Received: 17 August 2023 | Accepted: 8 January 2024

DOI: 10.1111/aphw.12528

ORIGINAL ARTICLE

Increasing vaccinations through an on-site school-based education and vaccination program: A city-wide cluster randomized controlled trial

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Abstract

Vaccination rates for mumps, measles, and rubella (MMR) and tetanus, diphtheria, pertussis, and polio (Tdap-IPV) fall short of global targets, highlighting the need for vaccination interventions. This study examines the effectiveness of a city-wide school-based educational vaccination intervention as part of an on-site vaccination program aimed at increasing MMR and Tdap-IPV vaccination rates versus on-site vaccination alone among sociodemographically diverse students from Berlin, Germany. The study was a 1:1 two-arm cluster randomized controlled trial, with schools randomly assigned to either the Educational Class Condition (ECC) or the Low-Intensity Information Condition (LIIC). Both received an on-site vaccination program, while students in the ECC received an additional educational unit. Primary outcomes were MMR and Tdap-IPV vaccination rates. In total, 6512 students from 25 randomly selected urban area secondary schools participated. For students providing their

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Funding information
German Federal Ministry of Health, Grant/Award Number: 1503/53105

vaccination documents on the day of the intervention (2273, 34.9%), adjusted Poisson mixed models revealed significant between-group differences in favor of the ECC (MMR: logRR = 0.47, 95%CI [0.01,0.92], RR = 1.59; Tdap-IPV: logRR = 0.28, 95%CI [0.10,0.47], RR = 1.32). When adjusting for socioeconomic and migration background, between-group differences became non-significant for MMR but remained significant for Tdap-IPV. Findings suggest that educational, school-based on-site vaccination appears to be a promising strategy for increasing vaccination uptake in adolescents.

KEYWORDS
educational, measles, school-based, self-efficacy, theory-based, vaccination

INTRODUCTION

Despite intensive efforts to prevent measles outbreaks worldwide, the World Health Organization's (WHO) goal of reaching herd immunity by 2020, defined as population-wide vaccination rates of 95% or higher, has not been met (WHO, 2020). In contrast, the past years have seen increasing outbreaks of measles and other vaccine-preventable diseases because of declining vaccination rates in the United States (US) and Europe (Chovatiya & Silverberg, 2020; Wilder-Smith & Qureshi, 2020). Barriers to health-care access and hesitancy related to immunization have been recognized as the main drivers of insufficient vaccination rates and low vaccination uptake (Smith et al., 2021; Wilder-Smith & Qureshi, 2020).

Adolescents are a key target group for interventions to increase vaccination uptake, as vaccination coverage is reportedly waning in adolescence compared to early childhood (Abdullahi et al., 2020). In Germany, for instance, the rate of children and adolescents with full mumps, measles, and rubella (MMR) vaccination coverage has stagnated at 93.6% for the past decade because of incomplete vaccination series, falling short of the WHO-defined target urgently needed to eradicate the disease (Poethko-Müller et al., 2019; WHO, 2020). Vaccination coverage against tetanus, diphtheria, pertussis, and polio (Tdap-IPV) is even lower. In 2018, approximately 90% of schoolchildren entering first grade in Germany were fully vaccinated against Tdap-IPV (Rieck, Feig, et al., 2020). After the initial immunizaton, German national health authorities recommend regular booster vaccinations every 5–10 years. However, over time, vaccination rates decline because of missed booster vaccinations and are therefore 10–20% lower in adolescents according to the German Standing Committee on Vaccination (Rieck, Steffen, et al., 2020; Ständige Impfkommission am Robert Koch-Institut [STIKO], 2016). School-based vaccination programs have shown promising results when it comes to increasing vaccination rates in children and adolescents, especially in high-income countries with strong school attendance (Perman et al., 2017).

Although the available evidence from randomized controlled trials (RCTs) is scarce, a literature review performed as part of the development of the present intervention found 10 RCTs addressing school-based vaccination interventions. A summary of the formerly published review (Bethke et al., 2022), including intervention conditions, outcome measures, and results, can be found in the supporting information (S1). In short, the majority of the studies focused on human papillomavirus vaccination (HPV) as an outcome measure (Davies et al., 2017; Forster et al., 2017; Grandahl et al., 2016; Rickert et al., 2015; Tull et al., 2019). Only three of these additionally addressed tetanus, diphtheria, and polio, (Daley et al., 2014; Esposito et al., 2018; Underwood et al., 2019), and none addressed measles vaccination. Four RCTs tested organizational elements such as reminder messages. Only four studies tested interactive educational intervention conditions, two of them educating school staff to be a multiplier for tailored educational units (Skinner et al., 2000; Underwood et al., 2019) and two working with medical experts in the schools (Esposito et al., 2018; Grandahl et al., 2016). Overall, the existing evidence suggests that school-based vaccination interventions seem to be an effective strategy to increase vaccination rates. However, the additional value of educational components remains unclear. For example, an Australian study showed that the intervention group that received an educational intervention showed an increase in knowledge about HPV compared to the control group that received only a school-based vaccination program; however, there was no difference in vaccination uptake (Skinner et al., 2000). Studies on this topic describe heterogeneous interventions, varying outcomes, and often rely on incomplete pre-trial vaccination data, thus making it difficult to draw conclusions regarding key intervention components and changes in actual vaccination behavior. In particular, the role of education with regard to the uptake of vaccinations has tended to go unnoticed in the past.

Addressing the additional benefit of educational components over and above a school-based on-site vaccination offer, a closer look should be taken at three behavior change theories, the Health Belief Model (HBM, Rosenstock, 1974), the Social Cognitive Theory (SCT, Bandura, 2001), and the Protection Motivation Theory (PTM, Rogers, 1975). Although not all prior RCTs were explicitly grounded on theories, psychological factors of these models have been used as foundation in prior educational vaccination programs in the past. The models highlight relevant behavioral change mechanisms and how they are assumed to be leading to intervention effects on vaccination uptake (Bethke et al., 2022). Considering a recently published review, it can be concluded that interventions offered outside of health-care institutions in alternative locations such as schools can effectively change vaccination behavior in people who already intend to receive vaccination by eliminating practical barriers (Brewer et al., 2017). Accordingly, within the framework of the HBM (Rosenstock, 1974), a special role is attributed to the cue to action, increasing the likelihood of engaging in health-promoting behavior. More specifically, the direct opportunity to be vaccinated on the schoolyard in a bus or in a tent, or the repeated presentation of this opportunity can serve as a cue to action. However, Brewer also suggests in line with HBM, that, especially facing persisting vaccination coverage problems, insights from psychological science can be useful (2017). Psychological factors proposed in the HBM are self-efficacy (i.e. strengthen the belief in one's own capacities), outcome expectancies, social norms, role models, and knowledge provision (i.e. knowledge of risk of a disease and the respective vaccination). Especially, the SCT (Bandura, 2001) emphasizes the role of self-efficacy in relation to behaviors such as seeking a vaccination. With regard to vaccination behavior, it can be assumed that mastery experience (e.g. receiving a vaccination), social modeling (e.g. someone else decides to receive a vaccination), verbal persuasions (e.g. positive encouragement from classmates), and improving physical and/or emotional states (e.g. through group discussions about fears) can increase the level of perceived self-efficacy. Furthermore, knowledge provision on health behavior and associated consequences is considered relevant to influence outcome expectancies (Bandura, 2001). Especially, knowledge provision on pathogens, immune system, vaccinations, vaccination calendar, and diseases can be used to address the psychological factors of perceived benefits and perceived threats (Rosenstock, 1974). According to Rogers (1975), health behavior such as vaccination behavior is more likely to be implemented when threat and coping appraisal are addressed. Risk communication for example can be applied to the MMR vaccination, providing information on the effectiveness of the MMR vaccinations, in relation to potential MMR-vaccine damage and the physical threat of a measles infection and individual vulnerability. Last, sociostructural factors, interacting with classmates, teachers, medical experts in group settings or within guided group discussions, should be considered as facilitators engaging in vaccination uptake (Bandura, 2001). Only two of the RCTs listed above considered specific theory-based psychological components such as beliefs and attitudes in the design (Grandahl et al., 2016; Underwood et al., 2019). However, it can be assumed that cues to action have a positive effect, especially in collaboration with other psychological, theory-based components (Becker, 1974; Rosenstock, 1974). As things stand, there is still very little evidence for this. Taking theory-based factors into account, these can make a decisive difference in the face of constantly declining/stagnating vaccination rates and require further attention.

