

SYSTEMATIC REVIEW

Preventive Interventions for Vaccine Hesitancy in Public Health Nurses: A systematic review of clinical trial protocols

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Abstract

Introduction: The primary aim of this study was to provide evidence-based insights to inform public health nursing practice regarding contemporary interventions designed to prevent vaccine hesitancy.

Methods: This study conducted a comprehensive examination of all trials related to vaccine hesitancy registered on ClinicalTrials.gov up to March 2, 2025. The 123 identified trials underwent systematic summarization based on critical characteristics, encompassing study status, study phase, study type, funding source, and the methodological approaches utilized to address vaccine hesitancy. Quantitative data about the characteristics of the included trials were analyzed using the JAMOVI statistical software package.

Results: A significant proportion of the identified studies, 52.0% (n=64), had reached completion, with results from 10.4% (n=13) of the total cohort accessible within the system. The majority of the trials, 81.6% (n=100), were classified as intervention studies, with initiation dates spanning from April 2010 to March 2025. The six trials originated from Türkiye. Of these, one study (20.0%) has been completed, the status of another (20.0%) is currently unknown, two (40.0%) are in the "Enrolling by invitation" phase, and two (20.0%) is actively recruiting participants. The review further indicated a substantial focus on experimental interventions aimed at mitigating vaccine hesitancy specifically related to the COVID-19 vaccine (n=60, 48.8%).

Discussion and Conclusion: The predominant intervention strategy under consideration incorporated behavioral techniques, specifically the dissemination of informational and reminder messages via Short Message Service (SMS) alongside the provision of didactic training. Following SMS-based interventions, motivational interviewing emerged as the next most common intervention approach.

Keywords: Anti-vaccine movement; Clinical trial; Public health nursing; Vaccine hesitancy

Vaccine hesitancy is a current public health problem that closely affects general public health and negatively affects herd immunity. Vaccine hesitancy is complex and context-specific, varying by time, location, and vaccine.^[1] Although vaccine hesitancy, which is considered a delay or refusal in vaccine acceptance despite the availability of vaccination services, has existed for many years, its

incidence has increased in the last 10 years.^[1,2] For this reason, the World Health Organization has listed 'Vaccine Hesitancy' among the top 10 reasons that threaten global health in its 2019 report.^[3]

Herd immunity is of critical importance to the prevention of epidemics. When the rate of vaccination exceeds certain thresholds, individuals who are not eligible for

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Table 1. Defining the search strategy with the PICO search tool

Population	Population: Child, adult, older adult and healthy or patient volunteers Setting: All healthcare settings (e.g., inpatient, outpatient, nursing homes, home care services) and community Problem: Vaccine Hesitancy
Investigated condition	Intervention, prevention, education, communication, training, observation
Comparison	Several types of intervention, public health nurse roles, public health nurse responsibility
Outcomes	Vaccine Knowledge, Vaccination Acceptance Rates, Intention to Vaccinate

vaccination due to immunodeficiency or other health conditions can still benefit from social immunity. This collective protection mechanisms prevents the spread of epidemics.^[4] In order to achieve herd immunity and prevent anti-vaccination, health workers—especially public health nurses—need to have comprehensive knowledge and adequate equipment about vaccines and vaccine hesitancy. Because, despite the increasing vaccine hesitancy, healthcare professionals are still the most reliable advisors and influencers of vaccine decisions.^[5] In addition, it is of great importance that nurses can approach parents who are hesitant about vaccination appropriately. With the widespread use of modern communication technologies, individuals are more likely to access false or negative information about vaccines on the internet. This situation leads to the spread of vaccine hesitancy. For this reason, public health nurses should have sufficient knowledge and equipment to prevent vaccine hesitancy. Effective results can be obtained when a hesitant person/parent is approached with an appropriate method.

Registration and data analysis processes of clinical trials have an important place for researchers and public health practices. For this reason, clinical trials have been recorded in ClinicalTrials.gov database, which is considered the world's largest clinical trial data repository, since 2000.^[6] Extensive analysis of clinical trials registered in databases such as ClinicalTrials.gov makes it possible to gain a deeper understanding of vaccine hesitancy and prevention studies in the light of current knowledge.^[7] The importance of such databases in terms of ensuring transparency in clinical trials is undeniable. However, the process of publishing the primary results of clinical trials in an academic journal or registering them in a ClinicalTrials.gov database can take up to four years.^[8] In this study, clinical trials associated with vaccine hesitancy in ClinicalTrials.gov database will be examined and the applicability of these trials in public health nursing will be discussed. In addition, the review is planned to guide future studies on vaccine hesitancy in the field of public health nursing.

