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School-based educational and on-site vaccination among adolescents living in rural areas

Submission date
03/08/2018

Recruitment status
No longer recruiting

Registration date
09/08/2018

Overall study status
Completed

Last Edited
08/08/2018

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Despite childhood vaccination programs being established in many countries around the world, MMR (Measles-Mumps-Rubella) vaccine as well as diphtheria, tetanus, pertussis (whooping cough), and polio rates are not optimal in adolescents. Sometimes vaccinations can be done directly at schools. The “Prevention Bus” is the first mobile medical practice in Germany and could potentially improve vacation rates in adolescents. This study aims to improve vaccination rates in adolescents with a combination of school-based education classes, a structured information and reminder system, and vaccination in the Prevention Bus on-site at school.

Who can participate?
Schools in rural municipalities in the federal state of Brandenburg, Germany, with students aged 15 and older

What does the study involve?
Schools are randomly allocated to one of two groups (high-intensity and low-intensity involvement group). Parents are informed in advance and consent is obtained. Both groups receive basic information about the project and the bus, one week before the bus will be at their school. The educational class, conducted by two doctors, takes place for both groups when the bus is on-site at the school. In both groups, the Prevention Bus delivers the vaccine for MMR, diphtheria, tetanus, pertussis, and polio after education is delivered by medical staff. In the high-intensity involvement group, students, parents and teachers of the participating classes are also provided with structured information on infectious diseases and vaccinations one week in advance. In addition, the school receives standardized reminders. In this group, students, parents and teachers also have the opportunity to reach the medical and psychological team through interactive media channels. The effectiveness of the intervention is primarily assessed by the difference between groups in the number of pupils who bring their complete documents (vaccination card, declaration of consent by parents) to school and are eligible for vaccination, if needed, in the bus. Differences in vaccination-related knowledge and beliefs are also measured.

What are the possible benefits and risks of participating?
Potential benefits of this study include the provision of an effective and cost-effective vaccination treatment, which may increase vaccination rates at scale. The educational class and the information/reminder system may be the basis for a future health and prevention course in German schools. Risks associated with participating in this study are not expected. A reaction to the vaccine given by our physicians is the pre percentage range. Complications (temporarily in need of medical supervision) due to the vaccine is in the per thousand range. Following recommendations by STIKO (vaccination committee at Robert Koch Institut, Germany, Berlin) participants only get vaccinated after receiving medical information on vaccine reaction and possible complications.

Where is the study run from?
Charité - Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
June 2018 to March 2019

Who is funding the study?
Federal Ministry of Health (Germany)

Who is the main contact?
Dr Joachim Seybold

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
1503/53105_2

Study information

Scientific Title
School-based educational and on-site vaccination intervention for the prevention of MMR and Tdap-IPV among adolescents living in rural areas

Acronym

PREV-BUS-RURAL

Study objectives
The primary hypothesis tests whether the preparedness to participate in on-the-spot vaccinations can be increased in the high-intensity involvement condition compared to the low-intensity involvement condition.
In secondary hypotheses, the group differences in vaccination behaviour, in knowledge and vaccination self-efficacy, and susceptibility to the disease will be tested. Further, post hoc subgroup analyses of the intervention effectiveness will be conducted, e.g., by gender, migration status and socioeconomic background, type of school, and availability of regular health care. With the prevention bus as an intervention strategy, barriers related to prevention in rural areas will be identified (feasibility), in order to increase the immunization rates at schools in German rural areas.

Within this two-arm RCT, both groups will receive an educational class, which was used and validated in a former trial. The former trial was conducted in an urban area in Germany in the school term of 2017/2018 (trial registration: https://www.isrctn.com/ISRCTN18026662). The procedure for the educational class unit of the former trial was identical to the procedure that will be applied for the low-intensity group condition in the current trial. All elements regarding procedure at schools and in- and exclusion criteria at student level are identical. This will allow cumulative and comparative analyses among both cohorts, the urban and the rural cohort. The trialists will be able to compare the effectiveness of their mobile approach in the rural area to data from an urban area from both trials. However, the present study does not replicate the former trial, but entails a new intervention arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Charité Berlin, 31/07/2018, ref: EA1/059/17

