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Effectiveness of CONFIVAC, an intervention to enhance paediatric nurses and paediatricians skills to promote vaccination: A mixed-methods cluster randomized trial

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ABSTRACT

Background: Vaccine hesitancy (VH) poses a significant challenge to achieving optimal vaccination coverages worldwide. Paediatric healthcare workers (PHCWs) are fundamental in promoting vaccination but often lack adequate training to address VH. We designed CONFIVAC, a short evidence-based training program to enhance PHCWs' effective behaviours, specific knowledge and communication skills in managing VH and fostering a culture of immunization in primary care. This study evaluates its effectiveness.

Methods: Mixed methods study including a cluster-randomized trial with 142 PHCWs in Barcelona and Central Catalonia, Spain, from October 2023 to February 2024 and a qualitative study. Paediatric teams were randomized into intervention (CONFIVAC) and control (standard care) arms. CONFIVAC included 12 h of online and in-person training on vaccine knowledge, communication strategies, and organizational tools. Participants answered self-administered questionnaires at baseline (T0) and four months later (T1). Key outcomes were vaccine-promoting behaviours (presumptive communication, anticipation of upcoming vaccines, and explicit vaccine recommendations) and self-perception of adequate training to handle VH. We performed logistic regression models to estimate odds ratios (OR) with 95 % confidence intervals using an intention-to-treat approach. Focus groups provided qualitative insights through thematic analysis.

Results: At T1, PHCWs in the intervention arm were more likely to use presumptive communication (aOR:4.05 [2.30;7.15]) and anticipate upcoming vaccines (aOR:2.64 [1.50;4.65]) than controls. Explicitly recommending vaccination when encountering cases of VH did not reach statistical significance (aOR:1.75 [0.89;3.44]). Self-perception of adequate training was higher in the intervention arm (aOR:3.85 [2.10;7.03]). Satisfaction with the training was high. Focus group participants reported improved communication strategies, more empathy towards VH families, and increased confidence in managing VH situations.

Discussion: CONFIVAC increased PHCWs' vaccine-promoting behaviours and self-efficacy, demonstrating the value of an accessible, evidence-based training program to support vaccination efforts in routine practice.

Trial registration: ClinicalTrials.gov NCT06489236

Abbreviations: VH, vaccine hesitancy; PHCW, paediatric healthcare worker; PPH, primary paediatric healthcare; SD, standard deviation.

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1. Introduction

Vaccine hesitancy (VH) is one of the top ten threats to global health [1]. VH, defined as the delay or refusal to accept vaccines despite their availability, is a complex phenomenon that can manifest in varying degrees of indecision or refusal regarding some or all vaccines [2]. Although vaccination is one of the most cost-effective measures in public health [3], misinformation and anti-vaccine discourses are on the rise across social media platforms, a trend further amplified by the COVID-19 pandemic [4–7]. This might have contributed to declining public confidence in vaccines in Europe in recent years [8].

Most vaccines are administered during childhood following national immunization schedules [9]. Primary paediatric healthcare workers (PHCW), including nurses and paediatricians, are primarily responsible for promoting these vaccines and play a critical role in influencing parental decisions [6,10–12]. However, the manner in which PHCWs convey vaccination recommendations can significantly affect vaccine acceptance [13,14]. Up-to-date vaccine knowledge, along with strong communication and organizational strategies, are essential for building trust with caregivers and promoting vaccination [7,15,16]. Many PHCWs, however, might feel unprepared to effectively handle families' vaccination doubts [6,17,18]. A study conducted in Barcelona, Spain, revealed that 30 % of PHCWs from the public system felt they lacked adequate information and training to effectively address families' concerns about vaccines, and over half expressed a desire for more vaccine-related information [19].

While some interventions have aimed to train PHCWs in addressing VH, most have been limited in scope. Predominantly conducted in the US, these interventions typically focus on theoretical knowledge, communication skills, or a combination of both, target mainly physicians, and are often limited to a single vaccine (e.g., influenza) [20]. Moreover, they tend to overlook the emotional burden experienced by PHCWs when addressing VH. To address these limitations, we developed CONFIVAC, an intervention based in behavioural models and frameworks designed to enhance PHCW's attitudes, skills and behaviours in promoting vaccination. [21] CONFIVAC comprises ten hours of asynchronous theoretical online training followed by two hours of in-person practical training featuring role-playing exercises. The program is built on three key pillars: 1) reinforcing knowledge about vaccines and countering misinformation; 2) building evidence-based communication skills to promote vaccination and address VH in consultations; and 3) learning and implementing organizational strategies to promote vaccination within paediatric consultations and healthcare teams. A detailed study protocol including a comprehensive description of the program design, content, and evaluation plan, is available elsewhere. [21]

In 2023–2024, we offered to all PHCWs working in two northeastern regions of Spain, Barcelona city and Central Catalonia, the participation in a study to evaluate CONFIVAC. The aim of this study is to evaluate its effectiveness in improving knowledge, beliefs, self-efficacy and vaccine-promoting behaviours as well as to assess the implementation process using a mixed-methods evaluation design.

2. Methods

2.1. Study design

We conducted a mixed-methods study, including a two-arm parallel cluster randomized trial targeting PHCWs in Barcelona city and Central Catalonia alongside a qualitative study from a phenomenological perspective.

2.2. Setting

This study was conducted between October 2023 and February 2024 in Barcelona and Central Catalonia. Spain has a free, public health system that provides comprehensive services free at the point of use, including childhood vaccinations. Systematic childhood vaccines are administered as part of routine preventive care, integrated into a schedule of paediatric healthcare check-ups offered by public primary paediatric healthcare (PPH) teams. Each PPH team serves the population living within their assigned territorial areas. In 2023, Barcelona had 41 PPH teams, with approximately 340 PHCW serving 194,000 children whereas Central Catalonia had 38 PPH teams, with approximately 110 PHCW serving 76,000 children across rural and urban areas. Childhood vaccines are primarily administered by nurses, who are also responsible for providing most of the information and counselling related to vaccination during routine visits. In Spain, standing orders are in place for vaccines included in the official childhood immunization schedule, meaning that nurses can administer these vaccines autonomously, based on their clinical judgment. However, in situations where families express doubts or hesitancy, they often seek additional advice from paediatricians. As a result, both professional groups play a central role in shaping caregivers' vaccine-related decisions.

2.3. Eligibility criteria

The inclusion criteria were being a paediatrician or paediatric nurse from a PPH team in these regions. The exclusion criteria were having previously participated in the design of the intervention or being a resident (either medical or nursing) due to their status as temporary staff in training programs.

2.4. Recruitment

We invited all PHCWs from PPH teams in Barcelona and Central Catalonia through email invitations that included a brochure summarising the research project, the contents of the free training program, and the incentives for participation, which included 2.5 educational credits and a certificate of participation in this research. Email invitations were distributed hierarchically, starting with the heads of paediatrics in each region, followed by PPH team directors, and then forwarded to PHCWs within each PPH team. We also conducted an online information session. PHCWs interested in joining the study were pre-enrolled by completing a brief online form, accessible through the brochure. The flowchart of the study is shown in Fig. 1. A total of 174 potential participants were assessed for eligibility. Two were excluded for not meeting inclusion criteria: one was a dentist, and the other was a nurse working exclusively in adult care.

