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Impact of multifaceted health education on influenza vaccination health literacy in primary school students: a cluster randomized controlled trial

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Abstract

Background Influenza remains a significant public health concern globally. We assessed the impact of multifaceted health education on influenza vaccination rates and health literacy among primary school students in China.

Methods This cluster randomized controlled trial enrolled fourth- and fifth-grade students from 20 primary schools in Dongguan, China. Schools were randomly allocated (1:1) by a computer program to either the intervention group, receiving multifaceted health education, or the control group, receiving standard health education. Data were collected at baseline and post-intervention. The primary outcome was influenza vaccination rate. Secondary outcomes included health literacy, influenza incidence, influenza-like illness incidence, and influenza vaccine protection rate. Both intention-to-treat (ITT) and per-protocol (PP) analyses were performed.

Results A total of 3463 students (1544 [44.6%] females; mean [SD] age, 9.9 [0.7] years) were enrolled. The ITT analysis included 3463 participants (control group [$n = 1811$]; intervention group [$n = 1652$]) while the PP analysis included 3275 participants (control group [$n = 1717$]; intervention group [$n = 1558$]). The influenza vaccination rate was significantly higher in the intervention group than the control group (ITT: 173 [10.9%] vs 130 [7.4%], adjusted risk ratios 1.54 [95% CI, 1.23–1.93], $P < 0.001$; PP: 165 [10.6%] vs 116 [6.8%], adjusted risk ratios 1.61 [95% CI, 1.27–2.03], $P < 0.001$). The knowledge component of children's health literacy scores significantly increased in the intervention group post-intervention (ITT: mean differences 0.12 [95% CI 0.04–0.20], $P < 0.01$; PP: mean differences 0.12 [95% CI 0.04–0.21], $P < 0.01$). No significant differences were observed for other secondary outcomes.

Conclusions The multifaceted health education significantly enhanced influenza vaccination uptake in primary school students. However, the increase was modest, indicating that more effective school-based influenza prevention programs are urgently needed to improve vaccine uptake in children.

Trial registration Registered at ClinicalTrials.gov on 09/08/2023 (registration number: NCT06048406).

Keywords Education, Influenza vaccination, Child health, Health literacy, Randomized trial

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Background

Influenza remains a significant public health concern globally [1]. In China, influenza has a great disease burden, especially in children [2]. Over 90% of influenza outbreaks in China were reported within educationally settings such as schools and childcare institutions [3]. Despite the established efficacy of vaccination as the primary preventive measure against influenza, vaccination coverage among Chinese children is disappointingly low, falling well below the World Health Organization's target of over 75% [4].

Health literacy, the ability to access, understand, and apply health information to make informed health decisions, is important for vaccination uptake [5, 6]. Parental vaccine literacy, which includes the capacity to comprehend, evaluate, and make informed choices regarding vaccinations, might significantly influence the immunization rates among children [7, 8]. Elevated parental vaccine literacy correlates with higher vaccination rates in children. Similarly, enhancing children's understanding of vaccines is vital for promoting health maintenance and vaccination willingness. Moreover, children may engage in a bidirectional exchange of knowledge with their parents, potentially reshaping parental attitudes toward vaccines and reducing vaccine hesitancy [9].

While the literature on the effects of health education interventions on vaccination rates and health literacy is extensive, focused research addressing these aspects among primary school students in China is scarce [10–12]. Given their distinctive cognitive development, this demographic may exhibit unique responses to health interventions. However, younger primary school students (below fourth grade) often lack the reading fluency and abstract reasoning skills required for reliable self-reporting in survey-based research. Conversely, sixth-grade students face academic pressures due to impending secondary school entrance examinations in China's competitive educational system, which may reduce their participation in extracurricular activities. Therefore, this study focused on fourth- and fifth-grade students as an optimal balance between cognitive readiness and research feasibility. Furthermore, the effectiveness of these interventions can be moderated by regional, cultural, and infrastructural variabilities within China [13]. Thus, this study aims to investigate the impact of health education intervention on influenza vaccination rates and health literacy among fourth- and fifth-grade students through a cluster randomized trial.

Methods

Study design and participants

This study was a cluster randomized controlled trial (RCT) conducted from September 2023 to February 2024 across primary schools in Dongguan, China. This trial was prospectively registered at the ClinicalTrials.gov Protocol Registration and Results System (NCT06048406). A detailed research protocol is available in Additional file 1: Trial protocol [5–7, 10–28], which was reported elsewhere [29]. The study was approved by the Ethics Committee of the School of Public Health, Sun Yat-sen University (approval number: No. 2023107).

All eligible fourth- and fifth-grade students aged 7–12 years in these schools were invited to participate. Students with contraindications to influenza vaccination, who have received an influenza vaccination within 6 months prior to the study start, diagnosed with influenza or confirmed as influenza-like cases at the commencement of the study, or unwilling to participate in the project, were excluded. All students and their parents or guardians gave written informed consent before participation.

Randomization and blinding

This study used stratified randomization based on two administrative districts in Dongguan, one in the central urban area and the other in the non-central urban area. Within each district, ten primary schools were randomly selected. Schools were then randomly assigned in a 1:1 ratio to either the intervention or control group. The allocation sequence was generated through simple random sampling by a computer program, managed by an independent assistant who was blinded to schools. Given the nature of the intervention, it was not possible to blind participants or the personnel delivering the intervention. However, to preserve the integrity of the study outcomes, both the outcome assessors and the data analysis were blinded to the group allocation, ensuring unbiased evaluation of the effectiveness.

