in addiction and tobacco use, and clinical and training tools, using the 5As method. The 5A-QUIT-N intervention will be evaluated in a pragmatic stepped-wedge cluster randomised trial. Within each cluster, during the 6 months before (control) and after (intervention) the intervention, women who smoke tobacco during pregnancy will be enrolled during their maternity stay after delivery. A transition period is planned between the control and intervention periods to deploy the intervention. All participating women will be interviewed using a heteroquestionnaire to assess smoking cessation, tobacco use monitoring by healthcare professionals and individual factors associated with tobacco use during pregnancy. The primary outcome was the point prevalence of abstinence at delivery, which is the proportion of women reporting abstinence from smoking for at least 7 days at delivery. 4200 women who smoked tobacco during pregnancy will be recruited over the entire study period (33 months) to evaluate the effectiveness. An estimated 4585 participants will be included for all aims.

Ethics and dissemination The study will be implemented in accordance with French regulations. The study including the consent process has been independently reviewed and approved by the French ethical board 'CPP Ile de France I' on 10 February 2022 (No CPPIDF1-2022-DI08-cat.2). The results will be disseminated on various academic and non-academic platforms. The results will be reported in international peer-reviewed journals and presented at international and national conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Improving support for pregnant smokers through an intervention based on the evidence-based 5As approach.
⇒ Evaluation of a complex intervention with a pragmatic randomised controlled trial in real conditions.
⇒ Use of a cluster design and stepped-wedge design to take account of the organisational dimension of the intervention.
⇒ All women who smoked tobacco during pregnancy had given their consent were interviewed with a standardised questionnaire at the maternity hospital where they gave birth.
⇒ Limitations include the variability of support provided by healthcare providers and potential confounding factors such as deployment context cannot be controlled.

INTRODUCTION

Smoking is the main modifiable risk factor associated with morbidity and mortality during pregnancy.[1] The adverse effects of smoking during pregnancy are well known; they include placental dysfunction, such as fetal growth restriction, abruption placentae, premature preterm rupture of membranes, lung infections, thromboembolism, as well as (for the unborn and newborn) intrauterine fetal death, hypoxic–ischaemic encephalopathy, sudden infant death syndrome, nicotine absorption into breast milk, respiratory conditions and higher probability of being a smoker later in life.[1–5] Furthermore, the long-term economic consequences of preterm birth and low birth weight are high for individuals and society.[6] Smoking cessation during pregnancy benefits both the mother and baby, regardless of pregnancy stage.[5]

In France, a national perinatal survey estimated that 16.6% and 12.2% of pregnant women had smoked at least one cigarette per day during the last 3 months of pregnancy in 2016 and 2021, respectively.[7–9] France is among the countries with the highest prevalence of smoking during pregnancy in Europe and worldwide.[10–12] Nouvelle-Aquitaine is one of the most affected French regions; in 2016, 20.3% of pregnant women had smoked at least one cigarette per day during the last 3 months of pregnancy.[7] Although this prevalence has decreased since 2016 in France, many women continue to smoke during their pregnancies. Indeed, a national survey showed that 54% of women who smoked immediately before pregnancy in 2016,[8] and 59% of women who smoked when they knew they were pregnant in 2021, continued smoking throughout their pregnancies.[9] As a naturally occurring health event during which women may be motivated to adopt healthier behaviours, pregnancy is a teachable moment, and therefore, a suitable opportunity for prevention.[13 14] Therefore, pregnancy can be an important period for smoking cessation interventions[2] because women are more likely to stop smoking[15] to protect the fetus and future child.[16] According to observational studies, 20%–40% of women smokers spontaneously quit during pregnancy, mostly during the early stages.[2 17 18] However, smoking cessation interventions for pregnant women have minimal effects: only 13% of women who do not spontaneously quit during pregnancy stop smoking.[19] However, the factors involved in smoking are well known; some are considered modifiable, including the smoking statuses of parents and partners, as well as psychological factors, healthcare staff motivation and implications.[17 19–22] There is considerable evidence that exposure to smoking cessation interventions in healthcare settings increases motivation to quit and abstain,[23] particularly for interventions received in the context of pregnancy,[24] making support from healthcare professionals (HCPs) a key predictor of smoking cessation.[25]

In France, although public authorities and health agencies are strongly mobilised regarding this issue (92% of women reported being asked about smoking during pregnancy by HCPs), a national perinatal survey showed that few women received advice about quitting or reducing smoking.[7] In 2021, 33% of women asked about smoking during their pregnancy reported receiving advice concerning quitting; 33% reported receiving advice concerning smoking reduction.[7 9] Although 88% of maternity hospitals have access to tobacco consultations, 91% of pregnant smokers reported reducing or stopping smoking without assistance; only 5.5% had a specialised tobacco consultation and 10% had other consultations.[9]

Considering that appropriate smoking cessation advice, the use of protocols and guidelines, and follow-up by HCPs may predict greater use of smoking cessation services by pregnant women,[26] this situation is unsatisfactory and suggests that the prevalence of smoking during pregnancy can be reduced via better mobilisation of HCPs during this teachable moment in a woman's life.[27]

There are several existing smoking cessation interventions for pregnant women.[27–29] Psychosocial interventions are most often recommended for pregnant women.[30] However, they are only efficient when delivered using a holistic maternal health approach and combined with various motivational interviews and theories of behaviour change strategies.[27 29] Compared with single interventions, combined interventions appear to be more effective for smoking cessation during pregnancy.

Barriers to the implementation of tobacco monitoring by perinatal professionals, reported in international literature, include healthcare pathways that do not encourage implementation or monitoring, HCPs who view smoking as a social activity and not an addiction, inability to empathise with the patient.[31] Time constraints, lack of motivation, a low perception of its effectiveness in involving refractory patients, a burdensome workload and administration for HCPs, as well as administrative and organisational aspects, are often mentioned as obstacles.[25 32] The absence of clinical protocols for the implementation of interventions has also been indicated as an inherent brake on the healthcare system.[25 33] Other barriers specific to HCPs include, in addition to lack of knowledge of patient counselling and referral to treatment, lack of confidence in personal intervention skills, lack of confidence in the use of Nicotine Replacement Therapy (NRT) for pregnant women, the perception that HCPs' advice cannot influence a patient's behaviour.[25] A review of the literature highlighted that HCPs admit they could better help pregnant women quit smoking by providing support, being understanding, referring them to effective interventions, specialists and structures specialising in smoking cessation support, as well as implementing behavioural support and access to pharmacotherapy.[21]

However, the available actions are multiple, heterogeneous and inconsistently appropriate for the context. Support for smoking cessation among pregnant women must, therefore, include a structured and organisational perspective.[34 35]

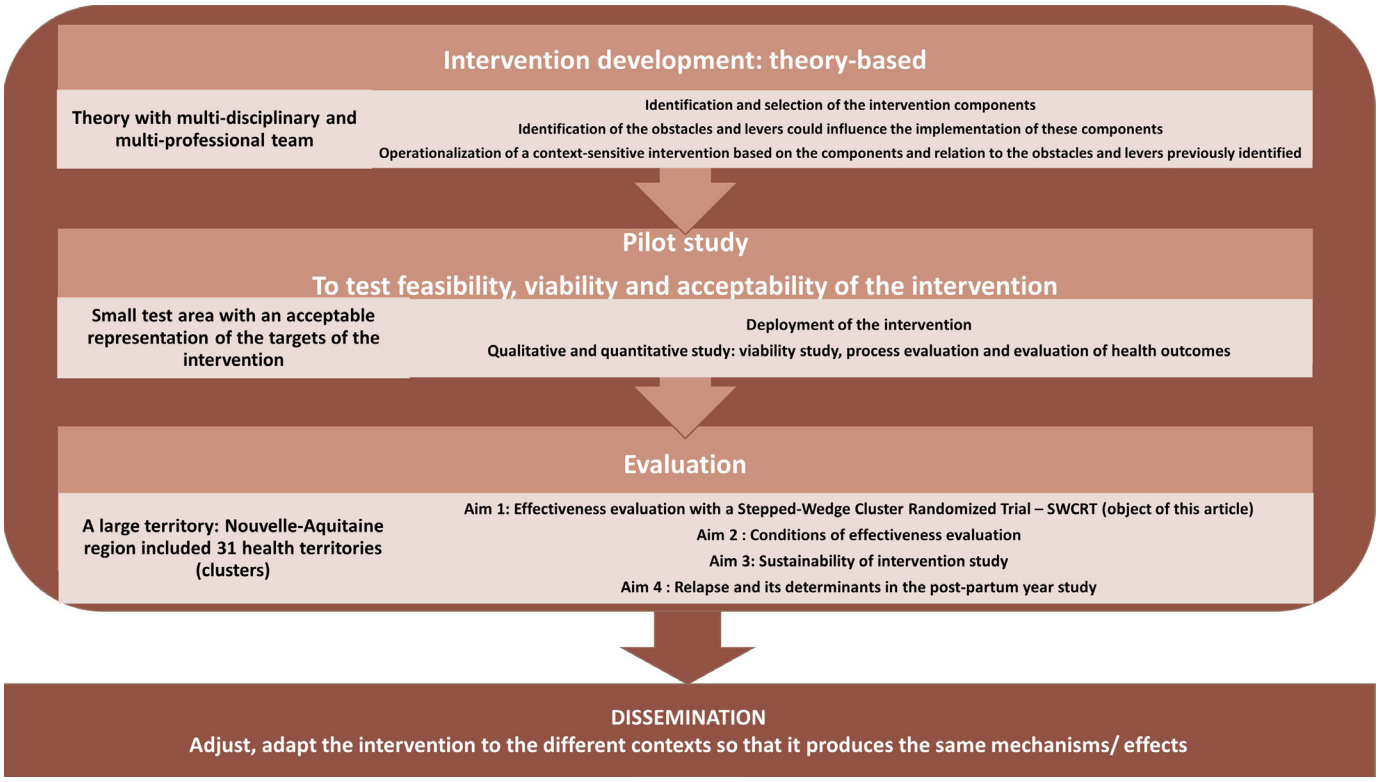

Figure 1 Stages in the development and evaluation of the organisation 5A-QUIT-N.

Aims and hypothesis

Our overarching goal with the 5A-QUIT-N intervention is to increase smoking cessation by pregnant women via mobilisation, organisation and coordination of locally available resources. The main study objective is to evaluate the effectiveness of the 5A-QUIT-N intervention on smoking cessation at delivery in real-life conditions among women who smoke tobacco during pregnancy (WSTDP) in Nouvelle-Aquitaine, France.

This paper describes the development, content and procedures of the 5A-QUIT-N protocol. This effectiveness study is a pragmatic stepped-wedge cluster randomised trial (SWCRT) of an implementation intervention involving HCPs in Nouvelle-Aquitaine, France.

Secondary aims

In parallel with this evaluation of effectiveness through the SWCRT (main aim), additional aims will investigate the conditions determining its effectiveness (aim 2), the sustainability of the intervention (aim 3) and the relapse and its determinants in the postpartum year (aim 4) (figure 1). The methods for these secondary objectives are briefly described in online supplemental material 1, and this article focuses on the method for the main effectiveness objective (figure 1).