In addition to behavior change theories, vaccination behavior has also been associated with sociodemographic characteristics, although the evidence is mixed and no clear conclusion can be drawn up to this point. Migration background and socioeconomic status (SES) are modifying factors in vaccination uptake. Data from the population-based German Health Interview and the Examination Survey for Children and Adolescents (KiGGS) revealed higher rates of basic vaccination in children with migration background compared to those without migration background, but lower booster vaccination coverage in those with migration background, underpinning the importance of considering demographic characteristics in vaccination uptake (Poethko-Müller et al., 2019). Further analysis of the KiGGs data revealed differing parental reasons for not vaccinating a child, on the basis that parents with deliberate and/or convenient reasons are generally less likely to have their children vaccinated. Deliberate reasons were expressed more in parents with high educational level, whereas convenient reasons were expressed less in parents with migration background (Diehl & Hunkler, 2022). A recent systematic review of 40 studies on interventions for increasing routine childhood vaccine uptake in low SES populations found that improving access is a key factor in reducing vaccination inequalities in marginalized population groups (Machado et al., 2021). A further systematic review of 41 studies focusing on interventions to reduce inequalities in vaccination uptake found the strongest evidence for locally designed multi-component interventions, particularly in urban, ethnically diverse, low-income, or disadvantaged populations (Crocker-Buque et al., 2017). However, migration- and SES-sensitive vaccination interventions tailored to the local needs of specific urban areas are still sparse, and little is known about effective vaccination approaches for adolescents with socio-demographically diverse backgrounds. Multi-component interventions seem promising regarding vaccination uptake in diverse target groups whilst recognizing differing sociodemographic backgrounds (Crocker-Buque et al., 2017).

There is an urgent need for effective interventions to reach herd immunity for measles, in particular, as well as for further diseases covered by MMR and Tdap-IPV. Reducing barriers by offering on-site vaccination is understood as an effective measure to increase vaccination rates in multiple public health approaches. Public health interventions must consider how to target small unvaccinated groups, as they are crucial for achieving effective herd protection. In this pragmatic trial, a multi-component intervention, defined by the Medical Research Council as a complex intervention, will be tested in order to create evidence that can be translated into practice (Skivington et al., 2021). More specifically, we aim to investigate the effectiveness of a theory- and evidence-based intervention to increase vaccination rates for MMR and Tdap-IPV in adolescent students attending schools in an urban area. To this end, we conducted a RCT offering on-site vaccination through the Prevention Bus alone or in combination with an educational unit aiming to foster vaccination-related knowledge and perceived vaccination self-efficacy. Drawing on the existing literature of the effectiveness of on-site vaccination offers (Bethke et al., 2022 and Table S1), both groups received this on-site vaccination offer. Our primary hypothesis would be that for the group with the additional educational unit, we expect higher vaccination rates post-intervention, compared to the group who received access to on-site vaccination alone. Furthermore, we account for the role of migration background and SES in relation to intervention effectiveness to yield unbiased results in this regard.

METHODS

Study design

The Prevention Bus study is a 1:1 two-arm cluster randomized controlled trial (cRCT) in randomly selected secondary schools from all urban districts within the inner-city boroughs of Berlin, Germany. The trial was conducted during the 2017/2018 school term. Students were randomized at the school level, to avoid potential contamination effects within schools. All participating students were offered on-site vaccinations (MMR, Tdap-IPV), carried out in the Prevention Bus. The Prevention Bus is a regular public transportation bus that was remodeled into a medical office in 2015. The detailed study design, procedures, technical details on the bus, and the analysis plan have been published elsewhere (Gellert et al., 2019). The Charité ethics board reviewed and approved the Prevention Bus study on April 6, 2017 (EA1/059/17), and the trial was registered at ISRCTN.com (ISRCTN18026662).

Participants

All secondary schools, public, private, and vocational, located within Berlin's urban boroughs were eligible for participation. The bus presence was planned for 5 days at each school to include at least three school classes per day, at high schools or integrated secondary schools, both representing secondary school types in Berlin, or vocational schools. Following economical considerations (Skivington et al., 2021), for example, a minimum utilization of the bus per school with comparable time of presence between schools, additional eligibility criteria included a minimum of 200 students. This includes students enrolled in grades 9–11 at secondary schools or a total number of 200 students per vocational school. A total of 75 schools were potentially eligible for participation. Based on a stratified, random order, 61 schools were selected and contacted via email, followed by a reminder email and a phone call for participation in the study until the required number of schools had confirmed their participation.

In total, 25 schools agreed to participate. See supporting information S2a for detailed SES and migration background information of participating schools.

All students in the pre-specified grades at the enrolled school were eligible for participation. Eligible students and their parents received paper-based consent forms and study information 1 week before the Prevention Bus visit. The information included a summary of the vaccinations offered (MMR and Tdap-IPV) and instructions on how to submit the signed forms and vaccination documents on the day of the intervention. All students had to give oral and written consent before any vaccination could be administered. Students under 18 years of age additionally needed a signed parental consent form to receive a vaccination. Further, parents of students younger than 15 years of age had to confirm the signed consent by telephone. For more information on the vaccination consent process, refer to supporting information S2a. Students had the option to withdraw participation at any time or to not answer the questionnaire. Data collection was anonymous.

Randomization and masking

In a first step, schools were stratified by the proportion of students with a migration background (i.e. below and above median) and the differing secondary school types (i.e. high school, vocational school, integrated secondary school). All potentially eligible schools were then randomly assigned within each stratum to one of two groups, the Educational Class Condition (ECC) or the Low-Intensity Information Condition (LIIC), before recruitment started (1:1) (Gellert et al., 2019; Suresh, 2011). The trial followed a single-blinded design. As strata size varied, a block randomization method and randomization within each cluster were performed before recruitment (Schulz & Grimes, 2002) using "blockrand" package in R. The previously performed pilot study, which was based on schools that were not included in the main study, highlighted the importance of clearly communicating the duration of the randomly allocated intervention conditions (ECC 90 min, LIIC 45 min) during the recruitment process (Bethke et al., 2022). The school heads assessed the general feasibility of the study in their school based on the time required for the intervention. Although schools remained blinded to their assigned intervention condition, blinding of the recruitment staff was not feasible, prompting the development of the standardized recruitment protocol. The protocol included information on offered vaccinations, communication with students, parents, and teachers, consent procedures, and bus parking arrangements, and did not differ between ECC and LIIC except for the required intervention time. Trained recruitment staff contacted schools according to the protocol, following the stratified, random order until one school had confirmed participation for every school week during the 2017/2018 academic calendar. Prior to the on-site visits, identical information regarding the available vaccinations and information on the procedure of vaccination delivery was provided to all schools, regardless of their intervention condition. All schools were unblinded and debriefed via email at the end of the school term. Study personnels carrying out the intervention on-site were not blind to intervention group assignments.