Intervention

Participants in the intervention group received a multifaceted health education package designed to enhance influenza vaccination literacy. In contrast, the control group continued with the standard health education provided by the schools, without additional components. The intervention period was from September 2023 to February 2024, during which the intervention group received targeted health education interventions monthly.

The intervention package included educational activities, distribution of educational booklets, four consecutive monthly reminders of vaccination, and distribution of vaccination souvenirs. Educational activities consisted of four monthly 40-min classroom lectures (September 2023–January 2024) covering influenza transmission, vaccination importance, vaccine mechanisms, and preventive health practices. Lectures were delivered by medical professionals and public health experts with experience in child education. Sessions were interactive, incorporating visual aids, structured activities, and Q&A sessions. Educational booklets, developed in collaboration with the Center for Disease Control and Prevention of Dongguan City (Dongguan CDC), were distributed to reinforce key messages. Parents received four consecutive monthly reminders from teachers about vaccination. Additionally, the intervention included the distribution of "Epidemic Prevention Little Guards" medals as vaccination souvenirs to incentivize participation. Souvenirs were distributed to schools prior to the intervention, and all vaccinated students in the intervention group received them from their teachers.

Data collection

Data were collected at two time points: at baseline in September 2023 and at the conclusion of the intervention in February 2024. Both students and parents or guardians participated in the study by completing self-administered questionnaires designed to capture a comprehensive range of information. The questionnaires assessed sociodemographic characteristics, personal health history, and levels of health literacy related to influenza vaccination. Follow-up data collection in February 2024 encompassed the updated health literacy assessments, vaccination status, influenza cases, and the influenza-like illness (ILI) cases.

Influenza cases were identified using records from the municipal CDC influenza surveillance network. Furthermore, the ILI was defined as instances of fever (body temperature $\geq$ 38 °C) with a cough or sore throat, with epidemiological evidence or a positive influenza rapid antigen test, and excluding other causes of similar symptoms. Identification of ILI cases was conducted through a school-based case reporting system, in which trained school medical staff and teachers monitored and recorded symptoms. This system, launched by the Department of Education of Guangdong Province, facilitated standardized illness reporting across participating schools. It also included a morning inspection and absenteeism registration system, where teachers monitored unexplained absences and contacted parents to determine if symptoms aligned with ILI criteria.

Outcomes

The primary outcome was the influenza vaccination rate of students, which was determined by records from the CDC vaccination system. Secondary outcomes included the influenza vaccination health literacy levels, influenza incidence, the ILI incidence, and the influenza vaccine protection rate.

Influenza vaccination health literacy was assessed across four dimensions: knowledge, attitude, behavior, and skills. To account for differences in knowledge and understanding between children and parents, the children's questionnaire contained 12 questions (knowledge: 7, attitude: 2, behavior: 2, and skills: 1), whereas the parental version contained 33 questions (knowledge: 9, attitude: 15, behavior: 6, and skills: 3). In the children's questionnaire, knowledge, attitudes, and behaviors were single-choice, with correct responses scoring 1 point and incorrect answers scoring 0. The skills question was multiple-choice, with each correct option receiving 1 point (total of 6 options). The total score ranged from 1 to 17. In parental questionnaire, knowledge questions were single-choice, scored similarly to the children's version. Attitude questions used a five-point Likert scale (0 to 4 points) to capture varying levels of health literacy. Behavior questions consisted of two binary-choice items (scored 0 or 1) and four three-option items (scored 0–2). Skills questions included two single-choice questions (scored 0 or 1) and one multiple-choice question (total of 6 points). The total parental health literacy score ranged from 1 to 87, distributed as follows: 0–9 for knowledge, 0–60 for attitudes, 0–10 for behavior, and 0–8 for skills.

The influenza incidence was calculated as the number of individuals diagnosed with influenza divided by the total number of individuals, multiplied by 100%. The ILI incidence was calculated as the number of ILI cases divided by the total number of participants, multiplied by 100%. The influenza vaccine protection rate was calculated as the difference between the incidence rate in unvaccinated individuals and the incidence rate in vaccinated individuals, divided by the incidence rate in unvaccinated individuals, multiplied by 100%.

Sample size

Based on the assumption that the anticipated influenza vaccination rate is 80% in the intervention group and 50% in the control group, the power of 0.8, and the two-sided α level of 0.05, approximately 1380 primary school students were required in each group [26, 27]. To account for potential sample attrition, the sample size was expanded by 10%, resulting in a final estimated total sample size of 3036 for statistical analysis.