2.5. Assignment of intervention

To minimise contamination, we used cluster randomisation. Altogether 174 PHCWs working at 55 PPH teams (69.6 % of the 79 teams eligible, 29 PPH teams from Barcelona and 26 PPH teams from Central Catalonia) pre-enrolled. The 55 teams were paired according to the total population served, socioeconomic status, vaccination coverage, and region (Barcelona or Central Catalonia) and then randomly assigned to intervention or control arm (standard care). PHCWs in the intervention arm received the intervention from October 2023 to February 2024 (autumn course edition), whereas PHWCs in the control arm received the course for ethical reasons after data collection had ended, from February 2024 to June 2024 (spring edition). Prior to enrolment PHCWs were informed that they could neither choose nor know their assigned course edition before baseline data collection. Following randomisation, participants were granted access to the online learning platform (Moodle). Enrolment was completed upon reviewing the participant information sheet and providing signed informed consent on the platform.

Out of the 172 individuals who were pre-enrolled, 142 participants signed the informed consent (77 in the intervention arm and 65 in the control arm). The imbalance by study arm in participant and team allocation numbers was due to variations in enrolment completion rates and the number of participants per team (median of 2 per team, range

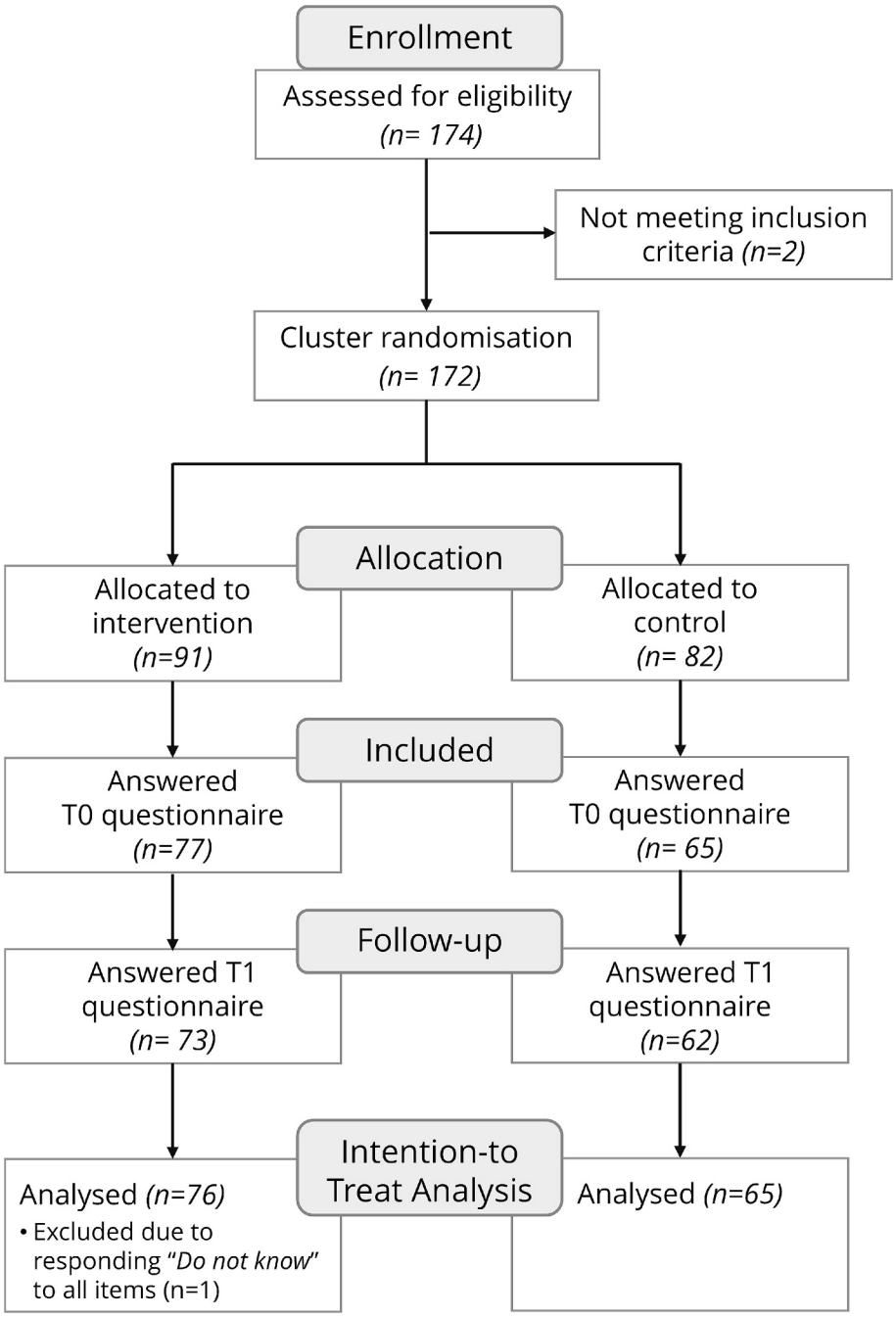

Fig. 1. Study flowchart. CONFIVAC, 2024.

from 1 to 10).

2.6. Data collection

Participants filled a questionnaire at baseline (T0) and four months later (T1). The online training was available from October to December 2023, while group in-person training sessions —conducted in small groups— took place in January 2024. At least one-month elapsed between the last in-person session and T1. The questionnaire was developed ad hoc using items from validated questionnaires to assess changes in the identified psychosocial determinants of vaccination and was pre- and pilot tested [22–24]. PHCWs' knowledge and beliefs about the safety and effectiveness of childhood vaccines, self-efficacy in managing vaccine hesitancy, frequency of vaccine promotion behaviours during paediatric visits, and perception of having sufficient training to address VH were measured using five-point Likert questions. The use of organizational tools within paediatric visits and at the PPH team level as well as sociodemographic information (age, sex, occupation, years of practice, and parenthood) were also collected. Participants in the intervention arm were also asked to fill a satisfaction survey at the end of the training program. Both questionnaires can be consulted in the study protocol. [21]

2.7. Outcomes

Key effectiveness outcomes included the frequency of three effective vaccine-promoting behaviours (use of presumptive communication, anticipate upcoming vaccines, recommend vaccination explicitly in cases of VH) measured on a scale ranging from "Never" to "Always", and the perception of having sufficient training to address VH, measured on

a scale from “Completely disagree” to “Completely agree”. [21]

As a secondary outcome, we assessed self-efficacy in managing vaccine-hesitancy using a 17-item questionnaire with responses recorded on a five-point Likert scale ranging from “Very incapable” (0 points) to “Very capable” (3 points), yielding a total score range from 0 to 68 points. Higher scores indicate greater self-efficacy. We also reported as secondary outcomes the remaining aspects assessed in the questionnaire: vaccine-related knowledges and beliefs, and the use of organizational tools to promote vaccination within primary teams.

Main process outcomes included overall satisfaction (rated on a 0–10 scale), likelihood of recommending CONFIVAC to a colleague (yes/no), and perceived applicability of the training (measured on a five-point Likert scale ranging from “A lot” to “Very little”). Secondary outcomes comprised the remaining items included in the satisfaction survey.