METHODS

To prepare the 5A-QUIT-N study protocol paper, we followed the Consolidated Standards of Reporting Trials extension for an SWCRT,[36] as well as the Standard Protocol Items: Recommendations for Intervention Trials checklist.[37]

Intervention

Development of the 5A-QUIT-N intervention

Before initiation of the trial, the intervention was developed by a multidisciplinary, multiprofessional team.[38] The development of the 5A-QUIT-N intervention involved several steps (figure 1) from 2018 to 2021, according to the development and evaluation phases of complex interventions (multicomponent, multiactor and multilevel) as proposed by the Medical Research Council.[39–41] Theory and field data were used to develop the first version of the intervention,[42 43] which was validated in a pilot study before regional roll-out to evaluate its effectiveness through an SWCRT.

The 5A-QUIT-N intervention is designed to optimise care delivery and monitoring of pregnant smokers and to foster cooperation on this issue using the 5As method, which refers to the five chronological steps that HCPs are encouraged to follow when supporting smoking cessation by a patient: ask, advise, assess, assist and arrange. Evidence-based French guidelines indicate that one-to-one counselling, such as the '5As method', with a counsellor trained in smoking cessation increases smokers' likelihood of quitting for various non-drug treatments.[44] A meta-analysis showed that intervention by HCPs using the 5As model improved the information delivered to pregnant smokers but did not demonstrate effectiveness concerning smoking cessation.[45 46] Many guidelines

and training programmes exist, but perinatal HCPs face barriers regarding implementation of the 5As method in routine practice.[31 47] One possible reason for such barriers is the lack of theoretical interventions based on the literature and professionals' experience.

The scheme does not aim to develop new resources; instead, it aims to optimise existing resources by organising them in new ways, considering reported barriers and facilitators.[43] Facilitators of this approach and obstacles to its implementation in medical settings (including perinatal) have been identified.[25 31–33 42 48] Key factors that influence the effective implementation of the 5As method by HCPs are HCP motivation, collaboration between HCPs and policy-makers, interventions integrated into an organised health pathway involving real coordination among HCPs, and a supportive context and environment of the health facilities involved.[21 31 32] Interventions should be brief, easy to implement and based on sound evidence-based recommendations.[25]

The 5A-QUIT-N intervention has been developed using theory and field data. A theory-based public health intervention is one with a foundation based on one or multiple theories that have demonstrated relevance in the field. Such public health interventions are collectively constructed with key stakeholders and require a multidisciplinary approach.[49] This intervention using the 5As method as a framework for organising resources is an additional opportunity to test the effectiveness of using this method for the management of smoking in pregnant women.

The 5A-QUIT-N intervention (figure 2) targets HCPs who monitor pregnancy (general practitioners, midwives and gynaecologists) and specialists in addiction and tobacco.

In each territory, addiction and tobacco specialists are first identified and visited by the intervention deployment coordinator in order to establish referral procedures for patients being monitored for their pregnancy by perinatal HCPs. The addictology or tobacco specialists targeted by the organisational intervention are HCPs (doctors, pharmacists, midwives, masseur-physiotherapists, dental surgeons, nurses, psychologists

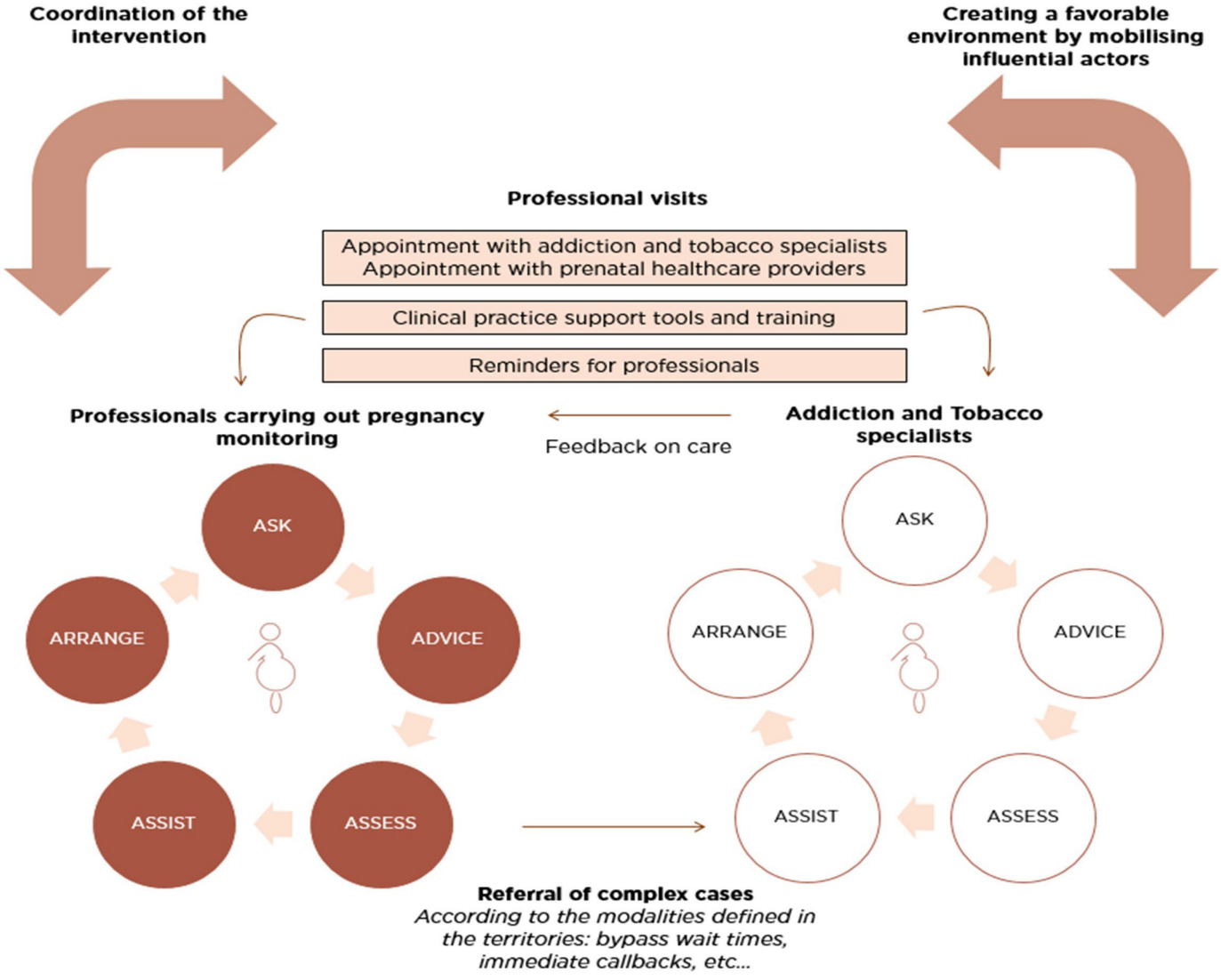

Figure 2 Organisation of the 5A-QUIT-N intervention.

or dieticians) holding a French state diploma in addictology or tobacco, who offer addictology or tobacco consultations in the Nouvelle-Aquitaine region. The visit aims to outline the care of pregnant smokers and facilitate access to care for pregnant women (eg, bypassing wait times to get an appointment with an addiction specialist sooner). The result of these visits is the establishment of a directory for each territory, listing the contact details of addiction and tobacco specialists and the associated referral methods. As international literature stated, this tool comes in useful for prenatal HCPs who want to support patients more effectively by referring them to specialists and structures that specialise in addiction and tobacco.[21]

The directory is then delivered to perinatal HCPs during visits led by an agent of the intervention deployment team. These agents receive a specific training to deliver the 5A-QUIT-N intervention and acquire an in-depth knowledge of the directory and the other tools. The intervention deployment team then organises and plans visits of HCPs who monitor pregnancy, who are the main targets of the 5A-QUIT-N intervention. Visits consist of presenting the intervention by explaining and discussing about the 5As method implementation in pregnancy care routine practice, with the aim of advising and assisting pregnant women to quit smoking and organising their follow-up. In addition, the 5A-QUIT-N booklet is given.

This tool includes the 5As method approach and five steps application in pregnancy monitoring care, a prescribing aid and comprehensive information on smoking cessation help and available aids. To increase knowledge, educate and strengthen skills in treating smoking cessation for pregnant patients, national clinical recommendations and a directory of nearby and online training programmes are also provided. This practical tool responds to the particular obstacles that HCPs have reported, such as a lack of knowledge about patient counselling, a lack of confidence in one's ability to intervene personally and a lack of experience prescribing NRTs to pregnant women.[25] The local directory of addiction and tobacco specialists is also delivered, associated with a template of a referral mail in order to facilitate the orientation of patients. These visits, which typically last between thirty and 1 hour, can be done individually or in groups, particularly for HCPs who work in maternity units. The agents are distributed and mobilised over the Nouvelle-Aquitaine region with the aim of giving priority to in-person meetings.

A period of time is then devoted to implementing the intervention in each territory, giving perinatal HCPs the opportunity to familiarise themselves with the 5As method and the tools presented, depending on the needs of their practice, the organisation already existing and their availability and willingness at the time of our visit. In this context, agents contact perinatal HCPs 2 months following the visit to report on the situation and discuss any challenges with patients and specialists to whom they have been referred.

Study design

The 5A-QUIT-N project was developed by university researchers and physicians from the Nouvelle-Aquitaine region. After a successful pilot study, the effectiveness of the 5A-QUIT-N intervention will be evaluated in an SWCRT. Enrolment in the SWCRT will extend from October 2022 to June 2025.

Setting

The trial will be conducted throughout Nouvelle-Aquitaine, excluding the area where the pilot study was conducted. It will include all maternity wards and all professionals in perinatal care and tobacco/addiction for the intervention. The study sites vary in size; they include rural and urban settings.[49] Pragmatic RCTs constitute the most valid approach to evaluate the effects of complex interventions like 5A-QUIT-N. The SWCRT is a relatively new study design that is gaining popularity.[50] It is an alternative to parallel cluster trials, which are typically used to evaluate service delivery or policy interventions at the cluster level. The SWCRT is a pragmatic study design with great potential for robust scientific evaluation of complex interventions.[50] An attractive reason for using a stepped-wedge design is that decision-makers may wish to deploy the intervention with a strong belief that it will be beneficial (as suggested by the results of the pilot study); in this case, the adoption of an SWCRT provides an opportunity for rigorous evaluation of a complex intervention during its systematic implementation. Some individuals justify the use of this model on ethical grounds to ensure that an entire population receives the intervention at a particular time. There are other advantages to use a stepped-wedge study design, including a better ability to recruit clusters. The stepped-wedge design is a scientific tool that provides a fair (ie, randomised) method for determining the order of deployment in the context of logistical constraints. A justification sometimes used regarding the difficulty of simultaneously introducing an intervention in all clusters should not be the only justification because a parallel-arm cluster trial can also be conducted with a staggered rollout.[51 52] These political, logistical and ethical constraints coexist in the 5A-QUIT-N project and were highlighted through the pilot study.