Statistical analysis

Data were analyzed according to intention-to-treat (ITT) analysis and per-protocol (PP) principles. The ITT analysis included all participants as originally randomized, regardless of adherence, ensuring the benefits of randomization were preserved and providing a pragmatic estimate of the real-world effectiveness. The PP analysis focused on participants who adhered to the study protocol, offering insights into the intervention efficacy under ideal adherence. Continuous variables were described using means ± standard deviation (SD) or median (interquartile range), depending on their distribution. Group comparisons were performed using two independent samples *t*-tests or Wilcoxon rank-sum tests. Categorical variables were reported as frequency and proportions, with comparisons made using chi-square tests or Fisher's exact test as appropriate. The effectiveness of the intervention on the influenza vaccination rate, health literacy levels, and the incidence of influenza and ILI was assessed using log-binomial regression, linear regression models, and Poisson regression, respectively. Given the possible residual imbalance in baseline characteristics after cluster randomization, we adjusted for town, sex, grade, father's age, mother's age, father's education, mother's education, father's occupation, mother's occupation, family income, number of siblings, and parent-rated child heath in the models. These models provided estimates of adjusted risk ratios (RRs), adjusted regression coefficients (β), and adjusted incidence rate ratios (IRRs), along with 95% confidence intervals (CIs). Exploratory subgroup analysis was conducted to explore potential differences in effect sizes by town, grade, and sex, using P values for interaction to examine heterogeneity across subgroups.

To address the potential impact of missing data, prespecified sensitivity analyses were conducted by repeating the analyses after excluding children with missing data for either outcome variable ($n = 273$). By combining ITT analysis, PP, and sensitivity analyses, we aimed to maintain the rigor of our statistical evaluation while addressing limitations related to missing data. All analyses were performed using Stata/MP version 18 (Stata Corp).

Results

A total of 3463 students consented to participate in the study between September 1 and September 24, 2023. A total of 93 students were excluded due to receiving an influenza vaccination prior to the study start. Additionally, data on influenza vaccination status, health literacy, confirmed influenza diagnoses, and influenza-like illness records were unavailable for 95 students. Thus, the ITT analysis included 3463 participants: 1811 students in the control group and 1652 in the intervention group. The PP analysis was conducted on 3275 participants, comprising 1717 in the control group and 1558 in the intervention group (Fig. 1).

The mean (SD) age of children was 9.9 (0.7) years, with 58.0% from non-central urban and 42.0% from central urban (Table 1). The randomization achieved similar distributions across both groups for variables such as sex, age, respondent, mother's education, parents' occupation, family income, and parent-rated child health (all $P > 0.05$) (Table 1). The proportion of students who were from central urban areas (49.4% vs 35.3%, $P < 0.001$) and grade 4 students (55.1% vs 50.4%, $P < 0.01$) were higher in the intervention group. Additionally, the proportion of parents aged 18–29 and 30–39, the proportion of fathers with secondary education or below, and the proportion of children with no siblings were lower in the intervention group (all $P < 0.05$).

Table 2 shows that during the intervention period, influenza vaccination rate were significantly higher in the intervention group than the control group (ITT: 173 [10.9%] vs 130 [7.4%], $P < 0.001$; PP: 165 [10.6%] vs 116 [6.8%], $P < 0.001$), with an adjusted RR of 1.54 (95% CI: 1.23 to 1.93) in ITT analyses and an adjusted RR of 1.61 (95% CI: 1.27 to 2.03) in PP analyses. Subgroup analysis showed a greater intervention effect in non-central urban participants compared to those from central urban areas (ITT: adjusted RR: 1.88, 95% CI: 1.43 to 2.47 vs adjusted RR: 1.08, 95% CI: 0.73 to 1.60, P for interaction = 0.02; PP: adjusted RR: 1.96, 95% CI: 1.47 to 2.61 vs adjusted RR: 1.14, 95% CI: 0.76 to 1.71, P for interaction = 0.02). However, there was a non-significantly differential effect among grade 5 compared to grade 4 children (ITT: adjusted RR: 1.69, 95% CI: 1.20 to 2.38 vs adjusted RR: 1.44, 95% CI: 1.06 to 1.96, P for interaction = 0.54; PP: adjusted RR: 1.77, 95% CI: 1.23 to 2.55 vs adjusted RR: 1.51, 95% CI: 1.09 to 2.07, P for interaction = 0.54). Similarly, no significantly differences were observed in the intervention effect between male and female children (ITT: adjusted RR: 1.58, 95% CI: 1.15 to 2.15 vs 1.44, 95% CI: 1.04 to 1.99, P for interaction = 0.76; PP: adjusted RR: 1.73, 95% CI: 1.25 to 2.39 vs 1.50, 95% CI: 1.07 to 2.12, P for interaction = 0.64) (Additional file 2: Table S1).

At baseline, the mean total health literacy score for children was 11.4 (SD 2.2) in the ITT analysis and 11.4 (SD 2.2) in the PP analysis. After the intervention, there were no significant changes in the total health literacy scores for children in the intervention group compared to the control group, with P values of 0.21 in both ITT and PP analyses. Notably, there was a statistically significant increase in the knowledge component of children's health literacy scores in the intervention group post-intervention, with a mean difference of 0.12 (95% CI: 0.04–0.20) in ITT analyses and a mean difference of 0.12 (95% CI: 0.04–0.21) in PP analyses. No significant changes were observed in the attitude, behavior, or skills components of children's health literacy scores after the intervention in either analysis group (all $P > 0.05$). In terms of parental health literacy, there were no significant changes in the total health literacy scores, or any of its components