2.8. Statistical analysis

We described participant's baseline demographic characteristics as well as main and secondary outcomes at baseline (T0) and post-intervention (T1) by allocation arm. We also described the results of the satisfaction survey. Categorical variables were summarised using counts and percentages, while continuous variables were described using means with standard deviations (SD). Differences in self-efficacy scores between the two arms at T0 and T1 were compared using a *t*-test, with a significance level set at $p < 0.05$.

To assess the intervention's effectiveness, we initially planned to estimate multi-level ordinal logistic regression models. However, due to insufficient observations at certain levels (i.e., several PPH teams had only one participant) and the violation of the proportional odds assumption, we performed single-level logistic regression models. Outcomes were dichotomised as 0/1, where 1 represented the most favourable response category (e.g., *Always* for behaviour-related outcomes). This decision was based on a preliminary analysis of data at T0, which revealed that participants had already a high baseline level across most outcomes. Odds Ratios were estimated along with 95 % confidence intervals. We estimated baseline-adjusted models (adjusting for values at T0) as well as fully adjusted models (adjusting for values at T0, gender, parenthood status, occupation, years of professional practice, and region). Logistic regressions were performed on an intention-to-treat basis, with participants lost to follow-up being assigned their baseline values at T1. All analyses were conducted using R software (version 4.3.0).

2.9. Qualitative study

A qualitative phenomenological study was designed to evaluate the effectiveness and the process, based on participants' perceptions. The sample was intentionally selected from intervention arm participants using predefined profiles to ensure diversity in gender, experience, rurality, parenthood, socioeconomic status, exam attempts, and satisfaction. To encourage participation, a small economic incentive was provided in the form of a gift card. Final sample consisted of 26 PHCWs, who participated in four focus groups (two with paediatricians and two with nurses) after signing an informed consent. Focus groups were held online via Teams in March 2024, with 6 to 8 participants per group and lasted 1.5 to 2 h. A topic guide was developed to structure the discussion (Supplementary Material 1). Sessions were recorded with participant consent and transcribed using Turboscribe. The transcriptions were subsequently reviewed by the research team.

We conducted a thematic content analysis [25], with the support of the software ATLAS.ti version 24.1. Themes were coded and classified, identifying common patterns as well as convergences and divergences in the data. Analytical categories were derived from the topic guide and through constant comparison of the data. To ensure the quality of the information, the data were triangulated among the research team.

2.10. Ethics

The study was conducted in accordance with the Declaration of Helsinki and approved by the Drug Research Ethics Committee Parc de Salut MAR (CEIm-PSMAR)(2021/9729/I) and by IDIAP Jordi Gol Clinical Research Ethics Committee (CEIm)(22/194-P). This study was registered on 5th July 2024 at ClinicalTrials.gov under the ID NCT06489236.

3. Results

Baseline characteristics of participants were similar in both study arms (Table 1). Most participants were women (93.0 %), nurses (66.9 %), had children (75.4 %), and had encountered VH families in the prior 4 months (90.8 %). Participants were evenly distributed by region, with 56.3 % being from Barcelona. Seven participants were lost to follow-up, with baseline characteristics similar to those who completed the study (Supplementary Material Table 1). One participant was excluded from the analyses due to responding *do not know* to all items. A description of the characteristics of PHCWs that participated in the qualitative study can be found in Table 2.

3.1. Effectiveness evaluation

3.1.1. Behavioural changes

Fig. 2 and Table 3 illustrate changes in vaccine promotion behaviours from T0 to T1. The proportion of participants who always initiate vaccination conversations using presumptive communication increased by 28 % in the intervention arm (43 % to 71 %) compared to a 2 % increase in the control arm (37 % to 39 %). Similarly, the proportion of participants who always anticipate upcoming vaccines increased by 16 % in the intervention arm (57 % to 73 %) while it decreased by 5 % in the control arm (55 % to 50 %). The proportion of participants who always explicitly recommend vaccination in cases of VH increased slightly by 3 % in the intervention arm (32 % to 35 %) compared to no change in the control arm (26 % at both time points). These differences were statistically significant for presumptive communication [aOR: 4.05

Table 1
Characteristics of study participants. CONFIVAC, 2024.

Variable		Control	Intervention	*p*-value
n		65	77	
Age, mean (SD)		44.8 (9.4)	45.7 (10.7)	0.617
Gender, n (%)	Woman	61 (93.8)	71 (92.2)	0.754
	Man	4 (6.2)	6 (7.8)	
Region, n (%)	Barcelona	33 (50.8)	47 (61.0)	0.289
	Central Catalonia	32 (49.2)	30 (39.0)	
Parenthood, n (%)		51 (78.5)	56 (72.7)	0.552
Occupation, n (%)	Physician	25 (38.5)	22 (28.6)	0.285
	Nurse	40 (61.5)	55 (71.4)	
Years of work experience, mean (SD)		19.6 (9.5)	20.1 (10.6)	0.793
Encountered a vaccine hesitant family in the prior 4 months at baseline, n (%)		58 (89.2)	71 (92.2)	0.748
Lost to follow-up, n (%)		3 (4.6)	4 (5.2)	1.000

Notes: p-values were calculated using Student's t-tests for continuous variables and Chi-square tests for categorical variables, except for “Gender” and “Lost to follow-up”, where Fisher's exact test was applied due to small cell counts. Vaccine hesitant families include those who had doubts about vaccines. Abbreviations: SD: standard deviation.

Table 2
Characteristics of participants in focus group discussions. CONFIVAC, 2024.

Informant	Occupation	Gender	Years of professional experience	Region	Overall satisfaction (0−10)
N1	Nurse	Woman	≥30	Barcelona	Missing
N2	Nurse	Woman	10–29	Barcelona	8
N3	Nurse	Woman	10–29	Central Catalonia	Missing
N4	Nurse	Woman	≥30	Central Catalonia	10
N5	Nurse	Woman	<10	Central Catalonia	Missing
N6	Nurse	Woman	<10	Central Catalonia	9
N7	Nurse	Woman	10–29	Barcelona	8
N8	Nurse	Woman	≥30	Central Catalonia	9
N9	Nurse	Woman	10–29	Barcelona	Missing
N10	Nurse	Woman	10–29	Central Catalonia	8
N11	Nurse	Woman	10–29	Barcelona	10
N12	Nurse	Woman	<10	Barcelona	8
N13	Nurse	Woman	≥30	Central Catalonia	Missing
N14	Nurse	Woman	10–29	Central Catalonia	Missing
P1	Paediatrician	Man	<10	Barcelona	9
P2	Paediatrician	Woman	10–29	Barcelona	Missing
P3	Paediatrician	Woman	≥30	Barcelona	8
P4	Paediatrician	Woman	10–29	Central Catalonia	7
P5	Paediatrician	Woman	≥30	Central Catalonia	9
P6	Paediatrician	Man	10–29	Central Catalonia	10
P7	Paediatrician	Woman	10–29	Barcelona	Missing
P8	Paediatrician	Woman	10–29	Central Catalonia	10
P9	Paediatrician	Man	≥30	Barcelona	8
P10	Paediatrician	Woman	10–29	Central Catalonia	10
P11	Paediatrician	Woman	≥30	Barcelona	8
P12	Paediatrician	Woman	<10	Barcelona	8