Procedures

The intervention conditions were developed based on a systematic literature review of current school-based, on-site vaccination RCTs and in accordance with the template for intervention description and replication (TIDieR) (Bethke et al., 2022). Considered were psychological factors from the SCT (Bandura, 2001), the HBM (Rosenstock, 1974), and the PTM (Rogers, 1975). Both conditions were developed by health psychologists in collaboration with physicians, nursing staff, and educators. Moreover, conditions were initially tested and validated together with school staff and students in a pilot study (Bethke et al., 2022). The intervention was developed to have minimal interference with school resources and as closely as possible to real world implementation conditions (Skivington et al., 2021). For more information on how procedures were established, please see the study protocol (Gellert et al., 2019).

All schools received on-site visits by a Prevention Bus study team consisting of two nurses, two physicians, and a bus driver. The prevention bus in the schoolyard provides a cue to action for getting vaccinated (Bandura, 2001; Rosenstock, 1974). Both ECC and LIIC were designed as group-based interventions and carried out in entire school classes. Single ECC and LIIC units were planned for a full school week for all eligible classes in the assigned schools.

Intervention units in the ECC lasted a maximum of 90 min and comprised an interactive educational unit (30 min) carried out by a trained physician. The educational unit comprised text, photo and video materials, and graphic illustrations. The educational unit offers knowledge about infections, how vaccinations work, risk communication about measles, and interactivity through open questions and group discussion using a role model. In the LIIC school classes, the total duration of the intervention unit was around 45 min. Physicians briefly (about 5 min) presented basic oral information on which vaccinations were offered and where and by whom it was applied. No additional or new information is shared besides organizational aspects that might influence self-efficacy, outcome expectancies, and threat and coping appraisal. In all ECC and LIIC school classes, the vaccination cards were checked in the classroom, and questionnaires were administered (10–20 min). This was followed by guided tour of the bus, where MMR or Tdap-IPV vaccinations were offered. ECC and LIIC classes spent the same amount of time in the bus (about 30 min). Receiving a vaccination is associated with a potential mastery experience and an increase in self-efficacy for all students in both conditions (Bandura, 2001). For a detailed description of the intervention conditions, refer to Figure S3, or the study protocol (Gellert et al., 2019). A summary table of the specific educational unit contents from the ECC including addressed psychological factors and the contents of the basic information from the LIIC is also publicly available (Bethke & Gellert, 2023).

For all outcomes, we used anonymous response/documentation formats, as prior consultations indicated that there were privacy concerns in the schools, among students and among parents regarding the utilization of a vaccination. The recruitment in the pilot study underpinned the importance of this approach. For this reason, linkage between questionnaire data assessed in the classroom and vaccination data assessed in the bus was only possible at aggregated class level.

Measures

The primary outcomes were vaccination rates for MMR and Tdap-IPV, which were operationalized as the total number of MMR and Tdap-IPV vaccinations delivered after class. Vaccination rates were calculated at class level, referring to how many vaccinations were delivered per class in relation to the need for vaccination with either MMR or Tdap-IPV (see S4). Because data in the Prevention Bus were documented anonymously and only at the class level, vaccination rates for MMR and Tdap-IPV were aggregated at class level for primary outcome analysis. If no student in a class had a vaccination card present, the school class could not be included in the primary outcome analysis. For descriptive reasons, we also documented vaccinations carried out at a later date in order to include students who did not bring their vaccination cards on the day of the intervention. Those students were defined as vaccination laggards. Adding the number of vaccinations given directly after class to the number of vaccinations administered to laggards provides the total number of vaccinations given while the bus was at the school.

Secondary outcomes included vaccination-related knowledge and perceived vaccination self-efficacy at the individual level. Both were assessed with a self-report questionnaire, validated in the pilot study; psychometric properties were evaluated as satisfactory (Bethke et al., 2022). The knowledge scale (sum score; min = 0; max = 6) included six single choice items addressing facts on vaccination, prevention, the spread of infectious diseases, herd immunity, and side effects. Self-efficacy was assessed with a short version of the European Health Literacy Survey Questionnaire (HLS-EU Q47) and included five items (4-point Likert-type scale ranging from 1 = *very difficult* to 4 = *very easy*; sum score; min = 5; max = 20) (Sørensen et al., 2015).

Covariates collected at the individual level included gender (0 = *male students*; 1 = *female students*), age (in years), migration background, and SES. Migration background was assessed with a validated German-language questionnaire for children and adolescents (Schenk et al., 2006). According to the instrument, a person has a migration status (0 = no; 1 = yes) if they meet at least one of the following criteria: the parents' country of birth was not Germany, the student was born outside of Germany, and/or a language other than German is spoken at home. The SES questionnaire (sum score; min = 4; max = 10) was based on a standard instrument formerly applied in Berlin schools by the Berlin Senate and takes into account parents' employment status and educational attainment (Delekat & Kis, 2001). This classification is comparable to the International Standard Classification of Education (ISCED) (OECD, 2015).

Statistical analysis

We calculated the sample size using GPower V.3.1.9.2, based on an expected increase in the MMR vaccination coverage from an initial rate of 88% to 97% in the ECC compared to the LIIC with an increase from 88% to 90%. The sample size was estimated with a 0.8 statistical power, a one-sided level of 0.05 α value, and an intraclass coefficient of 0.02 (Humiston et al., 2014). Because primary outcome data were analyzed at the school class level, we required a sample size of 335 participating classes (Gellert et al., 2019).

A multiple imputation (MI) procedure was performed with SPSS 27 separately for each intervention condition. Missing data were imputed at item level before we computed the self-efficacy scale (missing values of self-efficacy items ranging from 5.3% to 8.3%). In addition, we applied a MI procedure with fully conditional specifications and 20 imputed datasets (see S5).

Regarding primary outcome analyses on school class-based MMR and Tdap-IPV vaccination rates, we addressed the nested data structure (i.e. classes nested in schools) and the zero-inflation of the outcomes by using Poisson mixed models in Mplus 8.1. Imputed datasets were analyzed using a maximum-likelihood estimator. The intervention variable (LIIC = 0; ECC = 1) was modeled as a school-level predictor. Covariates were aggregated at the class level, as the individual linkage between vaccination data and predictors was not possible. First, the covariates age, gender, pre-intervention vaccination rate, need for vaccination, and class size were used as predictors of MMR (Model 1a) and Tdap-IPV (Model 1b) vaccination rates. Second, the covariates migration background and SES were modeled as additional covariates on MMR (Model 2a) and Tdap-IPV (Model 2b) vaccination rates to evaluate their role in vaccination behavior. To gain a better understanding of the intervention effects, intervention effect estimates from standardized model outputs were extracted.

With respect to secondary outcomes, we applied linear mixed models in Mplus 8.1 with three levels (students nested in classes in schools) predicting student-level vaccination-related knowledge (Model 3) and self-efficacy (Model 4). Again, the intervention variable was used as a school-level predictor.

Throughout the series of models, that is, Models 1a and 1b; Models 2a and 2b; and Models 3 and 4, we included predictors at class level in order to obtain comparable fixed effects between primary and secondary analyses across models.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

RESULTS

Between October 16, 2017 and June 29, 2018, a total of 25 schools, including 6512 students from 363 school classes, were allocated either to the ECC or the LIIC. Participant flow and withdrawal reasons are summarized in Figure 1.