Method

This study employs a systematic review design. Research Question was.

What are the characteristics and outcomes of interventions for vaccine hesitancy among public health nurses, as identified in clinical trials registered on ClinicalTrials.gov, and what is their applicability to public health nursing practice?

Search Strategy

The search strategy was collaboratively developed by the research authors (SÇ, BA) (Table 1). Data from this study is available in the Center for Open Science Data Repository: OSF | Preventive Interventions for Vaccine Hesitancy in Public Health Nurses: A systematic review of clinical trial protocols.

Search Outcomes

On March 2, 2025, a systematic search of the ClinicalTrials.gov database was conducted utilizing the keyword "vaccine hesitancy." Given the specific focus on all trials pertaining to this phenomenon, no restrictions were applied to the search parameters. The initial search yielded 125 records. Following a preliminary screening, two records were excluded from subsequent analysis as they did not include "vaccine hesitancy" as a primary keyword, resulting in a final sample of 123 trials (Fig. 1).

Inclusion and Exclusion Criteria

Inclusion criteria; 1. Clinical trials investigating interventions related to vaccine hesitancy 2. Studies examining hesitancy across all types of vaccines (e.g., childhood immunizations, seasonal influenza, novel vaccines) 3. Trials involving participants from all age groups (e.g., pediatric, adolescent, adult, elderly populations).

Exclusion Criteria; 1. Non-human studies 2. Clinical trial protocols and studies not available in English 3. Did not include "vaccine hesitancy" as a primary keyword.

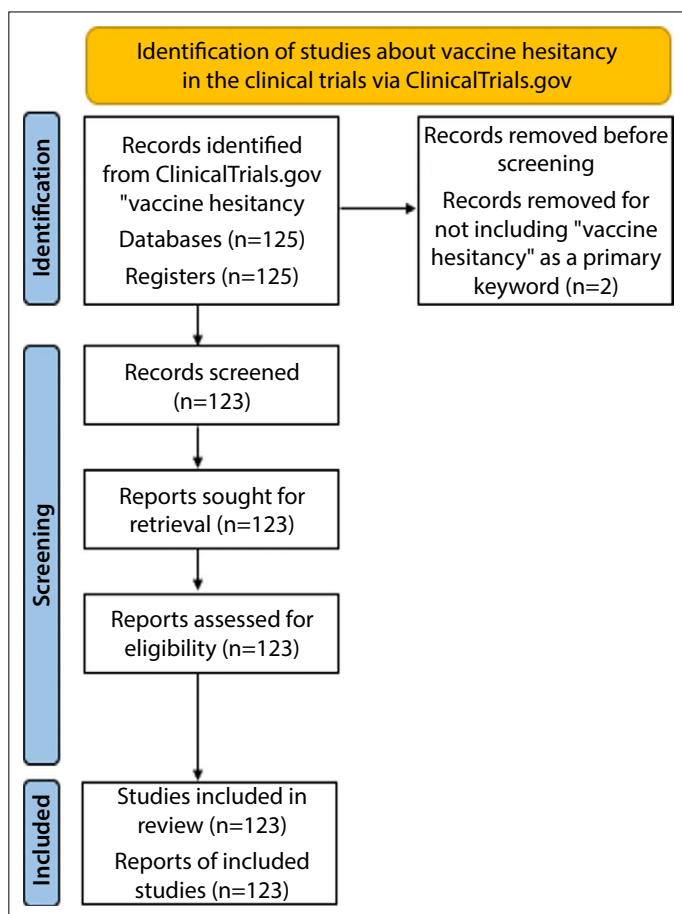


Figure 1. Methods used to identify studied in vaccine hesitancy.

Analysis

The initial dataset included 125 registered trials; however, 2 trials were subsequently withdrawn, resulting in a final sample size of 123 trials for the analysis (Table 2).

Quantitative data extracted from these trials were analyzed using the JAMOVI 2.3.28 (Jamovi (Version 2.6) free statistical software package.^[9] Descriptive statistics, including frequencies and percentages, were employed to summarize the characteristics of the included studies.

Ethical Considerations

Since the data of the study were obtained from a public data collection pool and no data was collected in a way that required ethics committee approval, ethics committee approval was not required

Results

Table 2 provides a comprehensive overview of the 123 clinical trials on vaccine hesitancy included in this analysis. Regarding trial status, while 12 studies (9.76%)

Table 2. Characteristics of clinical trials (n=123)

	Number	Percent
Study Status		
Recruiting	19	15.4
Not yet recruiting	8	6.5
Active, not recruiting	7	5.7
Completed	66	53.7
Terminated	5	4.1
Enrolling by invitation	6	4.9
Unknown	12	9.8
Study type		
Interventional	105	85.4
Observational	18	14.6
Study results		
With results	17	13.9
Without results	106	86.1
Funder Type		
Other U.S. federal agency	1	1.23
All others (individual, universities, institutions)	122	98.7

were registered in the system, participant enrollment had not yet commenced. A total of 19 trials (15.4%) were actively involving patients, and 66 trials (53.7%) had been completed. Furthermore, 5 trials (4.1%) were terminated, and another 7 trials (5.7%) were active but not currently recruiting participants.