(95 % CI: 1.64–10.92)] and anticipating upcoming vaccines [aOR: 2.64 (95 % CI: 1.15–6.26)] but not for explicitly recommending vaccination [aOR: 2.18 (95 % CI: 0.86–5.76)]. Changes in perception of having sufficient training and self-efficacy to handle VH are shown in Fig. 3 and Table 3. The proportion of participants who completely agreed they had sufficient training to address vaccination concerns increased by 17 % in the intervention arm (17 % to 34 %) and decreased by 7 % in the control arm (23 % to 16 %). This difference was statistically significant [aOR: 4.05 (95 % CI: 1.64–10.92)]. In terms of self-efficacy, both arms had similar scores at T0, with a mean (SD) score of 52.5 (7.9) for the control arm and 52.9 (8.1) for the intervention arm ($p = 0.74$). By T1, the score remained stable in the control arm (mean: 51.6 [9.1]) whereas it increased in the intervention arm to 57.1 (8.3). The mean difference between the two arms at T1 was 5.5 points, with a 95 % confidence interval of 2.6 to 8.5 ($p < 0.001$). Responses to the self-efficacy score questionnaire are reported in Supplementary Table S2.

In line with quantitative findings, focus group participants also reflected on their communication behavioural changes when maintaining vaccine conversations (Table 4). Presumptive communication was described as a "discovery" that effectively increased vaccine acceptance, with some participants acknowledging they had previously used it but felt guilty, unaware that this approach is supported by evidence. Several participants also reported that they now anticipate upcoming vaccines, a practice some already engaged in to some extent, but not systematically. Interestingly, while none mentioned making more frequently explicit vaccine recommendations, several noted that they have implemented new tools to support their recommendations. These include sharing tailored vaccine-related information with caregivers, shifting the focus from vaccine side effects to the risks of vaccine preventable diseases, and applying a structured approach to counter misinformation and debunk myths. Tools such as asking permission to provide information or sharing personal stories (particularly in relation to their own children) were perceived as more challenging, although some informants referred using the latter with good results. Importantly, many participants reported engaging in more active listening and asking more questions to better understand the reasons behind vaccine refusal. Paediatricians also shared being more inclined to "keep the door open" in cases of persistent vaccine refusal. Focus group participants also reported feeling better prepared, which led to reduced anxiety, diminished feelings of guilt, and increased confidence. Additionally, CONFIVAC provided a greater sense of purpose and fostered empathy, enabling PHCW to recognize caregivers' doubts as legitimate and enhance communication with VH families.

Secondary outcomes related to vaccine knowledge and beliefs are reported in Supplementary Material Table S3, whereas organizational changes are reported in Supplementary Material Table S4. Although significant improvements were observed in vaccine knowledge, qualitative findings show that PHCWs felt that they already had sufficient theoretical knowledge, especially paediatricians. Nonetheless, they acknowledged the value of reviewing challenging topics, such as vaccine composition and side effects. Regarding organizational changes, we did not find a significant overall increase in the use of organizational practices to promote vaccination. Qualitative results show that many participants had already implemented some of these practices prior to the program, including reviewing vaccination history, patient recalls, and opportunistic vaccination.

3.1.2. Process evaluation

Among participants in the intervention arm, 75 (97.4 %) attended the in-person session, 74 (96.1 %) took the final multi-choice test, and 69 (89.6 %) filled the satisfaction survey. Mean overall satisfaction was 8.7 out of 10 (SD: 0.9, range 7 to 10), all respondents (100 %) would recommend the program to colleagues, and 97 % found CONFIVAC quite or very applicable to their daily practice. Secondary satisfaction outcomes are summarised in Supplementary Material Fig. S1. In focus group discussions (Supplementary Material Table S5), participants emphasized the course usefulness and positively evaluated its format, materials, and contents, particularly the module on communications strategies. The asynchronous online component was appreciated for enabling flexible completion, while the in-person component was valued for the opportunity to practice theory through role-playing exercises and to share vaccine-related experiences with colleagues.

4. Discussion

We implemented and evaluated CONFIVAC, a training program designed to improve knowledge, beliefs, attitudes, self-efficacy, and vaccine-promoting behaviours among PHCWs. Four months after