Primary study design
Interventional

Study design
Two-arm randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
MMR vaccine (Measles, Mumps, Rubella), Tdap-IPV vaccine (Tetanus, Diphteria, Pertussis, Polio)

Interventions
Schools are randomly allocated to one of two groups (high-intensity and low-intensity involvement group). Parents are informed in advance and consent is obtained. Both groups receive basic information about the project and the bus, one week before the bus will be at their school. In both conditions, the Prevention Bus is delivering vaccine for MMR, diphtheria, tetanus, pertussis, and polio after education is delivered by medical staff.

The Prevention Bus will be at each school for approximately one school week to give all students the possibility to get information and vaccination if needed. Moreover, there will be an intervention at the classes from 9th to 11th grade (15 years onwards) in high schools and for all apprentices in their teaching facilities. More specifically, the intervention will be a 30-minute educational class, held by doctors for both the high-intensity involvement condition and the low-intensity involvement condition on knowledge, risk communication and enhancing self-efficacy regarding vaccination. Both conditions also include an anonymous questionnaire on sociodemographic background and knowledge regarding vaccination. The check of the vaccination card and a guided tour through the Prevention Bus is part of the intervention for both groups.

The low-intensity involvement condition will receive the above-described intervention. In addition, in the high-intensity involvement condition parents of students participating will receive one week before the bus will be at their school detailed information material on infectious diseases and vaccination (flyer) using risk communication methods. Also teachers of the school classes included will receive this material one week in advance. Furthermore, an additional reminder system will serve as cue to action for teachers to remind students more often, and short and long-term. Parents, teachers and students will further have the possibility to reach the medical and psychological team through interactive media channels.

The effectiveness of the intervention is primarily assessed by the difference between conditions in the number of pupils who will bring their complete documents (vaccination card, declaration of consent by parents) to school and will be eligible for vaccination, if needed, in the bus. Further, differences in vaccination-related knowledge and beliefs are measured.

Intervention Type
Biological/Vaccine

Primary outcome(s)
Preparedness: The availability of students for a possible vaccination is objectively measured through the number of pupils who bring their vaccination card to school and can get vaccinated if necessary, directly after the educational intervention (high-intensity involvement condition, low-intensity involvement condition) when pupils visit the Prevention Bus. The primary outcome will be weighted by the number of pupils who are eligible to take part in the study

Key secondary outcome(s)
1. The number of pupils, that get vaccinated directly after the educational intervention (high-intensity involvement condition, low-intensity involvement condition) when pupils visit the Prevention Bus. The secondary outcome will be weighted by the number of pupils who are eligible to take part in the study
2. Health literacy is measured using five items of the HLS-EU Q47 questionnaire addressing prevention and immunization treatment (educational class condition, low intensity information condition) before students visit the bus while they are still in their classroom
3. Health knowledge is measured with six previously developed immunization knowledge items, which psychometric properties were tested in the pilot study after treatment (educational class condition, low intensity information condition) but before students visit the bus while they are still in their classroom
4. Perception of susceptibility to infectious diseases, measured using a risk scale after the educational unit, when students are still in their classroom, but before they enter the bus

Completion date

31/03/2019

Eligibility

Key inclusion criteria
School level:
1. Municipalities in the federal state of Brandenburg with less than 200 inhabitants/km²
2. Summed minimum number of pupils in potential School classes per school: 200

Participant level:
1. Age (>15 years)
2. Signed informed consent by the parents

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Under 15 years of age

Date of first enrolment
22/08/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Germany

Study participating centre
Charité - Universitätsmedizin Berlin
Charitéplatz 1
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Germany
10117

Sponsor information

Organisation
Federal Ministry of Health (BMG) (Germany)

ROR
https://ror.org/05vp4ka74

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Gesundheit

Alternative Name(s)
Federal Ministry of Health, Germany, Federal Ministry of Health, BMG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Joachim Seybold (principal investigator) and Norma Bethke (study coordinator) after main group comparison has been published to researchers, only after they provide an abstract, describing their research objective that is related with the data. After approving the abstract, the data will be provided.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes