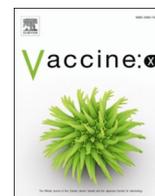


Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

## Vaccine: X

journal homepage: [www.elsevier.com/locate/jvaxc](http://www.elsevier.com/locate/jvaxc)

## A mixed methods study protocol for CONFIVAC, an intervention to enhance paediatric nurses' and paediatricians' skills to promote vaccination and vaccine confidence

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## ARTICLE INFO

## Keywords:

Vaccination hesitancy  
Vaccination  
Paediatrics  
Education, professional  
Communication  
Clinical trial protocol

## ABSTRACT

**Background:** Vaccine hesitancy (VH), defined as the delay in acceptance or refusal of vaccination despite its availability, is a global health threat. Paediatric healthcare workers (PHCWs) are key in promoting vaccination but often feel unprepared to manage VH effectively. We developed CONFIVAC, an intervention designed to strengthen the knowledge, self-efficacy, and skills of PHCWs in improving childhood vaccination, addressing VH, and fostering a culture of immunization within primary care. This study protocol outlines the design, contents, planned implementation, and mixed-methods effectiveness evaluation of CONFIVAC.

**Methods:** We will conduct a two-arm parallel cluster randomised controlled trial including PHCWs from 74 paediatric primary healthcare teams from Catalonia, Spain. Paediatric teams will be randomly assigned to the intervention or control arm (standard care). PHCWs in the intervention arm will participate in the training program CONFIVAC, which includes 10 h of online learning and 2 h of in-person training featuring role-playing exercises. Grounded in health behaviour theories, the curriculum includes evidence-based strategies to improve vaccination uptake. It addresses key topics such as vaccine knowledge, communication strategies, and organizational tools to promote vaccination. Process evaluation will assess overall satisfaction, likelihood of recommending CONFIVAC, and applicability. Main effectiveness outcomes will include vaccine-promoting behaviours (presumptive communication, anticipation of upcoming vaccines, and explicitly recommending vaccination in VH cases) and self-perception of having sufficient training to handle VH. We will perform adjusted ordinal regression models using an intention-to-treat approach. Quantitative results will be triangulated with qualitative insights from focus groups of PHCWs in the intervention arm employing a phenomenological approach.

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<https://doi.org/10.1016/j.jvaxc.2025.100635>

Received 31 December 2024; Received in revised form 21 March 2025; Accepted 21 March 2025

Available online 25 March 2025

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*Discussion:* CONFIVAC is expected to provide PHCWs with evidence-based knowledge, communication techniques, and organizational skills to address VH and promote vaccination. By enhancing their skills and confidence, we aim to improve vaccination uptake and streamline vaccine-related tasks in primary care settings.

**Trial registration:** ClinicalTrials ID: NCT06489236

## 1. Introduction

Childhood vaccination is one of the most effective and cost-efficient public health measures for reducing morbidity and mortality worldwide. [1,2] Ensuring high vaccination coverage is crucial to prevent cases and outbreaks, achieve herd immunity, and ultimately eliminate vaccine-preventable infectious diseases. [3] However, despite widespread vaccine access, European countries continue to experience annual outbreaks of preventable diseases. [4,5] This is related to vaccine uptake, which varies considerably across and within countries, even at the local level. [6,7] For example, in 2023, measles, mumps and rubella (MMR) vaccine coverage among 4-year-old children ranged from 73.9% to 97.4% across paediatric primary healthcare (PPH) teams in Barcelona city, Spain. [8] Variability across and within countries might be related to several factors, including sociodemographic differences, disparities in the quality of vaccination registries, variations in healthcare accessibility, differences in healthcare system performance, and vaccine hesitancy (VH), a growing concern that hinders immunization efforts. [9]

The World Health Organization's (WHO) Strategic Advisory Group of Experts on Immunization defined VH as the delay in acceptance or refusal of vaccination despite the availability of vaccination services [10]. In recognition of its impact, the WHO included VH as one of the top ten threats to global health in 2019. [11] In the Barcelona region, 79% of physicians reported in 2017 encountering vaccine-hesitant patients in their regular clinical practice. [12] While VH is not a recent phenomenon, some studies suggest that vaccine hesitant situations during medical consultations are on the rise and that trust in vaccines might have been eroded following the COVID-19 pandemic. [13,14] Additionally, the widespread presence of vaccine misinformation on websites and social media platforms may have further fuelled VH in recent years. [15–17]

Paediatric healthcare workers (PHCWs) are at the frontline of childhood vaccination and are uniquely positioned to support families in their child's health decisions. [18] For instance, the advice provided by PHCWs remains the most important determinant of vaccination acceptance. [19,20] However, PHCWs may not be or feel well prepared to address vaccination doubts and concerns arising from parents or legal guardians. In 2017, 17% of paediatricians and 40% of paediatric nurses from Barcelona's PPH teams reported lacking sufficient training, information, or resources to adequately address concerns from vaccine-hesitant families. [21] Additionally, half of them expressed needing more information about vaccines through in-person training sessions. [21] Managing VH during paediatric consultations can also be emotionally taxing for PHCW, leading to negative feelings such as frustration, anger or helplessness. [22] Previous interventions aimed at strengthening PHCWs skills to address VH targeted specific vaccines (e.g., influenza or human papillomavirus vaccines) or PHCWs (e.g., only physicians), did not address the emotional burden on PHCWs, and lacked a control group in their evaluation design. [23–26] Furthermore, to our knowledge, no comprehensive intervention has been implemented in our context on this matter. Thus, there is a need to develop, implement, and evaluate interventions that support PHCWs in promoting vaccination as well as preventing and managing VH in the primary health setting.

This manuscript presents the study protocol of an intervention developed to address the identified training needs of PHCW. We hypothesize that a comprehensive intervention based on needs, theoretical models, and evidence will be superior to usual practice at increasing PHCWs knowledge, beliefs, self-efficacy, and vaccine-promoting

behaviours to improve vaccination, manage VH in paediatric consultations and foster a vaccination culture within PPH teams. Ultimately, the goal of the program is to empower PHCWs to effectively promote vaccination and provide tailored evidence-based vaccination counselling to families, thereby improving vaccination coverage. Moreover, since PHCWs will be equipped with new empathy-based skills, we expect to reduce the emotional strain that arises from challenging vaccination interactions. This protocol outlines the intervention's design, planned implementation, and evaluation process.

## 2. Materials and methods

### 2.1. Intervention development

We followed the Intervention-Mapping approach to plan the design, implementation, and evaluation of the intervention. [27] First, we conducted a needs assessment based on the PRECEDE model. [28] Through a literature review and semistructured interviews with key informants (PHCWs and vaccination leads from PPH teams) we identified PHCWs behavioural determinants, environmental factors in primary care centres, as well as VH-related behaviours in both PHCWs and caregivers. [20]

Second, we identified the expected behavioural and environmental outcomes of the intervention: 1) PHCWs promote childhood vaccination and address vaccine hesitancy during paediatric visits, 2) PHCWs foster an immunization culture at the primary health care centre. To achieve these outcomes, we established eight performance objectives (POs), which are provided in **Supplementary 1** along with change objectives resulting from crossing behavioural determinants. We selected behavioural determinants that met the criteria of importance and changeability on the basis of theoretical models of health behaviour (e.g. Health Belief Model, [29] Social Cognitive Theory, [30] Theory of Planned Behaviour [31]). We identified knowledge, beliefs, attitudes, self-efficacy, skills, and social norms as key determinants to target that drive behaviour change.

Third, we formulated the intervention as a training program entitled "CONFIVAC - Vaccine Confidence: Skills to Promote Vaccination in Paediatric Practice". A description of the intervention following the Template for Intervention Description and Replication (TIDieR) can be found in **Table 1**. [32] CONFIVAC is designed to achieve POs and relies on theory-based methods and strategies to change determinants [22,27–32]. Change methods at the individual level include behavioural strategies such as providing arguments, consciousness raising, nudging, tailoring, discussion, self-monitoring of behaviour, modelling, guided practice, and feedback. To influence organizational change at the PPH team level we selected organizational diagnosis, team building, and structural redesign.