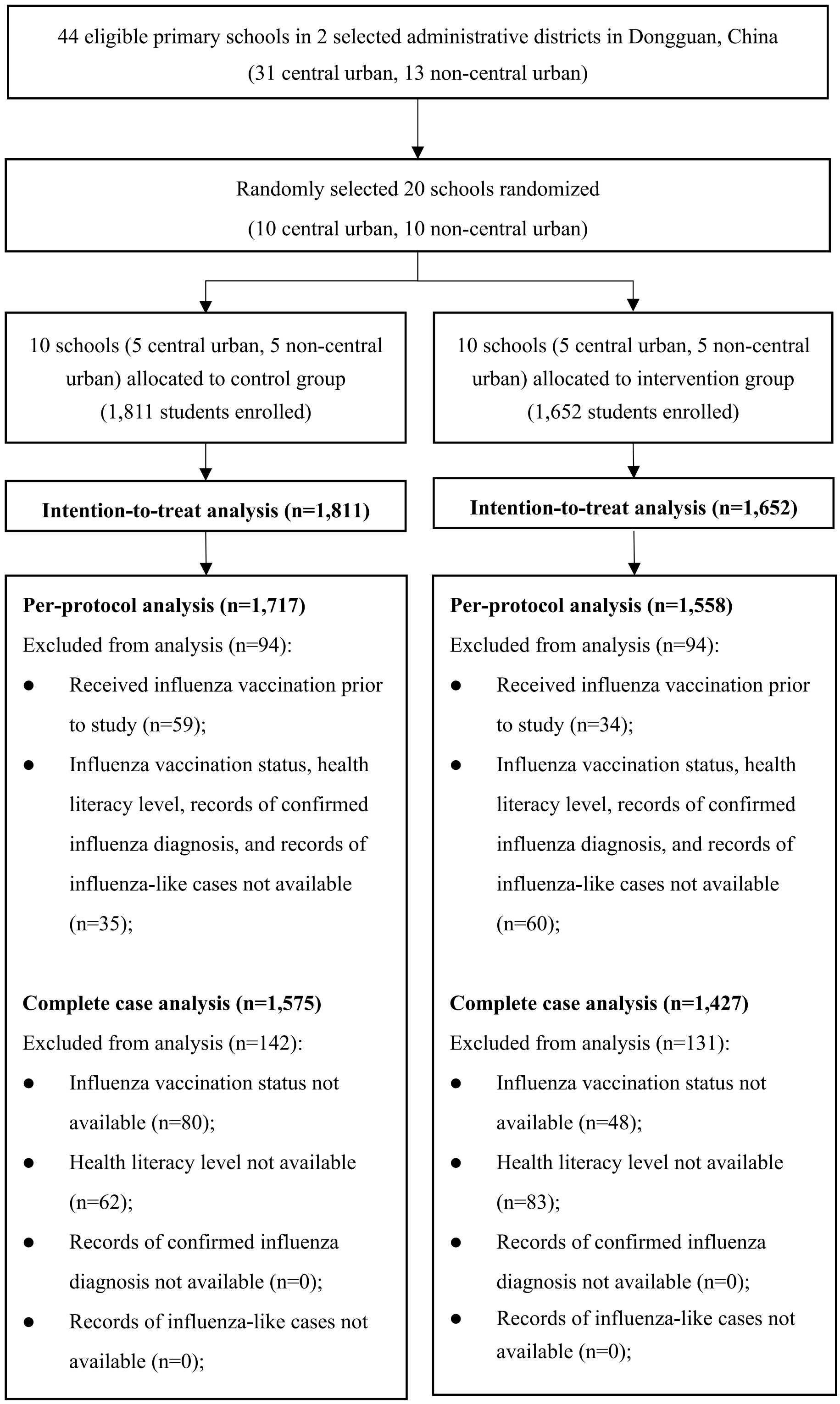

Fig. 1 Study flowchart

Table 1 Main characteristics of 3463 primary school students

	Total	Control	Intervention	*P* value
Number of participants, *N* (%)	3463 (100.0)	1811 (52.3)	1652 (47.7)	–
Town, *N* (%)				< 0.001
Central urban	1455 (42.0)	639 (35.3)	816 (49.4)	
Non-central urban	2008 (58.0)	1172 (64.7)	836 (50.6)	
Sex, *N* (%)				0.39
Female	1544 (44.6)	795 (43.9)	749 (45.3)	
Male	1919 (55.4)	1016 (56.1)	903 (54.7)	
Age, years, mean (SD)	9.9 (0.7)	9.9 (0.7)	9.9 (0.7)	
Grade, *N* (%)				< 0.01
4	1823 (52.6)	913 (50.4)	910 (55.1)	
5	1640 (47.4)	898 (49.6)	742 (44.9)	
Respondent, *N* (%)				0.55
Father	778 (22.5)	394 (21.8)	384 (23.2)	
Mother	2660 (76.8)	1403 (77.5)	1257 (76.1)	
Others	25 (0.7)	14 (0.8)	11 (0.7)	
Father's age, years, *N* (%)				< 0.001
18–29	48 (1.4)	29 (1.6)	19 (1.2)	
30–39	1771 (52.5)	979 (55.6)	792 (49.2)	
40–49	1429 (42.4)	694 (39.4)	735 (45.7)	
≥ 50	123 (3.6)	59 (3.4)	64 (4.0)	
Mother's age, years, *N* (%)				< 0.001
18–29	80 (2.3)	52 (2.9)	28 (1.7)	
30–39	2340 (68.6)	1276 (71.6)	1064 (65.3)	
40–49	961 (28.2)	439 (24.6)	522 (32.0)	
≥ 50	32 (0.9)	16 (0.9)	16 (1.0)	
Father's education, *N* (%)				< 0.01
Lower secondary or below	824 (24.6)	433 (24.7)	391 (24.4)	
Secondary	1093 (32.6)	616 (35.2)	477 (29.8)	
College	722 (21.5)	358 (20.4)	364 (22.7)	
Undergraduate or above	714 (21.3)	345 (19.7)	369 (23.0)	
Mother's education, *N* (%)				0.07
Lower secondary or below	949 (27.8)	501 (28.1)	448 (27.5)	
Secondary	1086 (31.9)	598 (33.6)	488 (30.0)	
College	811 (23.8)	404 (22.7)	407 (25.0)	
Undergraduate or above	563 (16.5)	279 (15.7)	284 (17.5)	
Father's occupation, *N* (%)				0.52
Manual	1776 (53.1)	920 (52.6)	856 (53.7)	
Non-manual	1072 (32.1)	558 (31.9)	514 (32.2)	
Others	494 (14.8)	270 (15.4)	224 (14.1)	
Mother's occupation, *N* (%)				0.41
Manual	1466 (43.0)	773 (43.4)	693 (42.6)	
Non-manual	960 (28.2)	512 (28.7)	448 (27.5)	
Others	982 (28.8)	496 (27.8)	486 (29.9)	
Family income, CNY/year, *N* (%)				0.22
≤ 100,000	1645 (47.5)	838 (46.3)	807 (48.8)	
100,000–200,000	1198 (34.6)	650 (35.9)	548 (33.2)	
≥ 200,000	620 (17.9)	323 (17.8)	297 (18.0)	
Number of siblings, *N* (%)				0.04
0	593 (17.1)	336 (18.6)	257 (15.6)	

Table 1 (continued)

	Total	Control	Intervention	*P* value
1	2218 (64.0)	1150 (63.5)	1068 (64.6)	
≥ 2	652 (18.8)	325 (17.9)	327 (19.8)	
Parent-rated child health, *N* (%)				0.71
Poor	24 (0.7)	13 (0.7)	11 (0.7)	
Average	397 (11.5)	200 (11.0)	197 (11.9)	
Good	3042 (87.8)	1598 (88.2)	1444 (87.4)	

SD standard deviation, *CNY* Chinese yuan, US$1 = 7 CNY

Table 2 Effects on influenza vaccination rate of students

	Total	Control	Intervention	*P* value	Intervention vs control	
					Adjusted RR (95% CI)	*P* value
Influenza vaccination rate of students, *N* (%)						
ITT	303 (9.1)	130 (7.4)	173 (10.9)	< 0.001	1.54 (1.23, 1.93)	< 0.001
PP	281 (8.6)	116 (6.8)	165 (10.6)	< 0.001	1.61 (1.27, 2.03)	< 0.001

Adjusted RR (95% CI): adjusted for town, sex, grade, father's age, mother's age, father's education, mother's education, father's occupation, mother's occupation, family income, number of siblings, and parent-rated child health