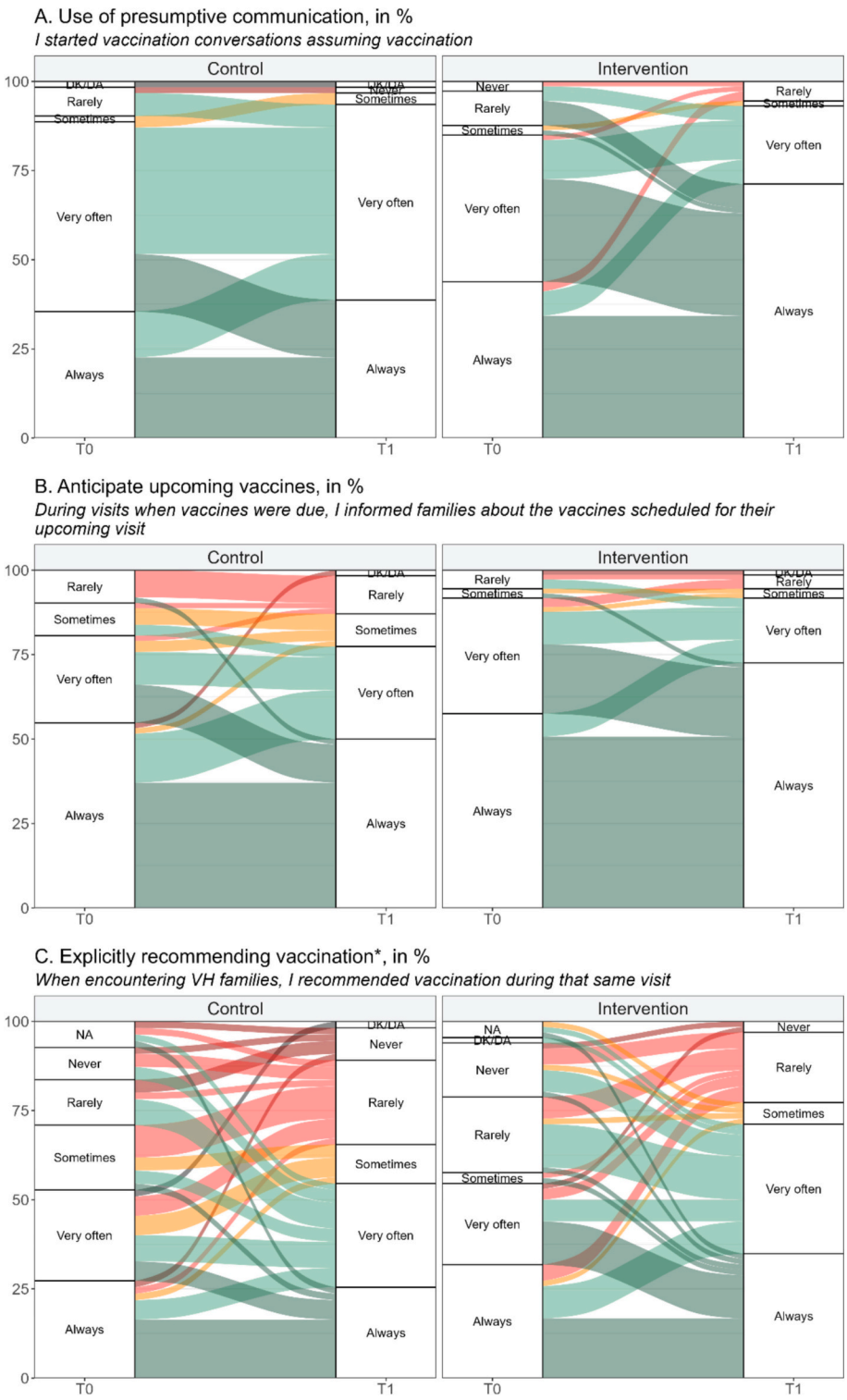

Fig. 2. Changes in vaccine promotion behaviours from baseline (T0) to post-intervention (T1). CONFIVAC, 2024. Legend: The flow and distribution of responses between T0 and T1 are visualized, with colours representing participant responses at T1. T0 responses are shown for all study participants ($N = 141$), while T1 responses include only those who completed the follow-up ($n = 135$). For outcomes marked with an *, responses are provided only for participants who had encountered a vaccine-hesitant family in the prior four months at T1 (control arm: $n = 58$ at T0, 55 at T1; intervention arm: $n = 68$ at T0, 66 at T1). Abbreviations: DK/DA: don't know/don't answer; NA: not applicable; VH: vaccine hesitant.

baseline, PHCWs in the intervention arm were significantly more likely to systematically use a presumptive communication and anticipate upcoming vaccines, but not of explicitly recommending vaccination. They also reported feeling more prepared and a higher self-efficacy in managing VH. Qualitative findings suggest that PHCWs have adopted communication tools to recommend vaccination that they perceive as effective and confidently engage in vaccine discussions with hesitant families. The program also reduced PHCW's anxiety while increasing their empathy during these interactions. The process evaluation revealed high satisfaction with the program, which participants found

Table 3
Vaccine promotion behaviours and perception of having sufficient training at baseline (T0) and post-intervention (T1). CONFIVAC, 2024.

		Control			Intervention			Odds Ratios	
Outcome *Question*	**Response**	**T0 n (%)**	**T1 n (%)**	**Change**	**T0 n (%)**	**T1 n (%)**	**Change**	**Baseline-adjusted (95 % CI)**	**Fully adjusted (95 % CI)**
Use of presumptive communication *I started vaccination conversations assuming vaccination*	Always	24 (36.9 %)	24 (38.7 %)	1.8	33 (43.4 %)	52 (71.2 %)	27.8	3.89 (2.46–8.40)	4.11 (1.93–9.13)
	Very often	34 (52.3 %)	34 (54.8 %)	2.5	32 (42.1 %)	16 (21.9 %)	−20.2		
	Sometimes	1 (1.5 %)	2 (3.2 %)	1.7	2 (2.6 %)	1 (1.4 %)	−1.3		
	Rarely	5 (7.7 %)	0 (0 %)	−7.7	7 (9.2 %)	4 (5.5 %)	−3.7	ref	ref
	Never	0 (0 %)	1 (1.6 %)	1.6	2 (2.6 %)	0 (0 %)	−2.6		
	DK/DA	1 (1.5 %)	1 (1.6 %)	0.07	0 (0 %)	0 (0 %)	0		
Anticipate upcoming vaccines *During visits when vaccines were due, I informed families about the vaccines scheduled for their upcoming visit*	Always	36 (55.4 %)	31 (50.0 %)	−5.4	43 (56.6 %)	53 (72.6 %)	16.0	2.54 (1.14–5.85)	2.64 (1.15–6.26)
	Very often	17 (26.2 %)	17 (27.4 %)	1.3	26 (34.2 %)	14 (19.2 %)	−15.0		
	Sometimes	6 (9.2 %)	6 (9.7 %)	0.4	3 (3.9 %)	2 (2.7 %)	−1.2	ref	ref
	Rarely	6 (9.2 %)	7 (11.3 %)	2.1	4 (5.3 %)	3 (4.1 %)	−1.2		
	DK/DA	0 (0 %)	1 (1.6 %)	1.6	0 (0 %)	1 (1.4 %)	1.4		
Recommend vaccination explicitly * *When encountering VH families, I recommended vaccination during that same visit*	Always	15 (25.9 %)	14 (25.5 %)	−0.4	22 (32.4 %)	23 (34.8 %)	2.5	1.98 (0.82–4.93)	2.18 (0.86–5.76)
	Very often	15 (25.9 %)	16 (29.1 %)	3.2	16 (23.5 %)	24 (36.4 %)	12.8		
	Sometimes	11 (19.0 %)	6 (10.9 %)	−8.1	2 (2.9 %)	4 (6.1 %)	3.1		
	Rarely	8 (13.8 %)	13 (23.6 %)	9.8	14 (20.6 %)	13 (19.7 %)	−0.9	ref	ref
	Never	5 (8.6 %)	5 (9.1 %)	0.5	10 (14.7 %)	2 (3.0 %)	−11.7		
	DK/DA	0 (0 %)	1 (1.8 %)	1.8	1 (1.5 %)	0 (0 %)	−1.5		
	Didn't encounter a VH family	4 (6.9 %)	NA	NA	3 (4.4 %)	NA	NA		
Perception of having sufficient training *I have sufficient training to address vaccination concerns*	Completely agree	15 (23.1 %)	10 (16.1 %)	−6.9	13 (17.1 %)	25 (34.2 %)	17.1	3.96 (1.65–10.37	4.05 (1.64–10.92)
	Agree	34 (52.3 %)	35 (56.5 %)	4.1	39 (51.3 %)	46 (63.0 %)	11.7		
	Neither agree nor disagree	11 (16.9 %)	13 (21.0 %)	4.0	15 (19.7 %)	2 (2.7 %)	−17.0		
	Disagree	5 (7.7 %)	3 (4.8 %)	−2.9	9 (11.8 %)	0 (0 %)	−11.8	ref	ref
	Completely disagree	0 (0 %)	1 (1.6 %)	1.6	0 (0 %)	0 (0 %)	0		
	DK/DA	0 (0 %)	0 (0 %)	0	0 (0 %)	0 (0 %)	0		

Notes: T0 responses are reported for all study participants (N = 141), while T1 responses include only those who completed the follow-up (n = 135). For outcomes marked with an *, responses are provided only for participants who had encountered a vaccine-hesitant family in the prior four months at T1 (control arm: n = 58 at T0, 55 at T1; intervention arm: n = 68 at T0, 66 at T1). All models were estimated by intention-to-treat. Fully adjusted models were adjusted by baseline responses, gender, occupation, region, years of work experience, and parenthood. Abbreviations: CI: confidence interval; DK/DA: don't know/don't answer; NA: not applicable; ref: reference; VH: vaccine hesitancy.

both useful and applicable to their daily practice.