Baseline characteristics, including participant demographics, are shown in Table 1. Of the participating students, 1424 (21.9%) attended high schools, 1714 (26.3%) integrated secondary schools, and 3374 (51.8%) vocational schools. The participation rate of contacted schools was different between conditions, with 15 schools (out of 30: 50%) participating in the ECC and 10 schools (out of 31: 32%) in the LIIC (see Figure 1), but was nonsignificant in relation to the intervention unit ($\chi 2[1] = 1.98$, $p = .159$), the migration background of schools ($\chi 2[1] = 0.06$, $p = .804$), or type of school ($\chi 2[2] = 2.71$, $p = .259$). Of the total sample, 2273 (34.9%) students brought their vaccination cards to school on the day of their scheduled intervention unit (ECC: 1306, 43.3%; LIIC: 967, 27.2%). Descriptive data for vaccination status by disease, dose, and need for vaccination can be found for each intervention group in Table 2. A complete MMR vaccination status was reported for 1215 (93.5%) students in the ECC and for 871 (90.3%) students in the LIIC. A need for MMR vaccination was shown by 85 students (6.5%) in the ECC and 94 students (9.7%) in the LIIC. Regarding Tdap-IPV vaccination, complete vaccination status was reported for 772 (59.3%) students in the ECC and for 579 (59.9%) students in the LIIC. Accordingly, in the ECC, 529 (40.7%) students and 387 (40.1%) in the LIIC presented a need for Tdap-IPV vaccination. Vaccination status (MMR and Tdap-IPV) was not documented properly for six vaccination cards in the ECC and for two vaccination cards in the LIIC.

Comparing primary outcomes across groups descriptively, a total of 45 MMR vaccination doses were administered directly after class in the ECC, while 35 MMR doses were administered in the LIIC. This represents an increase in the MMR vaccination rate from 93.5% to 96.5% for the ECC and from 90.3% to 93.7% in the LIIC for students who brought their vaccination cards on the day of the intervention. Regarding Tdap-IPV vaccination, 325 doses were administered

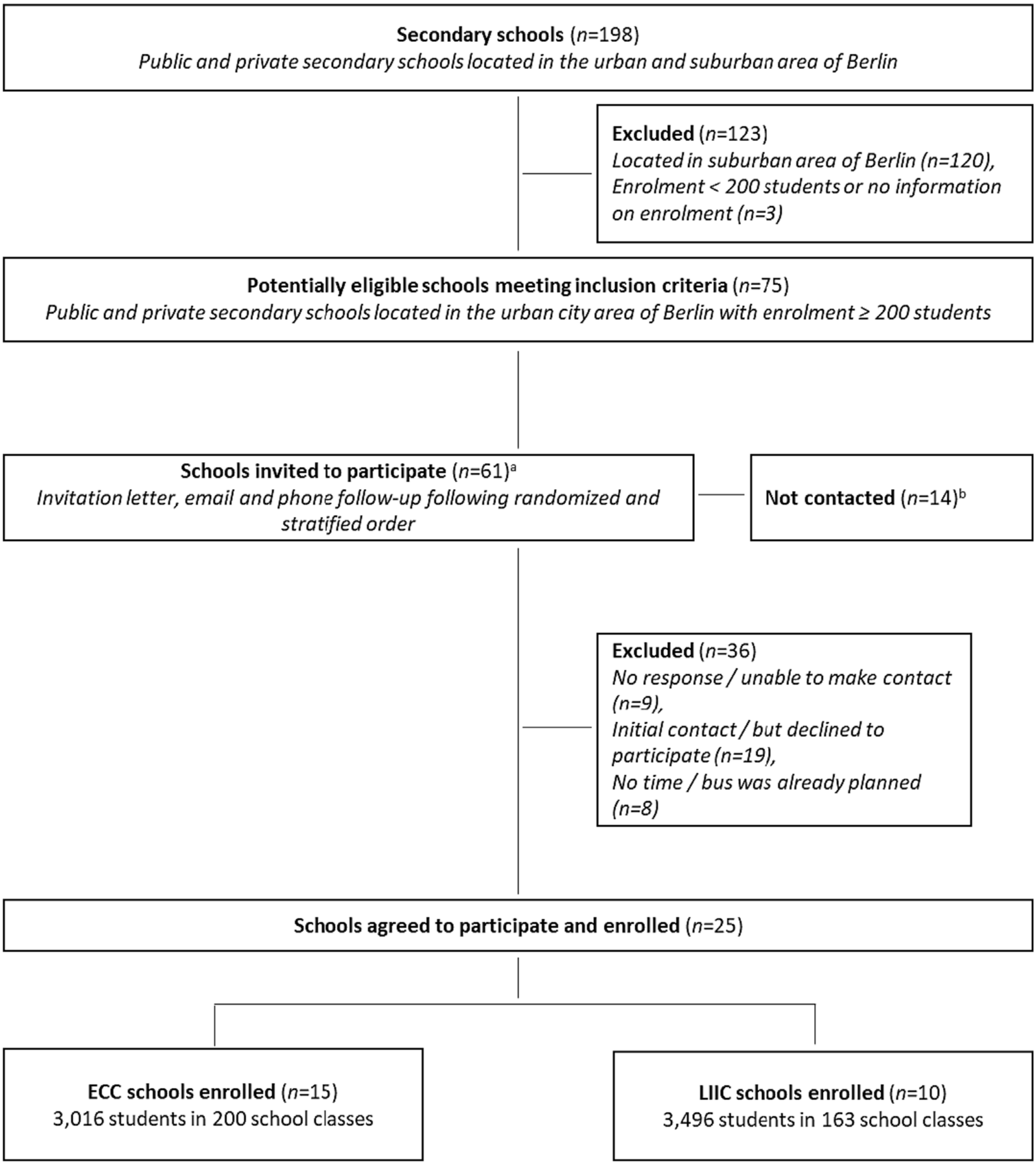

FIGURE 1 Trial profile. [a]Recruitment of schools followed a random order, until one school had confirmed participation for every school week of the school year 2017/2018. According to the study protocol, a stepwise invitation procedure was chosen as a recruitment method. For each cluster, the same number of schools were first contacted. When a school canceled, despite all activities, another school within the same cluster was contacted. [b]No further schools were contacted once the needed number of schools had agreed to participate. Abbreviations: ECC, educational class condition; LIIC, low-intensity intervention condition.

directly after class in the ECC and 211 doses in the LIIC. This represents an increase in the Tdap-IPV vaccination rate from 59.3% to 80.2% for the ECC and from 59.9% to 81.7% for the LIIC.

TABLE 1 Baseline characteristics of the intent-to-treat population.

	ECC $n = 3016$ students 163 school classes 15 schools	LIIC $n = 3496$ students 200 school classes 10 schools
School type - schools, *n* (%)		
High schools	4 (26.7)	4 (40.0)
Integrated secondary schools	6 (40.0)	1 (10.0)
Vocational schools	5 (33.3)	5 (50.0)
School type - students, *n* (%)		
High school	748 (24.8)	676 (19.3)
Integrated secondary school	1490 (49.4)	224 (6.4)
Vocational school	778 (25.8)	2596 (74.3)
Ø class size (SD)	18.5 (6.1)	17.5 (5.6)
Ø number of classes visited/school (SD)	10.9 (4.2)	20.0 (17.4)
Ø days on-site/school (SD)	4.7 (1.3)	5.2 (2.4)
Ø age in years (SD)		
$N = 6{,}477$	16.8 (3.7)	19.2 (4.2)
Female gender, *n* yes (%)		
$N = 6{,}464$	1499 (50.3)	1452 (41.7)
Migration background, *n* yes (%)		
$N = 6299$	1405 (48.1)	1005 (29.8)
SES, scale indicators, *n* yes (%) Education mother $N = 4537$		
No education degree	134 (7.0)	102 (3.9)
Elementary – Primary school degree	162 (8.5)	180 (6.8)
Secondary school degree	524 (27.4)	1034 (39.3)
High school degree	468 (24.5)	581 (22.1)
University degree	621 (32.5)	731 (27.8)
Education father $N = 4154$		
No education degree	131 (7.6)	99 (4.1)
Elementary – Primary school degree	147 (8.5)	194 (8.0)
Secondary school degree	406 (23.5)	917 (37.7)
High school degree	383 (22.2)	465 (19.1)
University degree	657 (38.1)	755 (31.1)
Employment status of parents $N = 6310$		
Both unemployed	236 (8.1)	215 (6.3)
One employed	941 (32.2)	834 (24.6)
Both employed	1742 (59.7)	2342 (69.1)

TABLE 1 (Continued)

	ECC $n = 3016$ students 163 school classes 15 schools	LIIC $n = 3496$ students 200 school classes 10 schools
Last seen a doctor, *n* yes (%) $N = 5921$		
Past month	1257 (47.2)	1466 (45.0)
Past 12 months	1128 (42.3)	1453 (44.6)
Past 1–5 years	237 (8.9)	298 (9.2)
More than 5 years ago	43 (1.6)	39 (1.2)

Abbreviations: ECC, educational class condition; LIIC, low-intensity intervention condition; SES, socioeconomic status.

In addition to vaccinations directly after class, also vaccinations of laggards were documented. These numbers are presented here on a descriptive level only. For further primary outcome analyses, only vaccinations directly after class are included. Combining MMR vaccinations carried out directly after class and for laggards, 102 (3.4%) vaccinations were carried out in the ECC and 81 (2.3%) in the LIIC. With respect to Tdap-IPV vaccination, 465 (15.4%) vaccinations were carried out in the ECC and 359 (10.3%) in the LIIC.

Concerning primary outcome analysis, Poisson mixed models predicting class-level MMR vaccination rate yielded a higher MMR vaccination rate in the ECC than in the LIIC ($\log RR = 0.47$, $SE = 0.23$, $p = .044$, 95% CI [0.01,0.92], $RR = 1.59$), when adjusting for covariates age, gender, class size, vaccination rate pre-intervention, and need for vaccination (Table 3). When additionally adjusting for SES and migration background, this effect on MMR became non-significant ($\log RR = 0.36$, $SE = 0.25$, $p = .147$, 95% CI [−0.13,0.85], $RR = 1.44$). The standardized effect from the same model translates into $\log RR_{stand} = 2.03$ ($RR_{stand} = 7.61$), reflecting a change in MMR vaccination rate in standard deviation units when the binary intervention predictor changes from zero (LIIC) to one (ECC). Across all covariates predicting MMR vaccination rate, only a need for vaccination showed significant positive associations. Models predicting class-level Tdap-IPV vaccination rates showed higher levels in the ECC compared to the LIIC ($\log RR = 0.28$, $SE = 0.10$, $p = .003$, 95% CI [0.10,0.47], $RR = 1.32$) when adjusting for the first set of covariates. When additionally adjusting for SES and migration background, the intervention predictor remained significant ($\log RR = 0.22$, $SE = 0.10$, $p = .031$, 95% CI [0.02,0.42], $RR = 1.24$), indicating robust findings on higher Tdap-IPV vaccination rates in the ECC than in the LIIC. In the standardized output, this effect translates into $\log RR_{stand} = 2.04$ ($RR_{stand} = 7.69$). Tdap-IPV vaccination rates were higher in classes with a lower SES and a higher need for vaccination.

Regarding vaccination-related knowledge, linear mixed models showed a significant difference ($B = 1.73$, $SE = 0.20$, $p < .001$, 95% CI [1.34, 2.12]) between ECC and LIIC, revealing superior vaccination-related knowledge levels in the ECC (Table 4). Moreover, we found significant relationships between covariates and knowledge. This indicates higher knowledge scores for classes with a higher proportion of older students, female students, a higher SES, and lower migration background. For self-efficacy, linear mixed models also revealed a significant difference ($B = 0.96$, $SE = 0.16$, $p = .010$, 95% CI [0.65,1.27]) between ECC and LIIC, with higher levels observed in the ECC. The covariates age and gender were significantly related to self-

TABLE 2 Documented vaccination status and number of doses delivered after the intervention unit.

Vaccination status for students with vaccination card present on the day of the intervention unit (after class) ***N*** **= 2273 (34.9% of the total sample)** ***n*** **(ECC after class) = 1306 (43.3% of the ECC)** ***n*** **(LIIC after class) = 967 (27.2% of the LIIC)**	**Before intervention**				**Vaccine doses delivered on-site after class**
	0 dose[b]	**1 dose**[b]	**2 doses**[d]	**≥3 doses**[d]	
	Basic vaccination to age 2 years (23 months), 2 doses[a]				**MMR, *n***
Mumps, *N* (%)	64 (2.8)	112 (4.9)	2051 (90.5)	40 (1.8)	After class
ECC, *n* (%)	32 (2.5)	51 (3.9)	1197 (92.0)	21 (1.6)	ECC: 45
LIIC, *n* (%)	32 (3.3)	61 (6.3)	854 (88.4)	19 (2.0)	LIIC: 35
Measles, *N* (%)	58 (2.6)	106 (4.7)	2051 (90.4)	53 (2.3)	
ECC, *n* (%)	31 (2.4)	48 (3.7)	1189 (91.3)	34 (2.6)	
LIIC, *n* (%)	27 (2.8)	58 (6.0)	862 (89.2)	19 (2.0)	
Rubella, *N* (%)	65 (2.9)	112 (4.9)	2051 (90.5)	38 (1.6)	
ECC, *n* (%)	33 (2.5)	52 (4.0)	1195 (91.9)	20 (1.5)	
LIIC, *n* (%)	32 (3.3)	60 (6.2)	856 (88.6)	3 (0.3)	
Missings, *N* (%)	8 (0.4)				
ECC, *n* (%)	6 (0.5)				
LIIC, *n* (%)	2 (0.2)				
	Need for vaccination		Complete vaccination status		
ECC, *n* (%)	85 (6.5)		1215 (93.5)		
LIIC, *n* (%)	94 (9.7)		871 (90.3)		

	0–1 dose[b]	**2–3 doses**[b]	**4 doses**[b]	**5 doses**[c]	**6 doses**[c]	**≥7 doses**[c]	
	Basic vaccination to age 1–3 years (14 months), 4 doses[a]			**Two booster vaccinations after 5–10 years (age 5–17 years)**[a]		**Booster vaccinations every 10 years (age ≥ 18 years)**[a]	**Tdap-IPV, *n***
Tetanus, *N* (%)	77 (3.4)	68 (3.0)	108 (4.8)	669 (29.5)	1,250 (55.1)	97 (4.2)	After class
ECC, *n* (%)	37 (2.8)	40 (3.1)	66 (5.1)	410 (31.5)	706 (54.2)	44 (3.4)	ECC: 325
LIIC, *n* (%)	40 (4.7)	28 (2.9)	42 (4.3)	259 (26.8)	544 (56.3)	53 (5.5)	LIIC: 211
Diphtheria, *N* (%)	80 (3.5)	68 (3.0)	118 (5.2)	683 (30.1)	1,236 (54.5)	83 (3.7)	
ECC, *n* (%)	39 (3.0)	39 (3.0)	70 (5.4)	417 (32.0)	700 (53.8)	37 (2.9)	
LIIC, *n* (%)	41 (4.2)	29 (3.0)	48 (5.0)	266 (77.5)	536 (55.5)	46 (4.7)	
Pertussis, *N* (%)	121 (5.4)	68 (3.0)	157 (6.9)	765 (33.7)	1,105 (48.7)	52 (2.3)	
ECC, *n* (%)	63 (4.8)	38 (2.9)	84 (6.5)	456 (35.0)	637 (48.9)	24 (1.9)	
LIIC, *n* (%)	58 (6.0)	30 (3.1)	73 (7.6)	309 (32.0)	468 (48.4)	28 (2.9)	
	Basic vaccination to age 1–3 years (14 months), 4 doses[a]			1 booster vaccination (age 9–14 years)[a]			
Polio, *N* (%)	101 (4.5)	123 (5.4)	595 (26.2)	1241 (54.7)	187 (8.2)	21 (0.9)	
ECC, *n* (%)	50 (3.8)	72 (5.6)	352 (27.0)	718 (55.1)	101 (7.8)	9 (0.7)	