ITT intention-to-treat analysis, *PP* per-protocol analysis

(knowledge, attitude, behavior, skills), following the intervention (all $P > 0.05$) (Table 3).

The influenza incidence in the intervention and control groups was 1.3% and 0.9% (ITT analysis) and 1.3% and 1.0% (PP analysis), respectively. The adjusted IRRs (95% CI) were 1.80 (0.92, 3.54) in the ITT analysis and 1.68 (0.86, 3.36) in the PP analysis. The ILI incidence in the intervention and control groups was 3.6% and 3.5% (ITT analysis) and 3.9% and 3.7% (PP analysis), respectively. The adjusted IRRs (95% CI) were 1.01 (0.69, 1.49) in the ITT analysis and 1.01 (0.69, 1.48) in the PP analysis. The influenza vaccine protection rate in the intervention and control groups was 52.1% and 31.0% (ITT analysis) and 62.9% and 23.5% (PP analysis), respectively. However, no significant differences were observed between the intervention and control group in influenza incidence, the ILI incidence, or the influenza vaccine protection rate during intervention period (all $P > 0.05$) (Table 4).

Additional file 2: Tables S2–S4 show that results remained in the sensitivity analysis after excluding 273 children for whom data for either outcome variable were unavailable. Additional file 2: Table S5 shows the association between baseline characteristics and influenza vaccination rate of students. We found that children from non-central urban were significantly associated with increased vaccination uptake (ITT: adjusted RR: 1.50, 95% CI: 1.16 to 1.94, $P < 0.01$; PP: adjusted RR: 1.55, 95% CI: 1.19 to 2.03, $P = 0.001$). However, no significant associations were observed between other baseline characteristics (i.e., age, grade, sex, parents' age, parents' socioeconomic position, number of siblings, and parent-rated child health) and vaccination uptake.

Discussion

This cluster randomized controlled trial demonstrated that a health education intervention significantly increased influenza vaccination rates among primary school students in Dongguan, China. However, despite this statistically significant increase, the overall vaccination rate in the intervention group remained very low at 10.9%, which is substantially below the thresholds required for herd immunity. These findings highlight the critical need for more effective strategies and comprehensive programs to improve influenza vaccine uptake among children. Additionally, while the intervention improved certain aspects of health literacy, such as knowledge about influenza, it did not translate into a substantial increase in other health literacy components or a significant reduction in influenza incidence and influenza-like illness rates. Therefore, there is an urgent need to explore and implement multifaceted approaches that address the broader influences on vaccination rates, including accessibility, financial incentives, and integration of vaccinations into routine school health services.