Analysis of participant age groups indicated that 36 trials (29.27%) included participants aged 0-17 years, 119 trials (96.75%) involved participants aged 18-64 years, and 103 trials (83.74%) included participants aged 65 years and older. It is important to note that some trials included participants across multiple age groups, hence the percentages exceed 100%.

The study results were registered within the system for 17 trials (13.9%), while the protocols for the remaining trials were not publicly available. Explicit documentation of patient informed consent forms was present in 12 trials (9.76%). In terms of funding sources, 122 trials (98.7%) funded by industry organizations.

Distribution of Trials by Year

The registration of clinical trials focusing on vaccine hesitancy on ClinicalTrials.gov appears to have commenced in 2010. A consistent number of one trial (0.8%) was registered in each of the years 2010, 2011, 2012, 2013, and 2016. This was followed by the registration of two

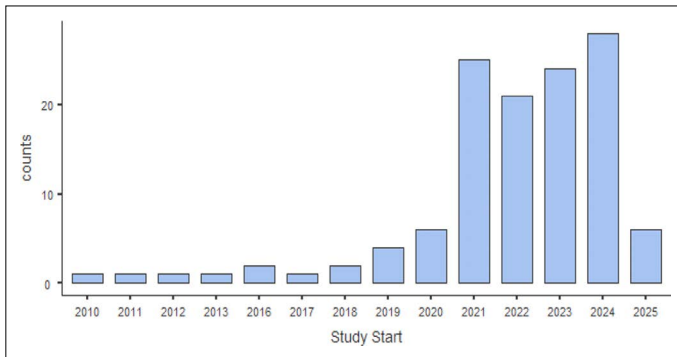


Figure 2. Distribution of registered trials on vaccine hesitancy by study start year.



Figure 3. Distribution of registered trials on vaccine hesitancy by country.

trials (1.6%) in both 2016 and 2018, and an increase to four trials (3.3%) in 2019, and six trials (4.9%) in 2020. The subsequent five-year period witnessed a marked increase in the number of registered trials, with 25 trials (20.3%) in 2021, 21 trials (17.1%) in 2022, 24 trials (19.5%) in 2023, 28 trials (22.8%) in 2024, and six trials (4.9%) registered in the first quarter of 2025 (up to March 2nd) (Fig. 2).

Countries Where Trials Were Conducted

The geographical distribution of the 123 analyzed trials indicated that the United States accounted for the largest

Table 3. Distribution of the types of vaccines intervened in trials

Type of vaccine	Number	Percent
Unspecified	40	32.5
HPV	12	9.8
Covid 19	60	48.8
Influenza	2	1.6
MMR vaccine	1	0.8
Dengue fever	2	1.6
Pneumococcal	1	0.8
Covid 19 and Influenza	3	2.4
Influenza, Pneumonia, Meningitis, HZV and COVID-19	1	0.8
MMR and Polio	1	0.8

HPV: Human Papillomavirus vaccine; MMR: Measles–Mumps–Rubella; HZV: Herpes zoster virus.

proportion, with 64 trials (52.0%) conducted within the country. Canada represented the second most frequent location, with 9 trials (7.3%). Türkiye ranked third, with 6 registered trials (4.9%) (Fig. 3).

Priority Vaccines Addressed by Trials

The analysis of vaccine targets within the registered trials revealed that interventions addressing hesitancy towards the COVID-19 vaccine were the most prevalent, accounting for 60 trials (48.8%). Notably, a substantial proportion of trials, 40 (32.5%), did not specify a particular vaccine type in their descriptions. Furthermore, 12 trials (9.8%) focused on interventions aimed at preventing hesitancy towards the Human Papillomavirus (HPV) vaccine (Table 3).

Priority Intervention in Clinical Trials on Vaccine Hesitancy

The most frequently employed interventions were "Other" (24.4%, n=30), followed by SMS-based interventions (12.2%, n=15) and didactic training (12.2%, n=15). Motivational interviewing and questionnaires were each used in 8.9% (n=11) of trials, while social media interventions and online training accounted for 7.3% (n=9) respectively. Less common strategies included chatbots (4.1%, n=5), surveys (2.4%, n=3), and counseling (2.4%, n=3). The least utilized interventions were video-based (1.6%, n=2), interviews (0.8%, n=1), and combined online/face-to-face training (0.8%, n=1) (Table 4).