Building on these strategies, each PO will be addressed with specific approaches. For **PO1**, PHCWs will be encouraged to adopt a presumptive approach when initiating vaccine conversations. This approach, which involves stating vaccination as a given rather than presenting it as an option, has been shown to reduce vaccine hesitancy more effectively than a consultative approach. [33,34] It also helps to establish a protocolised approach to vaccine offerings, potentially easing PHCWs discussions around vaccination. [35] For **PO2** participants will be expected to gain the skills to provide strong, tailored recommendations and shift families' risk perceptions from vaccine safety concerns to the risks of vaccine-preventable diseases. [20,36,37] To achieve **PO3-PO5**, PHCWs will learn to build trust with hesitant caregivers, fostering a

**Table 1**  
Intervention description and replication checklist.

Item	Description
Brief Name	CONFIVAC, an intervention to enhance Paediatric Nurses and Paediatricians skills to promote vaccination and vaccine confidence
Why	Paediatric healthcare workers (PHCW) play a key role in promoting vaccination and addressing the doubts and concerns caregivers may have regarding vaccines for their children. However, PHCWs might feel ill-prepared to tackle these concerns and effectively manage vaccine hesitancy (VH). We have developed CONFIVAC, a training program designed to strengthen the skills of PHCWs in promoting childhood vaccination, addressing VH, and fostering a culture of immunization within primary care settings. - Online training
What (materials)	<ul style="list-style-type: none"> <li>• Virtual learning platform (virtual campus)</li> <li>• Short video lessons</li> <li>• Printable summaries</li> <li>• Video case studies</li> <li>• Communication guide</li> <li>• Supplementary readings</li> <li>• Multiple-choice test</li> <li>- In- person training:</li> </ul> <ul style="list-style-type: none"> <li>• Presentation slides</li> <li>• Printed role-playing scenarios</li> <li>• Printed communication guideline</li> <li>• Printed checklist including communication strategies</li> <li>• Printed feedback forms</li> <li>• Debrief discussion prompts</li> <li>• Attendance sheet</li> </ul> <p>- Additional materials:</p> <ul style="list-style-type: none"> <li>• - Participant support email</li> <li>• Program completion diploma</li> </ul> <p>The training program consists of 10 h of asynchronous theoretical online training followed by 2 h of practical in-person training.</p> <p>- Online Training Structured in three modules including 13 topics:</p> <ul style="list-style-type: none"> <li>• Module 1: Vaccine confidence Topic 1: Vaccine confidence and hesitancy Topic 2: Immuno-preventable diseases and vaccines Topic 3: Doubts and legal aspects of vaccination Topic 4: Misinformation Topic 5: Combating misinformation</li> <li>• Module 2: Communication and emotional skills Topic 6: Self-care for healthcare workers Topic 7: Empathy Topic 8: Presumptive communication Topic 9: Motivational interviewing tools Topic 10: Additional communication tools Topic 11: Ending a visit: best practices for closure Topic 12: Common questions and myths about vaccination</li> <li>• Module 3: Organization of the centre Topic 13: Organizational resources to increase vaccination Topic 14: How to implement organizational changes</li> </ul>
What (procedures)	Participants will be able to view the contents of the training at their own pace and download materials as needed. Topics include short video lessons and printable summaries, with some modules featuring videos showcasing practical cases, a communication guide with suggested responses to common vaccine-hesitant arguments, and supplementary readings. At the end of the online training, participants will be required to complete a multiple-choice test.

**Table 1 (continued)**

Item	Description
	<p>- In-Person Training Designed to reinforce the theoretical knowledge through practical experience in small groups (maximum 15 participants). It will include:</p> <ul style="list-style-type: none"> <li>• 30-min overview of theoretical content</li> <li>• 60 min of role-playing exercises simulating vaccine-hesitant scenarios with participants alternating roles between healthcare professionals and family members</li> </ul> <p>- Scene 1: Family with a 2-month-old baby who previously expressed refusal of the Hexavalent vaccine. - Scene 2: Family that is unsure whether to vaccinate their one-year-old daughter against the flu. - Scene 3: Family with a one-year-old baby who refuses the measles, mumps, and rubella vaccine. - Scene 4: Family of a 12-year-old boy who is uncertain about vaccinating him against the human papillomavirus</p> <ul style="list-style-type: none"> <li>• 30-min debrief using structured discussion prompts to encourage PHCWs share and discuss best practices and experiences</li> </ul> <p>The contents of the training program have been designed and developed by a team of public health experts with feedback from experienced PHCWs, who reviewed and validated all the materials. Each in-person training will be led by two trained public health experts.</p> <ul style="list-style-type: none"> <li>• Online Training: Delivered via a virtual learning platform accessible from any internet-connected device, providing flexible access for participants.</li> <li>• In-Person Training: It will be held in small conference rooms within primary care and public health facilities, designed to accommodate up to 15 participants per session. These convenient locations will ensure ease of access for participants, maximizing participation.</li> <li>• Online Training: 10 h of asynchronous learning that participants will complete at their own pace over a three-month period to enhance accessibility and allow for flexible scheduling.</li> <li>• In-Person Session: A single 2-h session will be held after the completion of the online module. In our setting, it will be scheduled from 13:00 to 15:00, since this time frame allows participation from both morning and afternoon shifts</li> </ul> <p>The contents of the training program have been tailored to the needs of paediatric healthcare workers and reflect local immunization schedules as well as public health procedures (e.g., how vaccines are introduced into the vaccine schedule). Role-playing cases have been also adapted to reflect common vaccine-hesitant arguments encountered in the local context (e.g., the influenza vaccine for children was recently introduced in the Catalan immunization schedule)</p>
Who provided	
Where	
When, how, and how much	
Tailoring	
Modifications	Not applicable
How well (planned)	Intervention adherence will be assessed by reviewing the participants' completion of the online training program (i. e., the multiple choice test) and by tracking attendance at the in-person training session. Additionally, to encourage participation and accountability, an incentive in the form of a course certificate will be awarded, subject to passing the final exam.

collaborative environment for open vaccine discussions and minimising confrontation. [38,39] For that purpose, they will be introduced into five empathy-based communication strategies derived from motivational interviewing: 1) open-ended questions to explore caregivers' barriers, 2) affirmations to support caregivers, 3) reflections to demonstrate understanding and attunement to caregivers' feelings, 4) seeking caregivers' permission to provide additional information, and 5) acknowledging caregivers' autonomy to strengthen collaboration. [40,41] Additionally, to address common vaccination myths, participants will be trained in a three-step debunking procedure grounded in

cognitive psychological theory: 1) identify the myth and indicate its inaccuracy; 2) explain why the information is misleading, and 3) provide a coherent alternative explanation to correct the myth. [42] To prevent the familiarity backfire effect (i.e., unintentionally reinforcing a myth or misconception due to its repetition), participants will learn to identify when debunking is necessary and to avoid recreating on myths during vaccine-related conversations. [43] In relation to **PO6**, PHCWs will be encouraged to anticipate next vaccines before the end of visits, reinforcing existing vaccination intentions. [44] In **PO7**, participants will learn to make organizational changes in the paediatric consultation, such as rescheduling missed appointments. In **PO8**, PHCWs will be trained to establish a vaccination culture at the healthcare center by coordinating messaging and strategies among team members.

The implementation and adoption of the intervention will be achieved through: 1) establishing alliances between public health and primary care stakeholders, 2) conducting meetings with primary care centre managers, 3) offering incentives for PHCWs participation, such as training credits and certificates as research collaborators, 4) setting up an email inbox for participants' questions and follow-up, and 5) delivering regular reminders to participants throughout the training program.

Lastly, to evaluate the effectiveness of the intervention we will use a mixed methods design including a two-arm parallel cluster randomised controlled trial (cRCT) and a qualitative study exploring participants' perspectives through focus groups.