SWCRT design

The evaluation will involve an incomplete SWCRT, with a transition phase (figures 3 and 4).[50]

The trial design uses a gradual transition of clusters from the control condition (standard of care for each perinatal care and tobacco/addiction professional in their territory) to the intervention condition (organisation of pre-existing resources and 5A support), where the order of transition is randomised (figure 3). Each cluster has an equal exposure period within each sequence, rather than throughout the study (incomplete design). For each cluster, recruitment will occur during dedicated recruitment phases: for two 3-month periods before the intervention deployment (control) (orange), and then

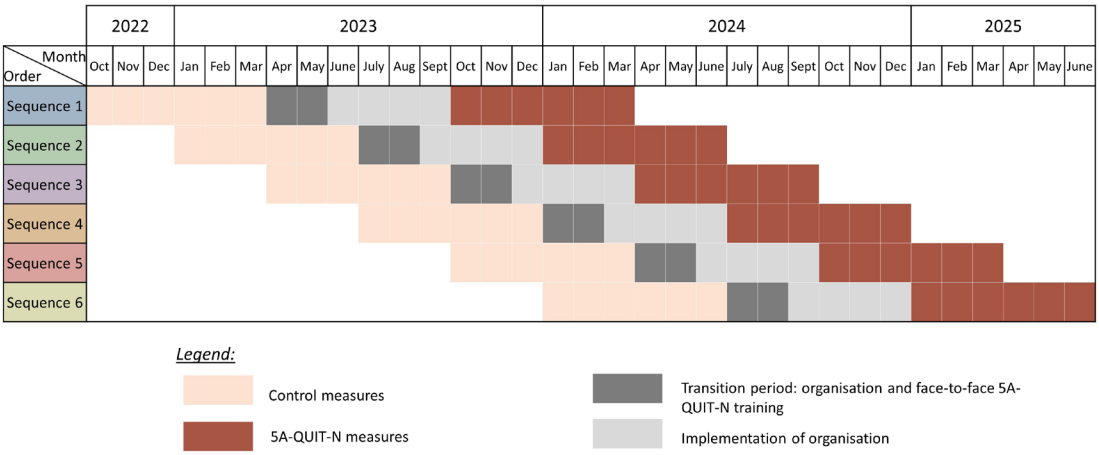

Figure 3 Incomplete cross-sectional stepped-wedge trial design for evaluating the effectiveness of the 5A-QUIT-N intervention.

for two 3-month periods after the intervention deployment (intervention) (brown). WSTDP will be included in the maternity ward after delivery to evaluate the proportion of pregnant women who ceased smoking (primary outcome). They will be continuously included during the 12-month collection time for each period. There will be a transition period without enrolment or data collection between the control and intervention periods to allow time to deploy the intervention and for women already receiving care to complete their pregnancies.

In this SWCRT, a cluster is the health region where the WSTDP live, give birth and are, therefore, likely to be followed for their pregnancy. The 31 clusters are grouped together into 6 meta-clusters, which are homogeneous in terms of overall inclusion capacity during a period of time.

The choice of a cluster trial is related to the collective nature of the intervention, based on the mobilisation of professionals and organisations in territories.[53 54] The cluster-based inclusion of patients at the territory level will avoid the risk of contamination bias between professionals in the same territory and WSTDP of the same professional; it will also incorporate the organisational constraints in each territory. The stepped-wedge design helps to focus resources on individual sites at specific times to maximise implementation success.[51 52]

The total duration of the study will be 2 years and 9 months, comprising a total of six sequences (meta-cluster).

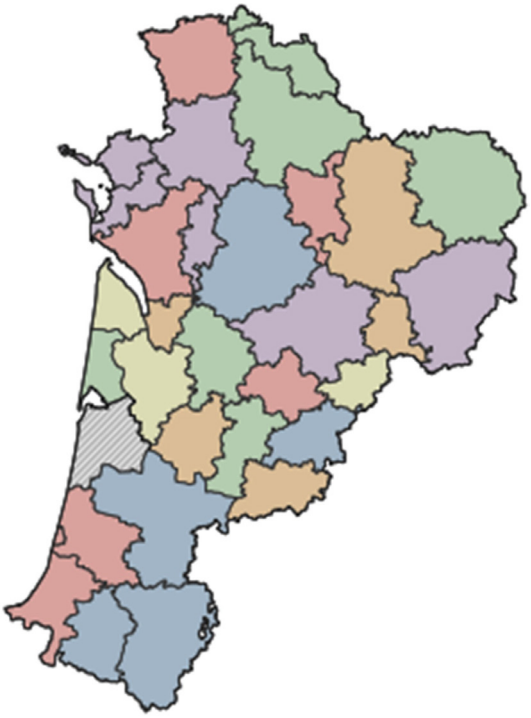

Figure 4 Map of okthe 31 clusters.

Secondary outcome design

The analysis will assess the conditions of effectiveness (aim 2), sustainability (aim 3) and relapse rates post partum (aim 4) (detail in online supplemental material 1).

Participants

Eligibility criteria

Cluster and meta-cluster levels

Study participation involves two different coexisting levels: the 5A-QUIT-N organisation is implemented at the territory level and concerns HCPs, whereas pregnant women will be enrolled in maternity districts to evaluate its efficacy.

The study area (Nouvelle-Aquitaine) is subdivided into 31 clusters, which are grouped into 6 meta-clusters corresponding to the 6 steps of the stepped-wedge including the 41 public and private maternity districts of the region. During the intervention deployment period and within each cluster, all institutions, structures, organisations and HCPs likely to participate in the pathway of pregnant women or specialists in addiction or tobacco will be affected by the intervention.[53 55]

Participant level

WSTDP inclusion criteria:

- Women who declare they have smoked at least twice weekly, for at least 1 week, at any time during their pregnancy.
- Who have given birth and consulted HCPs for their pregnancy in the cluster attached to the maternity hospital where they gave birth.
- Who reside in the Nouvelle-Aquitaine region.
- Who consent to participate.