In our study, the significant but moderate increase in influenza vaccination rates following the health education intervention was generally consistent with findings of previous interventional studies based on specific populations such as patients with chronic disease, healthcare workers, and elderly [10–12, 30]. However, this study

Table 3 Effects on health literacy level of children and their parents

	Baseline				After intervention				Intervention vs control, mean differences between post-intervention and baseline	
	Total	**Control**	**Intervention**	***P* value**	**Total**	**Control**	**Intervention**	***P* value**	**Adjusted *β* (95% CI)**	***P* value**
Child health literacy level (total), mean (SD)										
ITT	11.4 (2.2)	11.5 (2.1)	11.2 (2.3)	< 0.001	11.7 (2.1)	11.7 (2.1)	11.6 (2.1)	0.28	0.10 (−0.07, 0.26)	0.25
PP	11.4 (2.2)	11.5 (2.1)	11.2 (2.3)	< 0.001	11.7 (2.1)	11.7 (2.1)	11.6 (2.1)	0.38	0.10 (−0.07, 0.27)	0.26
Child health literacy level (knowledge), mean (SD)										
ITT	6.1 (1.1)	6.1 (1.1)	6.1 (1.1)	0.11	6.3 (0.9)	6.2 (1.0)	6.3 (0.8)	0.05	0.12 (0.04, 0.20)	< 0.01
PP	6.1 (1.1)	6.1 (1.1)	6.1 (1.1)	0.17	6.3 (0.9)	6.2 (1.0)	6.3 (0.8)	0.03	0.12 (0.04, 0.21)	< 0.01
Child health literacy level (attitude), mean (SD)										
ITT	1.7 (0.5)	1.8 (0.4)	1.7 (0.5)	< 0.001	1.7 (0.5)	1.8 (0.5)	1.7 (0.5)	< 0.001	−0.01 (−0.05, 0.03)	0.62
PP	1.7 (0.5)	1.8 (0.4)	1.7 (0.5)	< 0.001	1.7 (0.5)	1.8 (0.5)	1.7 (0.5)	< 0.001	−0.01 (−0.05, 0.04)	0.67
Child health literacy level (behavior), mean (SD)										
ITT	0.9 (0.4)	0.9 (0.4)	0.8 (0.4)	< 0.001	0.9 (0.5)	0.9 (0.4)	0.8 (0.6)	< 0.001	−0.01 (−0.05, 0.03)	0.68
PP	0.8 (0.4)	0.9 (0.4)	0.8 (0.4)	< 0.001	0.9 (0.5)	0.9 (0.4)	0.8 (0.6)	< 0.001	−0.01 (−0.04, 0.03)	0.68
Child health literacy level (skills), mean (SD)										
ITT	2.7 (1.4)	2.7 (1.4)	2.7 (1.4)	0.77	2.8 (1.4)	2.8 (1.4)	2.9 (1.4)	0.26	−0.00 (−0.12, 0.11)	0.95
PP	2.7 (1.4)	2.7 (1.4)	2.7 (1.4)	0.89	2.8 (1.4)	2.8 (1.4)	2.9 (1.4)	0.27	−0.01 (−0.12, 0.11)	0.89
Parental health literacy level (total), mean (SD)										
ITT	53.1 (10.5)	54.0 (10.3)	52.2 (10.7)	< 0.001	54.5 (11.1)	55.2 (11.0)	53.7 (11.2)	< 0.001	−0.09 (−0.82, 0.63)	0.80
PP	52.9 (10.5)	53.7 (10.3)	52.1 (10.7)	< 0.001	54.4 (11.1)	55.1 (11.0)	53.6 (11.3)	< 0.001	−0.17 (−0.90, 0.56)	0.64
Parental health literacy level (knowledge), mean (SD)										
ITT	5.5 (1.7)	5.6 (1.7)	5.5 (1.7)	0.37	5.8 (1.7)	5.8 (1.7)	5.8 (1.7)	0.92	0.02 (−0.11, 0.14)	0.80
PP	5.5 (1.7)	5.5 (1.7)	5.5 (1.7)	0.52	5.8 (1.7)	5.8 (1.7)	5.8 (1.7)	0.85	0.01 (−0.12, 0.14)	0.87
Parental health literacy level (attitude), mean (SD)										
ITT	39.4 (7.9)	40.0 (7.8)	38.7 (8.0)	< 0.001	40.0 (8.4)	40.6 (8.4)	39.3 (8.5)	< 0.001	−0.13 (−0.71, 0.44)	0.65
PP	39.3 (7.9)	39.9 (7.7)	38.7 (8.0)	< 0.001	39.9 (8.4)	40.5 (8.4)	39.3 (8.5)	< 0.001	−0.17 (−0.75, 0.41)	0.57
Parental health literacy level (behavior), mean (SD)										
ITT	4.8 (2.1)	5.0 (2.0)	4.5 (2.1)	< 0.001	4.9 (2.2)	5.0 (2.1)	4.7 (2.3)	< 0.001	0.10 (−0.05, 0.25)	0.18
PP	4.7 (2.0)	4.9 (2.0)	4.5 (2.1)	< 0.001	4.8 (2.2)	5.0 (2.1)	4.7 (2.3)	< 0.001	0.08 (−0.07, 0.23)	0.31
Parental health literacy level (skills), mean (SD)										
ITT	3.4 (1.7)	3.4 (1.7)	3.4 (1.7)	0.36	3.8 (1.8)	3.7 (1.8)	3.8 (1.7)	0.66	−0.08 (−0.21, 0.06)	0.26
PP	3.4 (1.7)	3.4 (1.7)	3.4 (1.7)	0.17	3.7 (1.8)	3.7 (1.8)	3.8 (1.7)	0.59	−0.09 (−0.23, 0.04)	0.17