### 3. Quantitative evaluation: cRCT

#### 3.1. Study setting

The study will be conducted in the healthcare regions of Barcelona city and Central Catalonia, both of which are located in Catalonia, an autonomous community in northeastern Spain. The Spanish National Healthcare system provides comprehensive, publicly funded healthcare to all residents, with services provided free at the point of use, including vaccines. Systematic childhood vaccinations are integrated into a series of scheduled visits and health check-ups that all children receive as part of routine primary paediatric care provided by PPH teams. However, vaccines are not mandatory in Spain. Each PPH team serves the population within a specific territorial division known as a basic health area. In 2023, Barcelona city had 41 PPH teams, with approximately 340 PHCWs serving 194,000 children aged <14 years whereas Central Catalonia had 38 PPH teams, with approximately 110 PHCWs serving 76,000 children aged <14 years.

#### 3.2. Eligibility criteria and recruitment

The inclusion criteria will be being a paediatrician or paediatric nurse employed on a PPH team in Barcelona city or Central Catalonia. Healthcare workers who previously participated as key informants in the design of the intervention, as well as medical intern residents (due to their status as temporary staff) will be excluded. Invitations will be sent via email to eligible candidates. To complete enrolment, participants will be required to review the participant information sheet and provide signed informed consent on the online learning platform.

#### 3.3. Assignment of intervention

We will use cluster randomization to prevent contamination between arms. PPH teams will be randomly allocated into two parallel arms: intervention and control. Randomization will follow a block design, with team names blinded throughout the process. PPH teams will be paired according to the following criteria: 1) total population < 14 years assigned to the team; 2) socioeconomic status of the basic health area served by the team; 3) overall vaccine coverage, measured as the proportion of children aged 0–14 fully vaccinated against diphtheria,

tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b, hepatitis B, measles, rubella, mumps, and meningitis C; and 4) region, Barcelona city or Central Catalonia. This information will be obtained from the Primary Care Services Information System. Within each pair, one team will be randomly assigned to the intervention arm and the other to the control arm. Once randomization is complete, allocation will be unblinded to the research team. The control arm will follow practice as usual for vaccination promotion and VH management (i.e., no specific criteria). PPH teams in the control arm will be offered the intervention upon completion of the study evaluation.

#### 3.4. Sample size calculation

Based on previous research conducted with PHCWs from Barcelona city, [21] we estimate that 71 % feel prepared to handle vaccination concerns during paediatric consultations. We assume this percentage to be similar for PHCWs in Central Catalonia. We expect that following the intervention the percentage of PHCWs that feel prepared to handle vaccination concerns in the intervention arm will be of at least 90 %. Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, 72 subjects in each arm will be able to detect a statistically significant difference of 19 % with an estimated loss of follow-up rate of 10 %. To account for the clustering effect and considering that we expect variability in cluster sizes, we estimated our design effect (DE) using the formula  $DE = 1 + ((CV^2 + 1)\bar{m} - 1)\rho$ , where  $CV$  is the coefficient of variation,  $\bar{m}$  is the average cluster size, and  $\rho$  is the intra-cluster correlation coefficient. [45] With approximately 450 PHCWs across 79 clusters (PPH teams), the average cluster size ( $\bar{m}$ ) is 5.69. With an estimated  $CV$  of 0.65 and a  $\rho$  of 0.05, we estimated a  $DE$  of 1.35. [46] This results in an expected sample size of 98 subjects and 18 clusters per arm.

#### 3.5. Data collection

Participants will fill a baseline and postintervention questionnaire in Catalan on the online learning platform. Upon completion of the baseline questionnaire, participants will be informed of their assigned arm. The postintervention questionnaire will become accessible one month after the end of the intervention and will remain open for one month. The questionnaire has been developed ad hoc based on validated scales from existing literature and has been pretested and piloted [47–49]. We will assess PHCW's knowledge and beliefs related to childhood vaccine safety and effectiveness (21 questions, adapted from a validated questionnaire that we developed to assess VH among PHCWs) [47], self-efficacy in managing vaccine-hesitant situations (17 questions, adapted from Barton et al.) [48], the frequency of vaccine promotion behaviours/intention of behaviours during paediatric consultations (11 questions, developed ad hoc), and the implementation of organizational changes during individual practice and in the PPH team (4 questions, developed ad hoc), as well as standard sociodemographic information (e.g., age, sex, professional role, parenthood status). Psychosocial determinants and vaccination promotion behaviours will be measured using five-point Likert scales. A translated version of the questionnaire can be found in **Supplementary 2**. Regular checks will be conducted throughout the data collection period to ensure data quality and completeness. PHCWs in the intervention arm will also fill a satisfaction survey in Catalan, a translated version is available in **Supplementary 3**. Data will be securely handled and stored to maintain confidentiality, with access restricted to the research team members only.