WSTDP exclusion criteria:

- Women who do not speak French.
- Who smoke only electronic cigarettes.
- Who are under legal protection.
- Who are COVID-positive during the maternity stay.
- Who have special childbirth circumstances (pregnancy denial, stillborn baby, newborn in neonatal care or abandonment at birth).

Relevant concomitant care and interventions are permitted during the trial for all participants.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Primary outcomes

The primary endpoint is the point abstinence at the time of delivery. Although the intervention is to achieve abstinence as early as possible and to continue throughout pregnancy for the health of the woman and the fetus, it is difficult to use this criterion for reasons of comparability. Point abstinence at the time of delivery is widely recommended in the literature[29 56 57] and can detect the delayed effects of an intervention, compared with a period of continuous or prolonged abstinence; thus, it avoids the exclusion of patients who have relapsed despite persevering in their attempt to quit.[56] The National Interagency Council on Smoking and Health has recommended that abstinence should be considered to be at least 24 hours at 3 months, 7 days at 6 months and 30 days at 12 months of follow-up.[56] In view of the time of exposure to the intervention during pregnancy follow-up (between the third and ninth month of pregnancy), abstinence for 7 days before delivery was chosen, as in other trials of smoking cessation during pregnancy assessing abstinence at the end of pregnancy.[58 59] A 7-day point prevalence abstinence is commonly used in pregnancy smoking cessation trials.[60]

The organisation of the care pathway for pregnant women and the organisation proposed in the intervention of this project impact our choices of method for effectiveness evaluation. Indeed, several temporal elements will influence the possible period of abstinence of women linked to our intervention, and therefore, limit the comparison between women of continuous abstinence over a long period. The first element is the difference in the time it takes to start pregnancy care and therefore the variability in the time it takes to implement support for smoking cessation in pregnancy by health professionals. Another element is that women are not comparable according to their consumption profile and complexity with regard to their smoking and therefore will not have a similar path for support for cessation in the proposed organisation, which could lead to delays, and therefore, a lower chance of long-term abstinence.

Secondary outcomes

The secondary health outcomes of intervention effectiveness are described in table 1. The secondary outcomes will provide more details on the impact of the intervention during pregnancy (aim 1) and on relapse in the postpartum year (aim 4).

Participant timeline

WSTDP will be continuously included during the 12-month collection time for each period. Women will be interviewed by a heteroquestionnaire on inclusion in the maternity ward, at 6 and 12 months after delivery (aim 4) (figure 5).

A qualitative part will be a multicase study to address the secondary objective regarding the conditions of effectiveness (aim 2) of the 5A-QUIT-N intervention. This aim will allow to identify the obstacles, levers and adaptations that were necessary between the constructed intervention and its actual implementation conditions. The outcome will be to identify and analyse the processes and mechanisms at play in the intervention strategy in order to determine the conditions of effectiveness and transferability of the intervention and study and analyse the viability of intervention.[40 61 62] To address this, a subgroup of professionals among the healthcare providers targeted by the intervention, stakeholders who participated in the project, a subgroup of WSTDP who were exposed to the intervention and a subgroup of coparents of the child will be included for qualitative measures.

The evaluation of the sustainability of the 55A-QUIT-N organisation (aim 3) will aim to describe the prevalence of each A of the 5A approach reported by the WSTDP and the prevalence of women who have stopped smoking during childbirth in the last 7 days in a sample at a distance from the deployment of the intervention. To do this, a subgroup of WSTDP who have just given birth between 18 and 20 months after the intervention was rolled out will be included.

The objective of studying relapse in the postpartum year (aim 4) will make it possible to describe and identify whether the intervention has an effect on the rate of relapse and its determinants in the postpartum period. To do this, follow-ups at 6 and 12 months post partum using the same questionnaire as at inclusion will be carried out. A subgroup of WSTDP, coparents and health providers likely to be consulted by postpartum women, will also be qualitatively interviewed to identify the levers and obstacles to preventing this relapse.

Table 1 The secondary health outcomes of intervention effectiveness during pregnancy and in post partum

Measure	Methods of data collection	Source	Time point
Primary health outcome of intervention effectiveness			
Self-reported 7-day point abstinence proportion at delivery among women who smoke during pregnancy	Structured interview with a heteroquestionnaire during the maternity stay or by phone	Women who smoke tobacco during pregnancy (WSTDP)	At inclusion (days 1–30 after delivery)
Secondary health outcomes of intervention effectiveness			
Mean number of cigarettes smoked per day (during pregnancy, at delivery and at postpartum follow-up)	Structured interview during the maternity stay or by phone	WSTDP	At inclusion (days 1–30 after delivery) and at the 6-month and 12-month follow-ups
Number of attempts to reduce smoking (at least one cigarette) during pregnancy or in the past 6 months	Structured interview during the maternity stay or by phone	WSTDP	At inclusion (days 1–30 after delivery) and at the 6-month and 12-month follow-ups
Number of attempts to quit smoking (for at least 24 hours) during pregnancy or in the past 6 months	Structured interview during the maternity stay or by phone	WSTDP	At inclusion (days 1–30 after delivery) and at the 6-month and 12-month follow-ups
Continuous abstinence (number of days) during pregnancy or in the past 6 months	Structured interview during the maternity stay or by phone	WSTDP	At inclusion (days 1–30 after delivery) and at the 6-month and 12-month follow-ups
Birth weight (in kg) and gestational age (in months) of the baby at birth	Structured interview during the maternity stay or by phone	WSTDP or health provider	At inclusion (days 1–30 after delivery)

A detailed analyses and statistical plan will be developed and will be the subject of a dedicated publication.