Characteristics of Trials in Türkiye

A review of the ClinicalTrials.gov database identified six clinical trials pertaining to vaccine hesitancy with a primary

Table 4. Common intervention in clinical trials on vaccine hesitancy

Common intervention	Number	Percent
SMS	15	12.2
Survey	3	2.4
Social media interventions	9	7.3
Motivational Interviewing	11	8.9
Multilevel Intervention	8	6.5
Other	30	24.4
Online training	9	7.3
ChatBot	5	4.1
Counseling	3	2.4
Questionnaire	11	8.9
Didactic training	15	12.2
Video-Based Intervention	2	1.6
Interview	1	0.8
Online and face to face training	1	0.8

SMS: Short message service.

location in Türkiye.^[10-14] The initiation years for these trials were observed to be 2022 or later. Regarding the status of these trials, only one has been completed. Of the remaining five trials, two are currently recruiting participants by invitation, two are in the "Not yet recruiting" phase, and the status of one trial is unknown. The primary purposes of these Turkish trials were categorized as prevention (n=3), supportive care (n=2), and health services research (n=1). In terms of intervention types, motivational interviewing and traditional training practices were the more frequently employed methodologies. The reported durations of these trials ranged from three weeks to one year (Table 5).

Discussion

The analysis of clinical trials registered in the ClinicalTrials.gov database provides important information to public health nursing about prevention methods for vaccine hesitancy. The fact that most of the trials have been completed (52.0%) indicates that there is a significant amount of completed research aimed at preventing vaccine hesitancy. Again, 15.2% of the trials actively recruited participants, indicating that there is continued interest and participation in research on preventing vaccine hesitancy. In addition, the increase in the number of trials indicates that the search for solutions to prevent vaccine hesitancy continues.

Interventional research constitutes the majority of studies on vaccine hesitancy, comprising 81.6% of all trials. This predominance indicates that researchers are actively

Table 5. Characteristics of trials in Türkiye

Number	Title	Year	Status	Type of study	Intervention	Estimated sample record	Primary purpose	Primary outcome	Response time
1	Nursing Strategies to Increase Vaccination Rates in Adolescents: Education, Video Animation and Games [Adolescent Vax]	2025	Not yet recruiting	Intervention	Vaccine education, video animation and game application	210	Healthcare research	Increase in Vaccine Information and Change in Positive Attitudes Towards Vaccines	3 weeks
2	Impact of Supportive Vaccine Communication on Vaccine Decision Processes	2024	Not yet recruiting	Intervention	Motivational interviewing-based intervention	58	Prevention	Vaccine literacy	1 year
3	Vaccination Hesitancy in Expectant Mothers	2024	Enrolling by invitation	Intervention	Didactic training	80	Supportive care	Vaccine literacy Vaccine hesitancy scale	3 weeks
4	Vaccine Hesitancy	2023	Enrolling by invitation	Intervention	Didactic training	80	Supportive care	Vaccine literacy Vaccine hesitancy scale	3 weeks
5	The Motivational Interview Technique in Pregnant Women Who Are Hesitant in Childhood Vaccines	2022	Unknown	Intervention	Motivational interviewing-based educational intervention	52	Prevention	Childhood vaccination Vaccine hesitancy scale	6 months
6	Intervention to Promote Childhood Vaccinations and Influence Vaccination Attitudes	2022	Completed	Intervention	Intervention based on the Health Belief Model	54	Prevention	Vaccination rate of children	1 year

engaging in systematic efforts to evaluate and address vaccine hesitancy. The relatively limited number of observational studies suggests that the primary focus in this field lies in assessing the effectiveness of intervention strategies.

The registration of clinical trials related to vaccine hesitancy on the ClinicalTrials.gov database spans the last 15 years, beginning in 2010.^[15] A significant development occurred in 2021, marked by an approximate threefold increase in the number of registered trials—a trend that has continued into 2025, with six trials already registered in the first four months of the year. This notable rise in clinical trial activity underscores the increasing prominence of vaccine hesitancy as a global public health concern and reflects an intensified scientific commitment to investigating and mitigating this complex phenomenon.