TABLE 2 (Continued)

	0–1 dose[b]	**2–3 doses[b]**	**4 doses[b]**	**5 doses[c]**	**6 doses[c]**	**≥7 doses[c]**	
	Basic vaccination to age 1–3 years (14 months), 4 doses[a]			**Two booster vaccinations after 5–10 years (age 5–17 years)[a]**		**Booster vaccinations every 10 years (age ≥ 18 years)[a]**	**Tdap-IPV, *n***
LIIC, *n* (%)	51 (5.3)	51 (5.2)	243 (25.2)	523 (54.1)	86 (8.9)	12 (1.2)	
Missings, *N* (%)	8 (0.4)						
ECC, *n* (%)	6 (0.5)						
LIIC, *n* (%)	2 (0.2)						
	Need for vaccination			Complete vaccination status			
ECC, *n* (%)	529 (40.7)			772 (59.3)			
LIIC, *n* (%)	387 (40.1)			579 (59.9)			

[a]Vaccination recommendation of the German Vaccination Committee (Ständige Impfkommission am Robert Koch-Institut [STIKO, Epid. Bull. 34/2016]).
[b]Indication for a vaccination.
[c]Conditional indication for vaccination for tetanus, diphtheria, and/or pertussis, depending on time lag to previous vaccination.
[d]No indication for a vaccination.
Abbreviations: ECC, educational class condition; LIIC, low-intensity intervention condition, MMR, mumps, measles, and rubella; Tdap-IPV, tetanus, diphtheria, pertussis, and polio.

efficacy, indicating higher self-efficacy scores for classes with a higher proportion of younger students and male students.

For a detailed descriptive presentation of the secondary outcomes, please see S6.

DISCUSSION

This study demonstrated that an outreach educational vaccination program can effectively increase MMR and Tdap-IPV vaccination rates, and result in higher vaccination-related knowledge and self-efficacy within a population of adolescents in an urban setting. The intervention was effective in providing catch-up primary vaccinations for MMR and booster vaccinations for Tdap-IPV for those students providing vaccination documents. Schools in the intervention group receiving the on-site vaccination offer in combination with an educational unit, including risk communication in order to promote vaccination-related knowledge and self-efficacy, showed a stronger increase in vaccinations rates and exceeded the MMR vaccination threshold of 95% for herd immunity by the end of the intervention (WHO, 2020). This was not the case in the control group, where students received an on-site vaccination offer accompanied by only basic information. For Tdap-IPV, a coverage above 80% was reached in both study groups, whereas the observed increase was stronger in the intervention group with the educational unit when statistically controlling for age, gender, pre-intervention vaccination rate, need for vaccination, and class size. When additionally statistically controlling for SES and migration background, the effect for the Tdap-IPV vaccination remained stable, whereas the group difference for MMR was no longer significant.

Our results align with prior RCTs implementing on-site vaccination interventions in school settings (for an overview, see Bethke et al., 2022). Nonetheless, there are important differences compared to other studies. Trials introducing standardized, evidence-based educational

TABLE 3 Estimates for Poisson mixed models predicting changes in primary outcomes at the class level.

Fixed effects	Model 1a: MMR vaccination rate[a] logRR (SE)	p	95% CI	RR	Model 2a: MMR vaccination rate[a] logRR (SE)	p	95% CI	RR	Model 1b: Tdap-IPV vaccination rate[b] logRR (SE)	p	95% CI	RR	Model 2b: Tdap-IPV vaccination rate[b] logRR (SE)	p	95% CI	RR
Class level																
Average age in class (years)	0.03 (0.03)	.325	−0.03; 0.09	1.03	0.05 (0.04)	.178	−0.02; 0.12	1.05	0.02 (0.02)	.116	−0.01; 0.05	1.02	0.01 (0.02)	.504	−0.02; 0.05	1.01
Gender (0 = class with male students only; 1 = class with female students only)	−0.38 (0.46)	.404	−1.27; 0.51	0.68	−0.42 (0.45)	.345	−1.30; 0.46	0.66	−0.23 (0.19)	.222	−0.60; 0.14	0.80	−0.23 (0.18)	.208	−0.59; 0.13	0.79
Class size	−0.01 (0.02)	.716	−0.05; 0.04	0.99	−0.01 (0.02)	.755	−0.05; 0.04	0.99	0.02 (0.01)	.098	−0.00; 0.03	1.02	**0.02 (0.01)**	**.040**	**0.00; 0.04**	**1.02**
Vaccination rate pre-intervention	−0.70 (0.55)	.197	−1.77; 0.37	0.49	−0.61 (0.56)	.274	−1.70; 0.48	0.54	−0.29 (0.23)	.207	−0.74; 0.16	0.75	−0.18 (0.23)	.440	−0.63; 0.28	0.84
Vaccination need	**0.36 (0.07)**	**<.001**	**0.21; 0.50**	**1.43**	**0.33 (0.08)**	**<.001**	**0.17; 0.48**	**1.38**	**0.18 (0.02)**	**<.001**	**0.14; 0.22**	**1.20**	**0.19 (0.02)**	**<.001**	**0.15; 0.22**	**1.20**
Socioeconomic status					0.04 (0.19)	.826	−0.33; 0.41	1.04					**−0.23 (0.08)**	**.004**	**−0.38; −0.07**	**0.80**
Migration background					0.66 (0.64)	.301	−0.59; 1.90	1.94					−0.14 (0.27)	.587	−0.66; 0.38	0.87
School level																
Intervention (0 = LIIC; 1 = ECC)	**0.47 (0.23)**	**.044**	**0.01; 0.92**	**1.59**	0.36 (0.25)	.147	−0.13; 0.85	1.44	**0.28 (0.10)**	**.003**	**0.10; 0.47**	**1.32**	**0.22 (0.10)**	**.031**	**0.02; 0.42**	**1.24**

[a]Models 1a and 2a: $n = 121$ school classes from 24 schools with a need for MMR vaccination. Predictors were grand-mean centered. Unstandardized parameter estimates. Significant effects are in bold.

[b]Models 1b and 2b: $n = 278$ school classes from 25 schools with a need for Tdap-IPV vaccination. Predictors were grand-mean centered. Unstandardized parameter estimates. Significant effects are in bold.

Abbreviations: CI, confidence interval; ECC, educational class condition; LIIC, low-intensity intervention condition; logRR, logarithm of rate ratio; MMR, mumps, measles, and rubella; SE, standard error; RR, rate ratio. Tdap-IPV, tetanus, diphtheria, pertussis, and polio.

TABLE 4 Estimates for linear mixed models predicting vaccination-related knowledge and self-efficacy at the student level.