Adjusted *β* (95% CI): adjusted for town, sex, grade, father's age, mother's age, father's education, mother's education, father's occupation, mother's occupation, family income, number of siblings, and parent-rated child health

ITT intention-to-treat analysis, *PP* per-protocol analysis

additionally assessed the effects of a comprehensive health education intervention among primary school students—a notable gap in the existing literature. Given the important role of school-aged children in influenza transmission within households and communities [31], our findings thus provided complementary epidemiological evidence to inform school-based influenza prevention policies. Our findings underscore the moderate effectiveness of educational interventions in increasing vaccine uptake, which strengthens the case for implementing school-located vaccination clinics. Such initiatives could be made more effective by concurrent health education programs, and policies could be crafted to support this dual approach.

Our findings provided indirect but persuasive evidence supporting the concept that children's attitudes toward vaccination might significantly shape parental decisions regarding immunizations [9, 32, 33]. The observed increase in vaccination rates in the children who received the health education intervention highlights the potential influence children may exert on their parents. This suggests that strategies designed to target health literacy improvements in children might not only enhance their individual knowledge and attitudes but could

Table 4 Influenza incidence, the ILI incidence, and the influenza vaccine protection rate during intervention period

	Total	Control	Intervention	*P* value	Intervention vs control	
					Adjusted IRR (95% CI)	*P* value
Influenza incidence, events/*N* (%)						
ITT	39/3463 (1.1)	17/1811 (0.9)	22/1652 (1.3)	0.24	1.80 (0.92, 3.54)	0.09
PP	38/3275 (1.2)	17/1717 (1.0)	21/1558 (1.3)	0.33	1.68 (0.86, 3.36)	0.13
ILI incidence, events/*N* (%)						
ITT	124/3463 (3.6)	64/1811 (3.5)	60/1652 (3.6)	0.78	1.01 (0.69, 1.49)	0.95
PP	123/3275 (3.8)	63/1717 (3.7)	60/1558 (3.9)	0.77	1.01 (0.69, 1.48)	0.95
Influenza vaccine protection rate[a], %						
ITT	42.9	31.0	52.1	0.39	NA	NA
PP	46.8	23.5	62.9	0.34	NA	NA

Adjusted IRR (95% CI): adjusted for town, sex, grade, father's age, mother's age, father's education, mother's education, father's occupation, mother's occupation, family income, number of siblings, and parent-rated child health

ITT intention-to-treat analysis, *PP* per-protocol analysis, *NA* not application

[a] Influenza vaccine protection rate calculated by excluding influenza or ILI cases prior to vaccination

also indirectly affect the broader community by altering parental perceptions and increasing the likelihood of vaccine acceptance. These observations underline the potential utility of incorporating child-focused health education into broader public vaccination campaigns and the development of immunization policies. Future policies might therefore consider the role of children as important ambassadors of health information, leveraging their capacity to influence household health behaviors and decision-making processes.

While our intervention significantly increased the uptake of influenza vaccinations, the observed post-intervention uptake rate (10.9%) remains well below the 60–80% threshold needed for herd immunity [34]. Several factors may influence influenza vaccination uptake, including financial considerations and parental vaccination behaviors. In China, influenza vaccines are not included in the national immunization program, and families must pay out-of-pocket, which may pose a financial barrier, especially for lower-income households. Policy interventions such as government subsidies or school-based vaccination programs could improve vaccine accessibility and uptake. Therefore, a multifaceted strategy that includes expanding vaccine access, financial incentives, incorporating vaccinations into national or regional immunization programs, and offering influenza vaccination within schools may be necessary to substantially increase vaccination rates among children [35, 36]. Additionally, while we did not assess parental influenza vaccination rates, previous studies indicate a strong correlation between parental and child vaccination behaviors [37–39]. We also acknowledge that family composition, particularly the number of children in a household, may influence vaccination decisions. However, as our study did not collect data on parental or sibling vaccination status, we were unable to analyze its influence. Future studies investigating whether the vaccination status of family members affects parental decisions regarding childhood vaccination are warranted.