Key effectiveness outcomes were the adoption of vaccine-promotion behaviours associated with increased vaccine acceptance, such as the use of a presumptive approach —presenting vaccines as a given rather than a choice— when initiating vaccine conversations [3,13,16]. CONFIVAC reinforced the systematic use of this approach while improving PHCWs' confidence and reducing feelings of guilt when using it. In addition, it also improved the behaviour of anticipating future vaccinations. This primes individuals by reinforcing vaccination as a default behaviour and a societal norm, keeping it present in their minds,

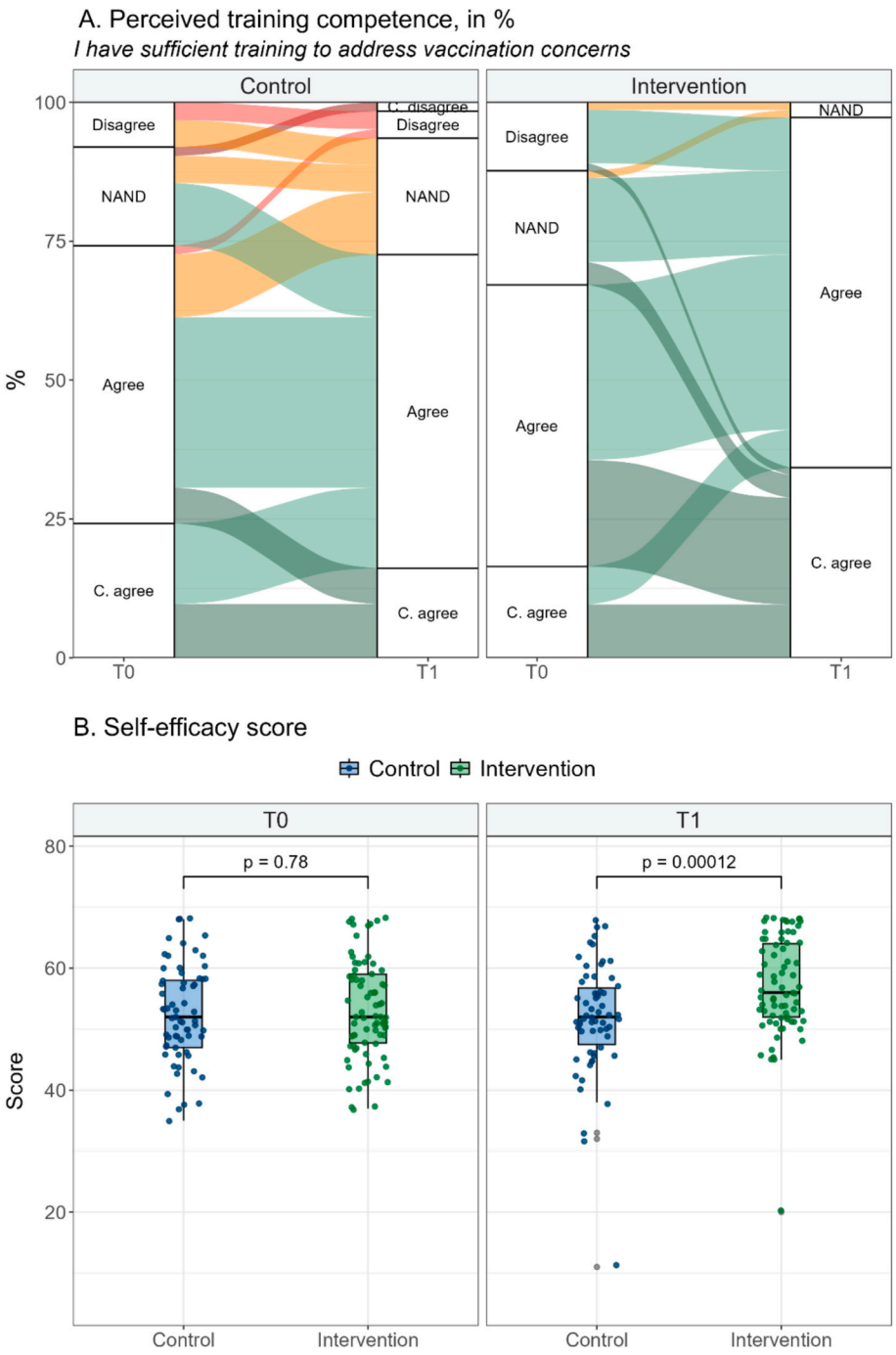

Fig. 3. Changes in perception of having sufficient training and self-efficacy to handle vaccine hesitancy from baseline (T0) to post-intervention (T1). CONFIVAC, 2024. Legend: Fig. A. The flow and distribution of responses from T0 to T1 are visualized, with colours denoting participant responses at T1. T0 responses are shown for all study participants ($N = 141$), while T1 responses include only those who completed the follow-up (n = 135). Abbreviations: NAND: neither agree nor disagree. Fig. B: Each dot represents an individual participant's self-efficacy score. The boxplots illustrate the distribution of scores within each study arm.

and potentially predisposing them to seek information, thereby facilitating open communication channels between families and PHCWs [26]. A strong provider recommendation is another well-established effective strategy for increasing vaccination [13]. While the difference in systematically making an explicit vaccine recommendation in cases of VH was not statistically significant between study arms, this might be due to the small sample size and the fact that PHCWs may view recommending vaccines as a "default" behaviour, making explicit recommendations less salient. Qualitative findings support this idea, as PHCWs did not specifically mention explicit recommendations during discussions, despite reporting successful examples of their use of tools introduced by CONFIVAC to strengthen vaccine recommendations. Interestingly, the proportion of participants that "very often" make explicit vaccine recommendations increased 13 % in the intervention arm (compared to 3 % in the control arm), suggesting that indeed the intervention had some effect. Finally, CONFIVAC significantly increased PHCWs' perception of having sufficient training to address VH, effectively meeting a training gap previously identified worldwide [6,18,19]. This is particularly important, as prior studies have underscored the need for targeted interventions to equip healthcare providers with the necessary skills and knowledge to effectively manage VH [6,27–30].

Evidence supporting educational interventions to address VH

Table 4
Effectiveness intervention qualitative results: key themes and supporting quotes from participants. CONFIVAC, 2024.