#### 3.6. Main outcomes

Intervention's main outcomes are described in **Table 2**. Main process outcomes will include overall satisfaction with the training program, the likelihood of recommending the intervention to a colleague, and the applicability of the gained knowledge and skills to usual practice.

**Table 2**  
Main process and effectiveness outcomes.

Evaluation	Outcome	Assessment question	Response format
Process	Overall satisfaction	Rate your overall satisfaction with the course on a scale from 0 to 10	Scale from 0 to 10
	Likelihood of recommending the intervention	Would you recommend this course to a colleague?	Yes / No
	Intervention's applicability	Please rate whether your learning is applicable to your daily practice	Five-point Likert scale ranging from <i>Very Little</i> to <i>Very Much</i>
	Use of presumptive communication	Over the past four months, during visits when vaccines were due, I initiated discussions about vaccination assuming the child would get vaccinated	Five-point Likert scale ranging from <i>Never</i> to <i>Always</i>
Effectiveness	Anticipate upcoming vaccines	Over the past four months, during visits when vaccines were due, I informed families about the vaccines scheduled for their upcoming visit	Five-point Likert scale ranging from <i>Never</i> to <i>Always</i>
	Recommend vaccination explicitly	Over the past four months, when encountering families with doubts or hesitations about vaccination, I recommended that their child get vaccinated during that same visit	Five-point Likert scale ranging from <i>Never</i> to <i>Always</i>
	Perception of having sufficient training to handle vaccination concerns	I have sufficient training to adequately address vaccination doubts that families may raise.	Five-point Likert scale ranging from <i>Completely disagree</i> to <i>Completely agree</i>

Effectiveness outcomes will be the use of presumptive communication, anticipating upcoming vaccines, explicit recommendation of vaccination in cases of VH, and the perception of having sufficient training to handle vaccination concerns. Effectiveness outcomes have been selected on the basis of behavioural change theories and prior research into strategies proven effective in improving vaccination coverage. Using a presumptive format to initiate vaccination conversations has been shown to increase parental acceptance rates. [33,34,50] Research grounded in priming theory also suggests that introducing upcoming vaccines before the end of a visit can strengthen parental intentions to vaccinate by reinforcing existing intentions and facilitating the scheduling of future appointments. [44] Strong provider recommendations have also been linked to vaccine receipt. [51,52] Finally, PHCWs' confidence in counselling vaccine-hesitant caregivers affects their perceived ability to engage in vaccination discussions and endorse vaccination. [53,54] As a secondary outcome, we will also include self-efficacy in managing VH during vaccination conversations. This will be measured using the 17-question scale adapted from Barton et al., [48] with responses recorded on a five-point Likert scale ranging from "very incapable" (0 points) to "very capable" (4 points), resulting in a total possible score ranging from 0 to 68 points.

### 3.7. Statistical analysis

We will describe the participants' baseline demographic characteristics as well as the main and secondary outcomes both at baseline (T0)

and postintervention (T1) by allocation arm. We will also describe the results of the satisfaction survey. To evaluate the intervention's effectiveness, we will conduct ordinal regression analyses comparing the intervention and control arms for the main outcomes at T1. Odds ratios will be estimated along with 95 % confidence intervals. Models will be adjusted for T0 values and factors that could influence the intervention's effect, including age, sex, parenthood status (yes/no), profession (paediatrician or nurse), and years of professional practice. If there are not sufficient observations for each level, we will forego multi-level analysis and adjust our models also by region (Barcelona/Central Catalonia). All analyses will be performed by intention to treat and will be conducted using R software (version 4.3.0).