Subgroup analysis by town showed a larger effect size among non-central urban students. This greater effect size may be explained by lower levels of hesitancy toward influenza vaccination in non-central urban areas, leading to higher participation and vaccination rates. Our results also showed that the effect size was greater for students in grade 5, although the result was not statistically significant. This trend could be attributed to the greater maturity of grade 5 students, potentially enabling them to better understand and communicate the health education information to their parents. These subgroup findings have important implications for the design and targeting of future health education interventions. The greater responsiveness among students from non-central urban areas suggests that interventions could be particularly effective in these communities, possibly due to an existing openness toward vaccination. Tailoring health education content to address specific local concerns and misinformation could further enhance vaccine uptake in these regions. Additionally, the potential greater receptiveness of grade 5 students to the educational material suggests that interventions might benefit from being adapted to the developmental stages of children. Educational programs that are age-specific and cater to the cognitive and emotional maturity of younger students could improve understanding and retention of health information, thereby increasing the likelihood of behavior change [40–42]. Such targeted strategies might also empower children to act as health advocates within their families, potentially amplifying the impact of vaccination campaigns.

In our study, no significant differences were observed in parental health literacy, total, attitude, behavior, and skills scores of child health literacy post-intervention. Notably, both children and parents showed high baseline overall health literacy levels: 11.4 out of 17 points for children and 53.1 out of 87 points for parents. This elevated baseline might be attributed to increased awareness of respiratory infections, likely due to the COVID-19 pandemic, as suggested by other studies [43, 44]. Given these high initial levels, the relative impact of our health education intervention may have been less discernible. This observation highlights the need for further research to explore the nuances of health literacy interventions in contexts where baseline literacy is already high. Future studies should consider the ceiling effect in health literacy improvements and investigate other potential benefits of health education in enhancing more specific or targeted health behaviors.

Moreover, we did not observe significant differences in influenza incidence, the ILI incidence, and the influenza vaccine protection rate during the intervention period. Since case identification relied on the municipal CDC's influenza surveillance network and the school-based reporting system, certain cases, such as those not requiring medical care or leading to school absence, may have remained undetected. This limitation, along with the potentially reduced sensitivity of the surveillance systems, may have led to an underestimation of the intervention's effects. Similar limitations in surveillance sensitivity have been documented in previous studies [45, 46]. Given the potential for a delayed effect of the intervention, cautious interpretation of above outcomes is needed. Future studies with longer follow-up periods and enhanced surveillance strategies are warranted to assess the impact of health education interventions on influenza-related outcomes.

Our study has some strengths, including random sequence generation, blinding of outcome assessors, and the use of school rather than the individual as the unit of intervention, which helped minimize contamination between groups. Additionally, vaccination uptake was confirmed through the CDC vaccination system, reducing recall bias. However, there were several limitations in the present study. First, the unexpectedly high baseline health literacy levels of both students and their parents could limit the generalizability of our findings to populations with lower initial health literacy. This high baseline may have also diminished the observable impact of the intervention, potentially skewing the efficacy assessment of the educational components. Second, the multifaceted nature of the intervention, which included various educational activities, complicates the identification of which specific component(s) were most effective. This complexity makes it challenging to pinpoint the elements of the intervention that are critical for enhancing influenza vaccination rates, thereby limiting the precise refinement of the intervention for future applications. However, despite the complexity, the interventions in this study are practical and can be replicated in other settings. Third, blinding participants was not feasible, which may have introduced social desirability bias in self-reported health literacy measures. Furthermore, the Hawthorne effect may have influenced parental vaccination decisions. Finally, the relatively short follow-up period restricted our ability to collect and analyze data on long-term outcomes such as the incidence rate of influenza post-intervention. We are planning to extend the follow-up to capture these important outcomes and provide a more complete picture of the effectiveness of interventions over time.

Conclusions

This cluster RCT showed that health education package (educational activities, educational booklets, reminders of vaccination, and vaccination souvenirs) moderately improved influenza vaccination rates among primary school students. While the improvement was significant, especially in non-central urban areas, vaccination rates remain below the threshold of the herd immunity. This highlights the need for integrated public health strategies that extend beyond education to effectively boost vaccination uptake. These findings support the development of comprehensive, scalable interventions essential for controlling influenza in schools and the broader community.

Abbreviations

ITT	Intention-to-treat
PP	Per-protocol
RCT	Randomized controlled trial
Dongguan CDC	The Center for Disease Control and Prevention of Dongguan City
ILI	Influenza-like illness
SD	Standard deviation
RR	Risk ratio
IRR	Incidence rate ratio
CI	Confidence interval

Supplementary Information

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Additional file 1. Trial protocol.

Additional file 2. Tables S1–S5. Table S1 Subgroup analysis of intervention effects on vaccination rate of students. Table S2 Effects on influenza vaccination rate of students (complete case analysis). Table S3 Effects on health literacy level of students and their parents (complete case analysis). Table S4 Influenza incidence, the ILI incidence, and the influenza vaccine protection rate during intervention period by intervention group (complete case analysis). Table S5 Association of baseline characteristics with influenza vaccination rate of students.

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Authors' contributions
All authors read and approved the final manuscript. The draft of the manuscript was written by LX and JYC. LX, JYC, WGX, XHH, and AZH initiated the study design. JYC, WGX, XHH, AZH, TYL, RHZ, JYX, and SYH performed the study and collected the data. JYC and SYH analyzed the data. LX, JYC, WGX, XHH, TYL, and JW revised it critically for important intellectual content, and all authors contributed to the final approval of the paper.

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Data availability
The datasets generated and/or analysed during the current study are not publicly available due to their containing information that could compromise the privacy of research participants, but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the Ethics Committee of the School of Public Health, Sun Yat-sen University (approval number: No. 2023107). All students and their parents or guardians gave written informed consent before participation.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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