Main categories and subcategories	Quotes
Communication behavioural changes	
Use of presumptive communication	*The presumptive communication (…) I've applied it in consultation these past few weeks, and the truth is it works. It's pretty cool. You take it for granted, most don't question it, and you move on. (…) The presumptive communication, for me, was like the big discovery of the course. [P1]* *Today it's the flu shot. And since I have adopted this attitude, a lot more people are getting vaccinated. [N2]*
Anticipate upcoming vaccines	*Not feeling (…) guilt when using presumptive communication (…) Sometimes (…) it feels like I'm just getting the job done. It's quick and straight to the point, and they say, 'Alright.' And I think, 'Wow, that was fast, wasn't it?' … But realizing that it's actually a tool that works, that it's practical and genuinely effective, has eased my mind a bit. [* *I anticipate (…), just so you know, at the next visit, there are these vaccines, which I didn't use to mention before, but now it's something I've incorporated into my daily routine. [N7]*
Sharing vaccine information with caregivers	*It has really helped me to give tools that they can read at home too, because it's not a way of forcing them, but of giving them a little freedom to investigate on their own, and that way, when they come back, they've already analysed or read it, and we can discuss it again. [P8]* *I think this, providing examples, being able to give them scientific information is what has helped me the most. [P9]*
Shifting perceptions towards infection risks	*I didn't do this, giving more importance to the disease, especially focusing on the risk of the pathology, rather than the vaccine. And now this is a change I've made. [N6]*
Countering misinformation	*I find it very interesting (…) how to debunk a false belief, and this is also very useful because it's the way to open their eyes and maybe change things drastically. [P1]* *It's been useful to know this, the impact this news can have [referring to misinformation], because I now approach it from here, like, how this information you've read has come to you. [N11]*
Asking permission to share information	*Perhaps the hardest thing for me is asking permission to give information. [P5]* *What might be harder are more personal cases. I find this a little difficult. [P3]*
Sharing personal stories	*Regarding experiences, for example, I do talk about them sometimes, right? And, for example, (…) we had a case of measles from a child who came from Barcelona and was with the grandparents. I always use this example. [P5]*
Concentrating efforts on hesitant caregivers	*Focus more on those, the ones you see are doubtful, the ones you could try to convince, and focus more on those. [P2]* *Before, sometimes maybe you just left it there, right? They don't want to vaccinate, fine. Now, you leave the door open. [P4]*
Keeping the door open for ongoing vaccine conversations	*There are those who are totally opposed, (…) you know you won't convince them, but you must leave the door open and relax a little with them (…) I tell them that if at any point they want to talk, I'm here. [P2]*
Active listening	*I didn't listen to them as much. I mean, either I didn't listen to them, or I probably put on a pose or something so they couldn't explain much to me. (…) Now it's like I'm more interested in what they're saying. (…) listening to them more, letting them express themselves a bit, and making them feel heard, I think that's been very good for me. [P11]* *And the other thing is, when there's a 'no' that's not radical, I used to ask little about why not (…). And now I do ask more, and why not? Because sometimes, if you ask why not, they give you an answer… And you say, wow, this is easy to solve, right? I can handle this one. [N2]*
Changes in emotional response & confidence	
Reduced anxiety and feelings of guilt	*Yes, I believe it has helped to reduce levels of (…) stress. (…) I think it has lowered a bit of this anticipatory anxiety. Then you say, well, let's see what is explained today, let's see how the conversation evolves and without blaming or anything. Well, I think this improves security, confidence, and reduces levels of stress and anxiety. [P1]* *And perhaps learn (…) that we shouldn't get frustrated, that another day they'll come back, the effort will be made again with those who have always been in denial. But maybe not feel frustrated and say, 'Oh no, it's your fault; you didn't manage to succeed.' (…) In the end, you end up blaming yourself. [N2]*
Giving value to the work	*Giving value to the work we do, which might be somewhat undervalued, but it's like the act of giving a vaccine, you inject it and that's it, but no, behind vaccines, there's a lot of psychology, a lot of emotion… like you said, because you're injecting a small child. You must use a good technique or provide good care to that child, and behind that, there are parents or a family who are scared, and all of that also reinforces everything you know, so, I give more meaning to the work I do, I give it more importance. [N7]*
Increased confidence	*I approach hesitancy, but with all the calm in the world, I mean, without worrying about having to give explanations, and now I do it with total naturalness, thinking that I'm doing it well. [N4]* *Above all, it's the confidence it gives you, more confidence when, above all, the change might be the most important one: not having to think and assume that they will be vaccinated. [P3]*
Increased empathy	*Clearly, the emotional aspect—how we feel about this communicative work—well, in a course, you gave us skills, and I suppose that over time, as we put them into practice, we will feel more confident with the changes you've proposed. I think it's still very recent, but I'm sure it's helpful. [N8]* *Losing the fear of the situation, being able to empathize more with those people who have doubts, saying, 'Well, I mean, they have doubts, let's see, they may be founded or not, but it's legitimate for them to have them,' and being able to approach it from a more empathetic point of view. [P2]* *I think it has helped me relate to them better. Because initially, they are vaccine hesitant and I am hesitant towards anti-vaxxers, right? (…) In this aspect, it has helped me, because before I felt like I took it very personally, right? (…) It helps to normalize it, knowing that it's a real problem, that this type of patient exists, and to be able to engage with them. [P7]*
Theoretical learnings	
Refreshing knowledge	*It refreshes everything about the safety and efficacy of vaccines. Of course, it's always good to refresh it because sometimes, as a colleague said, we go into vaccination almost automatically, and we have it so clear and so internalized that many times it's good to refresh what vaccines do. [N10]* *Yes, I didn't remember learning about the composition of vaccines in university, except for the egg and the more basic things… No, I wasn't aware of the composition of vaccines. [P10]*
Organizational changes	
Reviewing patient's vaccination history	*We've always done it, reviewing vaccination cards one by one. [P7]*
Patient recall	*I think we were already doing this before [referring to actively seeking patients with missed vaccines],*

(continued on next page)

Table 4 (*continued*)

Main categories and subcategories	Quotes
Opportunistic vaccination	*and we've continued doing it. The course helps with that. [P3]* *What we've done the most is a lot, a lot, a lot of opportunistic vaccination, especially with the flu vaccine. That's what has worked the most. [N1]* *After this course, we haven't made an organizational change, but well, we already do a lot, meaning we go on catching patients who come (…) not to get vaccinated, but for other reasons. [P4]*
Community outreach talks	*Regarding what you said about giving talks, (…) we also give some talks at the nearby daycare centre. [P10]* *What has changed a little with the team is that now, maybe more often, we meet, discuss incidents with some families, or talk a little more about vaccines. [N11]*
Fostering a culture of vaccination within the centre	*I think what's pending, and I find it good, is involving the organization, making changes at an organizational level. To look at how we're all doing, different professionals, even adults and paediatrics, (…) paediatrics obviously, and propose organizational changes within the team. [P9]*

remains limited, particularly outside the United States [29–31]. A 2018 Cochrane systematic review found low- to moderate-certainty evidence that education-based interventions for caregivers increase childhood vaccination rates, with even less certainty regarding their effectiveness for VH families [31]. Similarly, interventions that focus on increasing theoretical vaccine knowledge among PHCWs seem to have minimal impact on vaccination uptake, despite increasing PHCWs' self-confidence [3,30]. In contrast, CONFIVAC emphasizes *how* to deliver vaccine-related messages, rather than just focusing on *what* to communicate. This approach is consistent with the findings from two systematic reviews on effective interventions to address VH and increase vaccine uptake [29,30], which underscore the importance of communication training. However, previous interventions varied -in scope and used different evaluation methods, often lacking a control group, making direct comparisons with our results challenging [20,29]. Commonly used communication strategies in these interventions were the use of presumptive communication and motivational interviewing (MI), either alone or in combination [32–34], both of which have shown to increase vaccine uptake [3,16,29,35]. For example, the MOTIVE study from the US involved 4 h of in-person training covering vaccine hesitancy, MI principles, and use of a dedicated tool—the MOTIVE tool—which integrates a strong presumptive recommendation, followed by MI-based open-ended questioning and a routing system to guide responses to parental concerns [32]. Similar to CONFIVAC, the MOTIVE training included case-based simulations with feedback. Another example is *PIVOT with MI*, a US-based provider training programme that combines presumptive communication with MI in a multi-component format. It includes a brief online video module introducing key concepts, followed by in-person interactive sessions with didactics, skills assessments, role-play with coaching, summary tip sheets, and two refresher sessions at 3–6 and 9–12 months. [33] CONFIVAC builds on these approaches, while also extending its scope by offering a wider range of additional communication tools, such as making strong vaccine recommendations, tailoring vaccine-related messages to caregivers needs, sharing personal stories, or debunking myths when needed while avoiding a backfire effect [3,12,16].