### 3.8. Qualitative evaluation

The qualitative evaluation aims to explore and describe the perceptions, opinions, and experiences of PHCWs assigned to the intervention arm, providing a deeper understanding of the quantitative findings. We will employ a phenomenological approach to capture the lived experiences and insights of the participants.

### 3.9. Study population

The study population will consist of PHCWs assigned to the intervention arm. The inclusion criterion will be having completed the training program (intervention) at least one month before the qualitative study recruitment, allowing PHCWs some time to apply any gained knowledge and skills. The exclusion criteria will be having language barriers or belonging to the same PPH team as another participant in the focus group.

Sampling units will be chosen based on theoretically predefined profiles. To ensure discursive heterogeneity, we will use criterion sampling considering sex, years of professional experience, rurality, parenthood status, socioeconomic status of the basic health area served by the PPH team, number of attempts to pass the multiple-choice test, and overall degree of satisfaction with the training program. Since paediatricians and paediatric nurses have distinct roles in PPH teams, their profession may influence their experiences and discourses. To prevent these professional roles from interfering, focus groups will be segmented by profession. Selected PHCWs will be invited to participate through email. Sampling will be cumulative and sequential. We plan to conduct at least four focus groups with 6–8 participants each to achieve data saturation: two with paediatric nursing staff and two with paediatricians. The final sample size and number of focus groups will be determined by the saturation of information.

### 3.10. Data collection

Focus groups will be scheduled to maximise participants' availability and will be held online via video calls using the Teams training program platform enabling the participation of professionals from both study regions. Each session will be facilitated by a moderator and assisted by an observer. A semi-structured guide will ensure a comprehensive exploration of all relevant topics, including questions related to the intervention implementation process and intervention outcomes. Sessions are expected to last approximately 1.5 to 2 h and will be recorded in audio and video formats with prior verbal consent from all participants. Recordings will be securely stored, transcribed, and analysed anonymously, with access restricted to the research team.

### 3.11. Data analysis

We will first transcribe focus group sessions and subsequently review the transcription outputs. We will conduct a thematic analysis through the following steps: 1) we will familiarise ourselves with the texts through repeated readings; 2) we will code the transcribed text based on

the predefined topic guide and emerging data; and 3) we will organise these codes into categories and subcategories. All the steps will be discussed and agreed by all the research team members to ensure methodological consistency and data quality. We will use the ATLAS.ti software version 24.1 to facilitate the analysis.

### 3.12. Ethics

This study's protocol was approved by the following institutional review boards: Drug Research Ethics Committee Parc de Salut MAR (CEIm-PSMAR)(2021/9729/I) and IDIAP Jordi Gol Clinical Research Ethics Committee (CEIm)(22/194-P). Study participants will be previously informed and will agree to participate through signed informed consent. This study has been registered at [ClinicalTrials.gov](https://clinicaltrials.gov) with the ID NCT06489236.

## 4. Discussion

This protocol outlines the design and planned evaluation of an educational intervention tailored to address specific training needs of PHCWs in promoting vaccination and preventing and addressing VH during paediatric consultations. The intervention has been designed to equip PHCWs with evidence-based knowledge and communicational and organizational skills to ease in vaccination-related tasks and increase vaccination acceptance. This intervention is particularly timely in the wake of the COVID-19 pandemic, which might have undermined public trust in vaccines due to the widespread dissemination of misinformation on social media. [17,55] Furthermore, the recent introduction of new vaccines into the routine childhood immunization schedule in Catalonia, such as the human papillomavirus vaccine for adolescent boys in 2022 or the influenza vaccine for children in 2023, might present additional challenges for PHCWs. [56,57] In any case, the intervention has been designed to provide PHCWs with general tools to address expected VH arising from the introduction of new vaccines to the routine immunization calendar.