Fixed effects	Model 3: vaccination-related knowledge[a] ICC (class level) = 0.12 ICC (school level) = 0.32 Estimate (SE)	p	95% CI	Model 4: vaccination-related self-efficacy[a] ICC (class level) = 0.04 ICC (school level) = 0.05 Estimate (SE)	p	95% CI
Student level						
Intercept	**2.67 (0.15)**	**<.001**	**2.37; 2.97**	**14.43 (0.12)**	**<.001**	**14.20; 14.66**
Class level						
Average age in class (years)	**0.05 (0.02)**	**.005**	**0.01; 0.08**	**−0.05 (0.02)**	**.022**	**−0.09; −0.01**
Gender (0 = class with male students only; 1 = class with female students only)	**0.62 (0.21)**	**.003**	**0.21; 1.03**	**−0.70 (0.25)**	**.006**	**−1.19; −0.20**
Class size	−0.01 (0.01)	.535	−0.02; 0.01	0.01 (0.01)	.679	−0.01; 0.02
Socioeconomic status	**0.23 (0.08)**	**.003**	**0.08; 0.38**	0.09 (0.09)	.322	−0.09; 0.26
Migration background	**−0.64 (0.20)**	**.002**	**−1.04; −0.24**	0.20 (0.28)	.466	−0.34; 0.74
School level						
Intervention (0 = LIIC; 1 = ECC)	**1.73 (0.20)**	**<.001**	**1.34; 2.12**	**0.96 (0.16)**	**.010**	**0.65; 1.27**

[a]Model 3 and Model 4: $N = 6512$ students from 363 classes and 25 schools, average class size 17.94 students. Predictors were grand-mean centered. Unstandardized parameter estimates. Significant effects are in bold. Variance of random intercept: 1.60 (0.03), $p < .001$ (Model 3); 6.35 (0.12), $p < .001$ (Model 4).
Abbreviations: CI, confidence interval; ECC, educational class condition; LIIC, low-intensity intervention condition; SE, standard error.

programs are rare. Results typically reflect group differences regarding increase rates while neglecting vaccination base rates before intervention, which are meaningful regarding effective herd protection (Abdullahi et al., 2020; Bethke et al., 2022). For the students who brought their vaccination documents on the day of the intervention, we were able to show that the MMR vaccination rate increased from the base rate to above the critical threshold. Furthermore, most school vaccination studies mainly target adolescents in the context of HPV/hepatitis or influenza vaccination campaigns (Davies et al., 2017; Forster et al., 2017; Grandahl et al., 2016; Humiston et al., 2014; Rickert et al., 2015; Skinner et al., 2000; Tull et al., 2019); few studies consider Tdap-IPV booster vaccinations (Daley et al., 2014; Esposito et al., 2018; Underwood et al., 2019), and none offer basic measles immunizations. The increase in the MMR vaccination rate underlines the public health relevance of the study findings. Measles vaccination became mandatory for all school children in some high-income countries, including Germany. Nevertheless, taking into account further countries and other vaccinations, it is essential to address vaccine barriers, especially in selected subgroups with low vaccine coverage to achieve comprehensive vaccination rates needed for herd immunity. Lowering these barriers remains a critical goal in public health as this can lead to widespread vaccination uptake in the population.

In addition to the aim of increasing vaccination rates by providing access to on-site vaccination, this study especially addressed education of students as a factor associated with immediate and also long-term vaccination uptake (Bandura, 2001; Brewer et al., 2017; Gellert et al., 2019). Prior studies have often neglected complex decision-making processes underlying the decision to vaccinate or not. The present study design draws from a literature review we conducted, incorporating evidence from recent RCTs regarding the target population and school-based vaccinations. Furthermore, the elements of the educational intervention were based on factors of psychological models of behavior change, including vaccination-related knowledge and self-efficacy (Bandura, 2001; Gellert et al., 2019; Rogers, 1975; Rosenstock, 1974). Additionally the on-site procedures, materials, and questionnaires were piloted and validated before this study started (Bethke et al., 2022). The higher levels of vaccination-related knowledge following an educational intervention compared to an intervention without an educational component are consistent with other findings (Davies et al., 2017; Esposito et al., 2018). The findings show that vaccination-related self-efficacy was substantially higher for students participating in the educational unit. Also in the light of the recent COVID-19 pandemic as a global health crisis, this study supports the innovative potential of on-site vaccinations as part of public health initiatives to reach diverse populations. Over the course of the pandemic we saw progress in vaccination programs in terms of ease of access, very few interventions used educational components and, if so, mostly only at the mass level via flyers, posters, radio ads, television spots, or online posts (Ali et al., 2020). Increasing easy access without additional provision of a robust educational component has mostly not been sufficient to increase the COVID-19 vaccination levels to above the herd immunity threshold in many high-income countries. In terms of research, before the pandemic, there were relatively few publications, on reasons why people do not get vaccinated. More recent literature suggests that in the context of COVID-19, fear of the disease is associated with higher vaccination rates, but acceptance is low when social or economic consequences are feared (Bendau et al., 2021). In sum, in addition to providing low-threshold vaccination services, future interventions should aim fostering adolescents' vaccination-related skills and psychological capabilities. This may contribute to vaccination uptake not only in short term but also in the long run (Brewer et al., 2017).

Our study generated importantly needed additional insights related to the covariates SES and migration background in vaccination interventions. After controlling for SES and migration background, the increase in MMR vaccination was no longer significantly higher compared to the control group. This finding might be because of the fact that this study's population of students in need of MMR vaccination was relatively small. Regarding Tdap-IPV vaccination, the number of students in need of vaccination was substantially higher, and the initial findings remained stable in the adjusted models. Taken together, future studies should aim to include large study populations when addressing sociodemographic variables in the context of unmet MMR vaccination needs. In line with previous research, migration background did not diminish the deliberate intention to receive a vaccine in our study (Diehl & Hunkler, 2022). Moreover, our findings indicate that vaccine uptake is not less pronounced in students with a migration background. Regarding SES, we provide evidence that knowledge increase was smaller among low-SES students, while Tdap-IPV vaccination uptake was higher. This can be taken as an indication that educational offers should, if possible, be designed more in accordance with socio-demographic aspects or could be offered more intensively in regarding subgroups. The higher vaccination uptake rates confirm previous findings that offering access to vaccination is a key factor when it comes to increasing vaccination rates in hard-to-reach populations (Crocker-Buque et al., 2017; Machado et al., 2021). Our study results can serve as an indicator that the combined approach with low-threshold access and education is particularly suited to address the needs of diverse populations.

Practical implications

When planning future intervention programs, up to this point it seems to be well supported by evidence that multi-component interventions, reducing barriers, for example, through local outreach programs, that is, at schools, increase the uptake of vaccinations (i.e. Davies et al., 2017; Esposito et al., 2018; Machado et al., 2021; Skinner et al., 2000). By additionally offering health education to the vaccination offer, one can efficiently expand on-site services and increase stagnating vaccination coverage (Brewer et al., 2017). Furthermore, in the present study, a physician conducted the educational unit offered to students as part of the intervention. Because we have developed a standardized protocol, including training, this intervention could also be delivered by a nurse or trained educator in school settings after further evaluation in future studies. Also, study results can be used to develop more tailored interventions for subgroups. Given that Tdap-IPV vaccination uptake was lower in high-SES students, an increase in parental involvement might be an impactful strategy (Abdullahi et al., 2020; Smith et al., 2021). Lower self-efficacy levels were found in particular among students with a migration background and females. An effective approach might be to offer a comprehensive module that addresses diverse needs by offering tailored short standalone exercises and small group exercises.