In addition to educational interventions, organizational strategies have also proven effective in increasing vaccine uptake [12,26,36] and may also reduce the individual burden of vaccine-related tasks by streamlining workflows and promoting shared responsibilities [37]. Thus CONFIVAC also includes a module on organizational practices both within consultations (e.g., reviewing immunization records, anticipating vaccines, opportunistic vaccination) and across PHC teams (e.g., reminders, recalls, and school vaccination efforts) to foster a vaccination culture. However, many of these strategies were already partially established prior to CONFIVAC. For example, in Catalonia PHC teams use a shared electronic health records system with an integrated vaccine register that facilitates reviewing a patient's immunization status, flags missed vaccines and proposes future ones. In addition, vaccine uptake objectives among PHCWs are linked to economic incentives, standing orders allow nurses to administer routine vaccines without individual physician approval, vaccines for school-age children are delivered at schools, and text messaging campaigns are occasionally used. Therefore, CONFIVAC's primary focus was to equip PHCWs with the skills to reinforce and consistently utilize these existing tools, while introducing adaptable practices for specific contexts, rather than pursuing a broad organizational redesign. Thus, the absence of statistically significant changes in organizational practices probably reflects their pre-existing implementation, as corroborated by focus group discussions. Additionally, the post-intervention measurement period may have been too short to detect meaningful changes. Finally, we also acknowledge that training PHCWs alone may be insufficient for broader organizational changes, which often require additional resources and structural support.

Another key finding of our study is the increase in self-efficacy to handle VH, consistent with previous studies on vaccine-related educational interventions for healthcare workers [16,17,29]. Given that self-efficacy has been shown to be associated with vaccine recommendations and acceptance [27], this improvement is significant. Participants also reported feeling less anxious and experiencing a greater sense of accomplishment. This is particularly relevant given that PHCWs often feel emotional distress when dealing with VH situations [20]. A recent scoping review highlighted that many existing interventions fail to address the emotional burden associated with these encounters, leaving healthcare workers unprepared to manage their own feelings effectively [20]. To bridge this gap, our intervention included a dedicated module on emotional management, equipping PHCWs with tools for self-monitoring and regulation during challenging consultations. These findings highlight the importance of addressing both vaccination-related and PHCW's emotional well-being [16,38].

The major strength of this study lies in its robust evaluation, which employed a mixed-methods design combining a cluster-randomized clinical trial with a qualitative study. Additionally, CONFIVAC was developed using a grounded methodology (Intervention Mapping) [39] and included inputs from paediatric practitioners, ensuring its alignment with real-world healthcare needs. Relevance and timeliness are further demonstrated by the high prevalence of VH in our setting, with 90 % of participants reporting recent encounters with VH families. Addressing such a widespread issue, alongside the involvement of paediatric practitioners, likely contributed to CONFIVAC's successful implementation, which was marked by high levels of satisfaction, perceived usefulness, and strong adoption rates. These outcomes highlight the program's practical value and reinforce its strength as a context-responsive intervention. Moreover, CONFIVAC fills a critical gap in the literature, as few interventions targeting VH have been conducted and evaluated with control groups and using a mixed methods design in European countries. Another key strength of CONFIVAC is its comprehensive scope. The program covers a broad range of training content, including theoretical knowledge, communication skills, and organizational strategies. It is also inclusive in its approach, targeting both nurses and physicians, and focuses on systematic vaccines rather than a single vaccine. The program's hybrid format is another significant advantage. The online training component enhances accessibility and sustainability [11], while the two-hour in-person session—featuring activities such as role-playing—are likely to increase effectiveness, as supported by previous evidence [29].

However, this study has also limitations. First, the sample size was small, and the follow-up period was limited to four months after the

baseline, and in some cases, just one month after the end of the intervention. This short timeframe may hinder the possibility to observe certain changes or to fully assess the program's long-term effects. Second, our sample may not be fully representative of the wider population of PHCW. Although it appears broadly comparable in terms of age and sex based on previous studies conducted in our setting [19,40], the proportion of paediatricians was lower than expected. This may be explained by the fact that nurses are primarily responsible of vaccination in routine practice and may therefore have been more motivated to participate in the training. Third, social desirability bias (i.e., participants overreporting positive outcomes) could also affect the validity of the results. Fourth, outcomes were measured among providers rather than caregivers, meaning that changes in providers' practices were not assessed from the caregivers' perspective, and the intervention's impact was not assessed at the family level. This choice was made to reduce complexity and avoid interfering with clinical practice: collecting data from families would have significantly increased the complexity of the study and the involvement of the research team in care settings, which could have influenced healthcare professionals' behaviour (Hawthorne effect). Additionally, no data were collected on vaccine coverage, so the direct impact of the program on vaccination uptake remains unknown. While this was not an objective of the current study, we plan to explore the impact of CONFIVAC on vaccine coverage in the future. However, previous evidence suggests that communication-focused interventions can improve vaccine uptake and reduce vaccine hesitancy among caregivers [13,15,29]. Lastly, although the study was registered after the start of the intervention, its design and implementation followed a pre-defined protocol submitted to the funder, with no relevant post-hoc modifications.

5. Conclusion

CONFIVAC, a comprehensive training program for PHCWs encompassing vaccine knowledge, communication skills, and organizational tools, was associated with short-term improvements in vaccine-promoting behaviours, self-efficacy in addressing VH, and vaccine-related knowledge. Additionally, it had a positive impact on PHCWs' emotional well-being, an area underexplored in the literature. This study underscores the value of targeted, accessible, and behavioural models-based training programs in enhancing healthcare workers' skills and confidence in promoting vaccines.

ICMJE criteria

All authors attest they meet the ICMJE criteria for authorship.

CRediT authorship contribution statement

Elena Roel: Writing – review & editing, Writing – original draft, Supervision, Methodology, Formal analysis, Data curation, Conceptualization. **Elisabet Henderson:** Writing – review & editing, 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. **Anna Ramírez-Morros:** Writing – review & editing, Project administration. **Xavier Bruna:** Writing – review & editing, Methodology. **M. Isabel Pasarín:** Writing – review & editing. **Cristina Rius:** Writing – review & editing. **Elia Díez:** Writing – review & editing, Supervision, Methodology, Funding acquisition, 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.

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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.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2025.127603.

Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

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