From a public health perspective, this intervention could have a significant impact. By increasing vaccination acceptance, we expect that our intervention could lead to higher vaccination coverage. [25] This, in turn, would reduce the risk of outbreaks and lower the morbidity and mortality associated with vaccine-preventable diseases. Furthermore, VH is known to be emotionally challenging for PHCWs, especially in time-constrained environments. [26] By improving PHCWs' self-efficacy in handling VH, we expect to reduce the emotional strain during vaccine-related consultations, ultimately improving the quality of healthcare delivery. This is particularly important given the ongoing workload and mental health impacts on PHCWs resulting from the COVID-19 pandemic. [58]

Our study has several strengths. First, its methodological rigor. We developed the intervention using Intervention Mapping, a grounded framework that has been shown to be effective in designing health promotion programs. [59] The contents of the training program comprehensively address key determinants of vaccination and were developed based on theoretical models. Additionally, program materials and practical tools provided are evidence-based. Unlike many prior interventions that lack details on the contents of their training, we provide a thorough description of both the content and methods of our intervention. [23] Second, the intervention has been adapted to the needs of PHCWs in our context given that its contents and materials have been validated by a multidisciplinary research team including public health experts and PHCWs professionals. This collaboration integrates clinical and population perspectives on vaccination and is likely to enhance acceptance across health sectors. Our evaluation design is another major strength, since we will conduct a cRCT to evaluate the program effectiveness together with a process evaluation and use mixed methods for data collection. Another notable strength is the inclusion of emotional management tools in the intervention content—an area with limited

evidence to date—but crucial given the emotional toll of VH. [26]

However, we acknowledge several limitations. First, due to the characteristics of the intervention, blinding study participant's assignment through the study will not be feasible, which may introduce bias in the responses from both study arms. Nonetheless, participants will be blinded during baseline data collection. Second, there is a risk of social desirability bias in self-reported data from PHCWs, particularly in the intervention arm, which could lead to an overestimation of the intervention's effectiveness. Third, while we will cluster randomize participants to minimize the risk of contamination, interactions between PHCWs in professional (e.g., conferences) or personal contexts could still result in some exposure. Finally, although we expect that the intervention might contribute to increased vaccines uptake, our study has not been designed to assess such outcomes. Future research should address this issue to provide direct evidence of the impact of the intervention on vaccination coverage.

### CRedit authorship contribution statement

**Elisabet Henderson:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Conceptualization. **Sara Valmayor:** Writing – review & editing, Project administration, Methodology, Conceptualization. **Victoria Porthé:** Writing – review & editing, Methodology, Conceptualization. **Alba Asensio:** Writing – review & editing, Methodology, Conceptualization. **Xavier Bruna:** Writing – review & editing, Validation, Methodology. **Usue Elizondo-Alzola:** Writing – review & editing, Methodology. **Anna Ramirez-Morros:** Writing – review & editing, Project administration. **Gemma Ricós:** Writing – review & editing, Validation, Methodology. **Josep Vidal-Alaball:** Writing – review & editing. **M. Isabel Pasarín:** Writing – review & editing. **Cristina Rius:** Writing – review & editing. **Elena Roel:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Conceptualization. **Elia Díez:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization.

### Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the author(s) used ChatGPT to review the text for proper English usage. After using this tool, the author(s) carefully reviewed and edited the content as needed, taking full responsibility for the final content of the publication.

### Funding source

This work was supported by *Fondo de Investigaciones Sanitarias* from Instituto de Salud Carlos III (ISCIII), Ministry of Science and Innovation, Spain, through the Health Research Projects program (AES 2021) and cofunded by the European Union, grant no. PI21/01710.

### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Acknowledgements

We acknowledge the contributions of the members of the CONFIVAC Research Group, whose collective expertise and collaboration were integral to this study. The members include **Marta Cabanas** (Directora de Sectors Sanitaris, AIS Barcelona Litoral Mar, Consorci Sanitari de Barcelona, Spain), **Carmen Gallego** (Unitat de Metodologia, Qualitat i Avaluació Assistencial, Gerència d'Atenció Primària i a la Comunitat Delta, Institut Català de la Salut, Barcelona, Spain), **David Palma**

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jvaxc.2025.100635>.

## Data availability

No data was used for the research described in the article.

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