Sample size

The aim of the pilot study was to assess the viability of the intervention in a real-life context before rolling it out more widely in the region in a trial. There was no effect study during this pilot, which is why the number of subjects required was calculated on the basis of the literature. Among women who smoked when they became aware of pregnancy, 59% continued to smoke in the third trimester in France[9]; this proportion was 54% in Nouvelle-Aquitaine.[9] According to a meta-analysis of this specific population and a study evaluating smoking cessation intervention in France, our intervention in the Nouvelle-Aquitaine region is expected to have an effect of 10 percentage points[29 63] (ie, 44% of women will continue to smoke at the end of pregnancy). In Nouvelle-Aquitaine, the rate of women smoking tobacco at the end of pregnancy is 54%, we hypothesised that our intervention will reduce this rate to 44% after intervention deployment.

The incomplete study design includes six sequences of six clusters (maternity districts), with two 3-month preintervention recruitment periods, two 3-month intervention deployment periods (without data collection) and two 3-month postintervention deployment periods for each sequence. The calculated mean recruitment potential is 60 women per month per sequence (ie, approximately 25 patients per 3-month period per cluster). Because recruitment is continuous, the recruitment potential may considerably differ among centres, but it was impossible to incorporate this factor into the study size calculation. To counterbalance the effects of such different

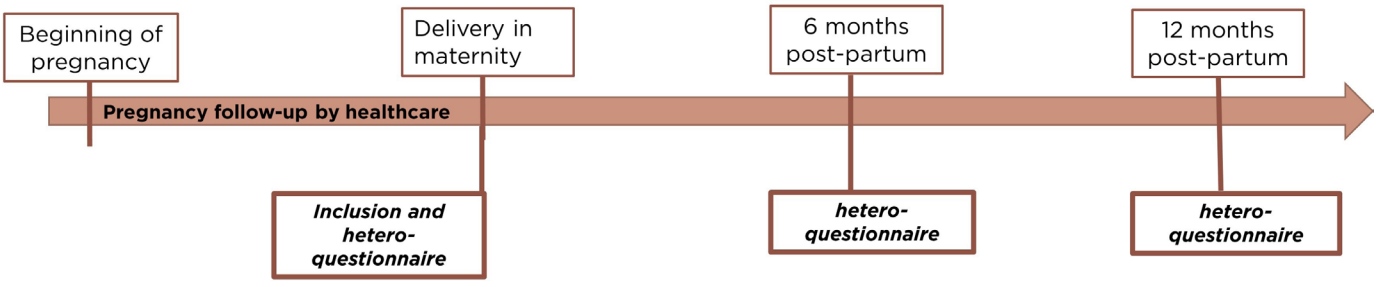

Figure 5 Participant timeline for women who smoke tobacco during pregnancy included in maternity wards.

cluster sizes, we formed meta-clusters that homogenised the total recruitment. To show the expected reduction of 10 percentage points in the proportion of women smoking at the end of pregnancy, with an alpha risk of 5%, an intracluster correlation of 0.01, an intracluster autocorrelation decay of 0.8 and a potential recruitment of 25 women per cluster per period, along with this incomplete design and considering the transition periods and a discrete-time decreasing correlation matrix, the expected power of the study will be 93%. In total, 25 (patients)×7 (clusters)×6 (sequences)×4 (periods)=4200 women will be recruited during the entire 33-month study period.

An additional group (n=175) of women will be included 18 months after the intervention to assess the sustainability of professional practices and the impact of the intervention (aim 3) (detail in online supplemental material 1).

For the qualitative studies (aims 2 and 4), a minimum of 120 women included for the main objective, 90 coparents, 120 professionals targeted by the intervention or likely to be consulted by postpartum women and the stakeholders who participated in the deployment of the intervention will be investigated.

An estimated 4585 participants will be included to pursue all aims.

Recruitment

Intervention

For HCPs who will be exposed to the intervention, collective information will be available on a website, and no individual consent will be collected as recommended by international guidelines.[53 55] Any care provider can refuse to participate in individual aspects of the intervention (eg, training).

Measures

All women attending maternity hospitals during the data collection periods will be screened for eligibility by the project investigators. Eligible women who verbally agree to participate will be included after they have been informed of research and regulatory constraints (information letter in online supplemental material 2). The data collection is pseudonomised and the oral consent and answers are directly collected on an electronic case report form.

Feasibility study

A pilot study confirmed the feasibility of the study, including both the deployment and evaluation of the intervention. A French study assessing pregnant women who had recently given birth in a maternity wards similar to ours showed acceptance rates of 89.5% in 2016 and 86.4% in 2021 among eligible women.[7 9]

Randomisation

A randomisation list will be drawn up by a statistician before the study begins. In this stepped-wedge trial, the order of transition from control to intervention for each meta-cluster will be randomised.

Data collection and analyses

Data collection methods

To address the study objective, determinants of smoking cessation will be collected through quantitative interviews. If it is impossible to collect the main judgement criterion in a cluster (ie, there is no access to the cluster maternity units to evaluate women who have recently given birth), the cluster will be excluded from the SWCRT.

The heteroquestionnaire used in this trial to collect quantitative data was created based on French surveys in similar populations, using tools validated in people with tobacco addiction or pregnant women.[9 64] Systematic literature reviews have identified factors associated with smoking cessation during pregnancy; these can be classified into factors acting at individual, social and HCP levels necessary for consideration in analyses of intervention effectiveness (table 2).[20 25 29]

Statistical analysis

The main analysis will be performed according to an intention-to-treat strategy: all randomised WSTDP will be included in the group to which they were initially randomised, and all of their data will be used regardless of protocol deviations during the trial. In a stepped-wedge study, exposed (intervention) and unexposed (control) observation periods take the place of 'arms' in parallel cluster trials. Therefore, the date of intervention implementation is important in the analysis because it allows participant classification into control and intervention groups. The organisational intervention 5A-QUIT-N uses a collective approach, such that all HCPs working in a cluster will be exposed to the intervention. All HCPs practising within the cluster will be considered exposed, regardless of whether they have modified their practices. The planned date of intervention implementation will be used to classify[21] participants into control and intervention arms.