Strengths, limitations, and suggestions for future research

Strengths of the present study include the randomly selected schools within an urban area, the large sample size, measuring actual vaccination uptake instead of merely measuring self-reported vaccination behavior or vaccination intentions, and the consideration of SES and migration background as explanatory factors. Nevertheless, there are several limitations of the present study. First, only 35% of the students brought their vaccination card with them on the day of the intervention. Even though this figure is comparable to other studies, reasons for not bringing vaccination documents from home need to receive more attention (Bethke et al., 2022). Although the final vaccination decision rests with the students themselves, bringing vaccination documents depends in part on teacher engagement and parent outreach. These aspects appear to have been insufficient and merit further amplification in future studies. As a result, we strongly suggest digitalizing vaccination cards, as this can reduce barriers in vaccination documentation and may increase participation rates and vaccination uptake (Brewer et al., 2017). Reasons why parents may not have been willing to provide the vaccination documents should also be addressed and, where appropriate, differentiated and addressed between deliberate and convenience (Diehl & Hunkler, 2022). Nevertheless, among the group of students who fulfilled the vaccination card requirement, our results showed a statistically significant difference between students in the combined condition (educational unit and on-site vaccination) compared to students with on-site vaccination alone. It should be pointed out that the significance of the increase in the vaccination rate can only be determined for those students who have brought their vaccination documents with them. Although our sample was comparably large, especially for generalizability and public health relevance, this result should be replicated in larger samples. Second, a limitation of this study is that intervention conditions differed in length. The study took place under real-life conditions with a strong focus on ecological validity. Because resources such as study staff, that is, medical staff who otherwise work in limited staff clinical care settings, as well as school teaching hours and teaching staff are limited, we opted for a shorter basic information unit. However, based on experience of the pilot study, the communication of the duration of the intervention units was identified as crucial regarding the recruitment of schools. Although the recruiters used standardized recruitment protocols adapted to the different intervention lengths, we cannot rule out selection bias because of the duration of the intervention. We suspect that some school heads might have been aware of their allocation to a basic information respectively vaccination only condition based on the requested timeslot of 45 min per school class, which could have impacted their decision to participate in the study. Schools seemed more interested in participation if besides vaccination an educational added value for students was expected. This also appears to be reflected in the variation in vaccination card return rates across intervention conditions. To control for a systematic difference between the groups, we included in the analysis of primary and secondary outcomes not only differentiated sociodemographic data but also vaccination card-related data, the vaccination rate in the class, and the absolute number of students in need of vaccination. Following this, we highly recommend that future studies take this into account during the study planning phase and include intervention conditions of equal duration and offer alternative education if the monetary support of the study allows this. Dropout analysis revealed no statistically significant difference in the rate of acceptance for study participation between the schools contacted. Because the teachers and students on site had no knowledge that there were other intervention groups and primary outcome analysis controlled for corresponding variables, we assume that withdrawal differences at school level and vaccination card return rate at individual level had no influence on the results. Third, we did not have a control group without an on-site vaccination offer, where solely vaccination uptake at regular medical services outside of schools would have been measured. Following the SCT and the HBM, both intervention conditions included psychological factors such as self-efficacy, through possible mastery experience by direct vaccination (Bandura, 2001), or a cue to action, represented by the presence of the prevention bus in the schoolyard (Rosenstock, 1974). The effectiveness of outreach, school-based immunization has been well established (Davies et al., 2017; Esposito et al., 2018; Humiston et al., 2014). Nevertheless, in this study, we pursued the question of the added beneficial effect of an educational unit in combination with an on-site vaccination on actual vaccination behavior. The educational unit addressed more complex aspects of decision-making for vaccination as aiming at the improvement of psychological, theory-based behavior change aspects such as outcome expectancies, perceived threats and benefits, or perceived self-efficacy (Bandura, 2001; Rogers, 1975; Rosenstock, 1974). We were able to show a stronger increase in vaccination rates in the group that received the educational unit in addition to the vaccination offer compared with those who received the vaccination offer alone. While this test follows our primary hypothesis, which based on the ground truth that a vaccination offer is effective, future trials may test the educational unit with vaccination offer versus vaccination offer alone versus educational unit alone versus neither educational unit nor on-site vaccination offer. While this design was beyond the scope of the present study and likely less feasible in the school setting, it would give further insights into the interplay of cue to actions (i.e. the vaccination offer) and psychological factors (i.e. the educational unit). Fourth, the combination in this multicomponent intervention consists of evidence-based and theory-based intervention parts. Behavior change models assume that what increases the probability of adopting a behavior is actually the combination of different aspects that work in orchestration and support the achievement of an adequate increase in vaccination rates (Bandura, 2001; Rogers, 1975; Rosenstock, 1974). A summary of addressed psychological factors included in the educational unit was published (Bethke & Gellert, 2023). The chosen approach obviously prevents drawing absolute conclusions about the efficacy of single intervention components such as a group discussion versus no group discussion. When performing a study outside of laboratory conditions, it is always a challenge to meet the needs of diverse target groups and the requirements of real-life settings. Regarding vaccination uptake, there is considerable evidence that the appropriate approach involves a combination of different intervention components, particularly for multicomponent interventions with an RCT design, reducing vaccination-related barriers (Machado et al., 2021). In sum, when translating scientific evidence, feasibility and ecological validity should have already been considered when planning the intervention, as otherwise the entire intervention could fail in practical implementation (Kessler & Glasgow, 2011).

CONCLUSION

In conclusion, one of the greatest challenges in achieving vaccination rates that meet herd immunity thresholds or fulfilling requirements regarding regular boosters is engaging the small percentage of individuals who hesitate or forget to get vaccinated. Notably, important drivers of low vaccination rates are not people who have a negative attitude toward vaccination, but rather those who lack opportunities and information to make the decision to get vaccinated (Brewer et al., 2017). Vaccination programs that apply low-threshold approaches to reach the broad population are needed. Furthermore, the role of sociodemographic aspects, which show large heterogeneity across individuals within schools and classes, is often overlooked. Considering that vaccination campaigns usually entail a large organizational effort and high costs, it is worthwhile to include relevant success criteria in the planning phase. While offering low-threshold vaccination programs alone in this field, it may not be sufficient to face the complex barriers regarding vaccination behavior. Our study shows that low-threshold approaches with immediate access to vaccination in combination with a target group-appropriate educational unit in schools are effective. Our findings suggest that schools are an appropriate place to successfully implement both basic and booster vaccination programs for adolescents from diverse sociodemographic backgrounds.

ACKNOWLEDGMENTS

We acknowledge the contribution of Claudia Hartmann and André Solarek in the study preparation and organization. We thank the Prevention Bus team for their work, enthusiasm, constant feedback, and team spirit. In addition, we would like to thank the school headmasters, teachers, caretakers, parents, and student participants for supporting and participating in this study. This study was funded by the German Federal Ministry of Health (BMG; Grant Number 1503/53105). Open Access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTEREST STATEMENT

NB, JS, JLOS, and JK declare no competing interest. PG received payments from Pfizer for a presentation.

HvB received payments for lectures/presentations/manuscript writing by CSL Behring and Takeda. He further received payments in his function as a Board Member from Bayer Healthcare and SOBI. He is an Associate Member of the standing committee on vaccination against measles at the Robert Koch Institute, Berlin, Germany.

DATA AVAILABILITY STATEMENT

The datasets generated and analyzed during the current study are not publicly available because of the sensitivity of the data. In exceptional cases, de-identified data that underlie results reported in this article can be shared with investigators after approval of a proposal, including a detailed statistical analysis plan with a signed data access agreement. The data can be used for only the aims stated in the approved proposal with investigator support.

ETHICS STATEMENT

The Charité ethics board reviewed and approved the Prevention Bus study on April 6, 2017 (EA1/059/17) and the trial was registered at ISRCTN.com (ISRCTN18026662).

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[Correction added on 21 February 2024, after first online publication: Reference details for Bethke & Gellert (2023) have been corrected in this version.]

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Bethke, N., O'Sullivan, J. L., Keller, J., von Bernuth, H., Gellert, P., & Seybold, J. (2024). Increasing vaccinations through an on-site school-based education and vaccination program: A city-wide cluster randomized controlled trial. *Applied Psychology: Health and Well-Being*, *16*(3), 1326–1348. https://doi.org/10.1111/aphw.12528