A substantial proportion of clinical trials on vaccine hesitancy are conducted in the United States, reflecting the prominence of this issue within the country's public health agenda.^[2] Vaccine hesitancy emerged as a critical concern following the 2015 measles outbreak originating at Disneyland, which spanned six months and spread across seven U.S. states, as well as Mexico and Canada.^[16,17] This event significantly elevated vaccine hesitancy as a public health priority. The persistence of vaccine hesitancy in subsequent years likely motivated researchers to focus on this phenomenon more intensively.

In Türkiye, the six currently available trials on vaccine hesitancy appear to have been initiated in response to the heightened concerns stemming from a 2015 court case addressing vaccine refusal. The global surge in vaccine hesitancy, which reached its zenith during the COVID-19 vaccine rollout, has further underscored the urgency of addressing this multifaceted challenge through rigorous research and intervention strategies.

In order to combat vaccine hesitancy, a multifaceted, evidence-based approach is required, including transparent risk communication, the establishment of trust between healthcare professionals and individuals, and the proactive combatting of misinformation, especially on digital platforms. A variety of practices that healthcare professionals can implement together must also be considered.^[18] An analysis of interventions aimed at mitigating vaccine hesitancy reveals that SMS-based information and reminder messages, along with didactic educational approaches, are the most frequently employed methods, followed by motivational interviewing techniques. Providing accurate information, addressing

patient concerns, and reducing barriers are imported strategies to access decrease vaccine hesitancy.^[19] These observations underscore the necessity for public health nurses to consider the efficacy of SMS communication and motivational interviewing in addressing vaccine hesitancy.

The diverse primary objectives and intervention methods employed in trials related to vaccine hesitancy underscore the inherently complex and multidimensional nature of this public health issue. This complexity necessitates the adoption of innovative, diverse, and adaptable strategies to address vaccine hesitancy effectively. Future research could significantly enhance the understanding of this phenomenon by investigating the synergies and long-term outcomes of combining various intervention techniques.

Educational interventions that are tailored to cultural and social contexts and which integrate vaccine literacy into broader health education may be key intervention strategies that public health nurses can implement.^[18,20] Additionally, the notable incorporation of "social media applications" and "online education" within recent studies highlights the transformative impact of digitalization on this field. Social media platforms, with their capacity to engage and influence a broad audience, and online education, offering flexible and accessible learning opportunities, provide valuable tools for disseminating information and countering vaccine hesitancy. These digital avenues present promising prospects for expanding the reach and efficacy of public health interventions.

The relatively low number of clinical trials addressing vaccine hesitancy in Türkiye, compared to other countries, highlights the necessity for increased research in this domain. The completion of only one out of five trials underscores the time required for the generation and dissemination of results. Among the remaining four trials, two were initiated by invitation, one had yet to commence participant recruitment, and one remained with an unidentified status. These findings suggest that various challenges impede the progress of these trials. The limited number of studies, delays in trial completion, and instances of duplicate entries in the database collectively emphasize the importance of conducting further research and adopting meticulous data management practices in this field.

Conclusion

In conclusion, this analysis of clinical trials registered on ClinicalTrials.gov underscores that vaccine hesitancy constitutes a significant public health challenge, evidenced

by substantial and increasing research activity dedicated to this area. The predominantly intervention-oriented nature of the registered trials suggests a focus on developing practical strategies to address this issue. The observed growth in the number of trials over time further highlights the escalating scientific and public health concern surrounding vaccine hesitancy. Moreover, the findings indicate that geographical context and salient public health events can influence research priorities, with specific communication methods, such as SMS-based interventions and motivational interviewing, emerging as prominent strategies within these intervention trials.

To address and prevent vaccine hesitancy effectively, public health nurses play a critical role through the following actions:

- Recognize the complexity of vaccine hesitancy and actively collaborate with multidisciplinary professionals, such as doctors, psychologists, pharmacists, educators, and communication specialists.
- Engage in public awareness campaigns and design educational materials to dispel misinformation and build public trust, as misinformation and mistrust are key contributors to vaccine hesitancy.
- Utilize diverse communication channels, including social media platforms, brochures, seminars, and other mediums, to enhance public awareness of vaccines.

Employ SMS-based information and reminder messages as part of their strategies to counter vaccine hesitancy.

- Conduct motivational interviews to understand the root causes of individuals' hesitancy and provide empathetic, supportive guidance tailored to their concerns.
- Clearly and honestly communicate the risks and benefits associated with vaccines in an accessible and understandable manner, honing their communication skills to build trust and transparency.
- Observe the results of finished clinical trials concerning vaccine hesitancy and utilize empirically supported methods to enhance their strategies.
- Continuously assess the effectiveness of their strategies and interventions, adapting them as needed to ensure optimal results.
- By implementing these measures, public health nurses can contribute significantly to overcoming vaccine hesitancy and promoting public health confidence.

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