Sensitivity analyses under treatment (planned date) and per protocol (exclusion of participants included between the planned and actual dates) approaches will be performed. The multiple imputation strategy will be used to manage missing data in the main analysis.

All comparisons will be made with a type I error of 5%. A random effects logistic regression model will be used to analyse the primary endpoint and to incorporate the stepped-wedge study design. To the extent possible, this model will consider random effects on cluster, time and intervention. All secondary endpoints related to the primary objective are quantitative endpoints. The two randomisation groups will be compared regarding these criteria using mixed linear regression with cluster, time and intervention as random effects if possible.

Ethics and dissemination

Ethics approval

The study will be implemented in accordance with French regulations. The research including the consent process

Table 2 Data to be collected from a standardised heteroquestionnaire administered to WSTDP at delivery

Individual factors	Sociodemographic and socioeconomic[20 22]	Age, level of education, income and employment
	Health status[22]	General health status, presence of chronic pathology and treatment, health status during pregnancy, weight, height of mother and child at delivery
	Psychological status[22]	Depressive symptoms in the perinatal and prenatal periods were assessed with the French version of the Edinburgh Prenatal Depression Scale[65]
	Tobacco use in life and during pregnancy	Self-reported frequency and quantity of tobacco use before and during pregnancy and 7 days before delivery, attempts to reduce or quit during pregnancy, craving intensity, motivation to quit, self-efficacy[64 66–68]
	Tobacco dependence and use disorder	Diagnosis and severity of tobacco use disorder in the past 12 months based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnostic criteria[69 70] Fagerström Test for Nicotine Dependence version suitable for retrospective assessment of tobacco[71 72]
	Other substance use	Frequency and craving for alcohol, cannabis, stimulants or sedatives
Healthcare professional levels	Types of professionals visited for pregnancy follow-up and other reasons during pregnancy	Profession (eg, midwife, gynaecologist, general practitioner, tobacco specialist, pharmacist or dentist) and location (independent, hospital, private or public)
	Tobacco monitoring during pregnancy by healthcare professionals[25 26]	Whether the pregnant woman has been asked about her current and lifetime tobacco use (Ask), whether she was advised to quit (Advise), assessed regarding motivation to quit (Assess), referred to specific interventions (Assist), the number and type of smoking cessation tools used and whether follow-up was arranged during her pregnancy (Arrange)
Surroundings and social support	Relationship and social factors[20–22 25]	Living arrangements (married, cohabiting or homemaker), support from partner or others (whether her family and friends agree with her smoking during pregnancy) and exposure to environmental smoking, particularly partner smoking

has been independently reviewed and approved by the French ethical board 'CPP Ile de France I' on 10 February 2022 (No CPPIDF1-2022-DI08-cat.2).

Confidentiality

During the study, the data will be pseudononymised.

Dissemination plan

The results will be disseminated on various academic and non-academic platforms. The results will be reported in international peer-reviewed journals and presented at international and national conferences.

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Acknowledgements We would like to thank Jordan Guillot and Michael Schwarzinger, members of the promoter team who participated in the development of the clusters and the members of the 5A-QUIT-N scientific committee.

Collaborators 5A-QUIT-N Group: 5A-QUIT-N scientific committee (François Alla, Marc Auriacombe, Séverine Barandon, Patrick Brochard, Adrianna Burtin, Florence Calluaud, Annie Campagne, Louise Delavenne, Macha Cambier, Linda Cambon, Philippe Castera, Estelle Clet, Fidéline Collin, Dominique Dallay, Fleur Delva, Léo Donzel Godinot, Gaëlle Dreveau, Melina Fatseas, Florence Francis-Oliviero, Emmanuelle Gagnou, Charlotte Kervran, Marion Kret, Anne-Florence Le Faou, Séverine Martiren, Cathy Meier, Rachid Salmi, Chantal Raherison-Semjen, Rébecca Ratel, Emilie Roquand-Wagner, Loïc Sentilhes, Nolwenn Stevens, Martine Valadie-Jeannel, Isabelle Vidal, Jérôme Wittwer, Judith Martin-Fernandez, Sarah Perrin, Carla Monin, Césarine Sambou, Clément Berliet, André Nguyen) the investigators of the CHU of Bordeaux (Claire Brandet, Marina Touron, Johanne Bozec, Sarah Tarmoul, Thininhane Ouaker, Manon Crepin, Sandra Ros, Sabrina Fournier, Gwendoline Mazurie, Clara Corfias, Isabelle Quintana, Younès Yaaraf), the investigators from associated hospitals (clinical research associates from the Mont-de-Marsan, Agen, Limoges and Bayonne public hospitals, as well as from the Jean-Villar and Belharra clinics).

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Funding This trial is funded by the French General Direction of Healthcare Supply (Direction Générale de l'Offre de Soins) ('DGOS PREPS19-0060') and the French National Cancer Institute and the French Institute for Public Health Research (Institut National du Cancer et Institut de recherche en santé publique) ('INCa IReSP TABAC19-028_C') and the New-Aquitaine Regional Health Agency (Agence Régionale de Santé de Nouvelle-Aquitaine) ('ARS Fonds de lutte contre les addictions 2023').

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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