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School-based educational and on-site vaccination among adolescents

Submission date
01/12/2017

Recruitment status
No longer recruiting

Registration date
05/12/2017

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Infections and Infestations

[X] Prospectively registered
[X] 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 have been established in many countries around the world, MMR vaccine (Measles-Mumps-Rubella) 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 adolecents. The study aims to improve vaccination rates in adolescents with a combination of school-based education classes and on-site vaccination in the "prevention bus" on-site at school.

Who can participate?
Schools in the city center of Berlin, Germany with classes 9 to 11 (students aged 15 and older)

What does the study involve?
Schools are randomly allocated to one of two groups. Those in the first group receive an educational class. Those in the second group receive low-intensity information. In both conditions, the “prevention bus” is delivering vaccine for MMR, diphtheria, tetanus, pertussis, and polio after information or education is delivered by medical staff. Parents are informed in advance and consent is obtained. The effectiveness of the education is primarily assessed by the difference between conditions in the number of pupils who receive vaccination in the bus. Further, differences in vaccination-related knowledge and beliefs are measured. A minimum number of 355 school classes is required to determine effectiveness.

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. Further, the educational class 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 2017 to August 2018

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

Who is the main contact?
Dr Joachim Seybold (Public)
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Study website
https://praeventionsbus.charite.de/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1503/53105

Study information

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

Acronym
PREV-BUS

Study objectives
The primary hypothesis tests whether the willingness to participate in on-the-spot vaccinations can be increased in the educational class condition compared to the low-intensity information provision condition. In secondary hypotheses, the group differences in knowledge and vaccination self-efficacy will be tested. Further, post hoc subgroup analyses of the intervention effectiveness will be conducted, e.g., by gender, migration status and socioeconomic background, and type of school. With the prevention bus as an intervention strategy, barriers are identified (feasibility) in the context of the prevention work, to increase the immunization rates at Berlin schools.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Charité Berlin, 10/08/2017, ref: EA1/059/17

Study design
Cluster randomized controlled trial (cRCT)

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
https://praeventionsbus.charite.de/fileadmin/user_upload/microsites/ohne_AZ/sonstige/praeventionsbus/Aufkl%C3%A4rungsb%C3%B6gen/info_Eltern_homepage.pdf

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

Interventions
The Prevention Bus will be at each school for approximately one week. Giving all students the possibility to get information and/or vaccination if needed. Besides that, there is an intervention at the classes from 9th to 11th grade (15 years onwards) in high schools and for all apprentices in their teaching facilities. The intervention in schools is held by doctors and nurses and will either be an educational class condition or a low-intensity information condition based on the randomisation. The low-intensity information condition includes an anonymous questionnaire on sociodemographic background and knowledge regarding vaccination. Furthermore, the check of the vaccination card and a guided tour through the Prevention Bus is part of the intervention. In

addition to the anonymous questionnaire and the check of the vaccination card, the educational class condition includes a 30 minute class on knowledge, risk communication and enhancing self-efficacy regarding vaccination.

Intervention Type
Biological/Vaccine

Primary outcome measure
Vaccination rate is objectively measured through the number of pupils that get vaccinated, directly after receiving treatment (educational class condition, low-intensity information 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.

Secondary outcome measures
1. 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) but before pupils visit the bus while they are still in their class room.
2. Health knowledge is measured with six previously developed immunization knowledge items, which psychometric properties were tested in our pilot study after treatment (educational class condition, low intensity information condition) but before pupils visit the bus while they are still in their class room.

Overall study start date
01/06/2017

Completion date
31/08/2018

Eligibility

Key inclusion criteria
School level:
1. Centric boroughs within circle line ("Ringbahn" - public Transport Berlin)
2. Summed minimum number of pupils in potential School classes: 230

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

Participant type(s)
Mixed

Age group
Child

Lower age limit
15 Years

Sex
Both

Target number of participants
Anticipated sample size of 510 school classes (N=25 per class); a required sample size of 335 school classes was determined a-priori

Key exclusion criteria
Under 15 years of age

Date of first enrolment
08/12/2017

Date of final enrolment
14/07/2018

Locations

Countries of recruitment
Germany

Study participating centre
Charité - Universitätsmedizin Berlin
Charitéplatz 1
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Sponsor information

Organisation
Federal Ministery of Health (BMG)

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Sponsor type
Government

Website
https://www.bundesgesundheitsministerium.de/

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

Publication and dissemination plan
The study protocol is planned to be submitted in a peer-reviewed journal before recruitment will be finished. Planned publication of the study results in a high-impact peer reviewed journal within one year after the end of the study.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan
For further questions regarding the data please contact Joachim.seybold@charite.de (principle investigator) and norma.bethke@charite.de (study coordinator).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/01/2019	24/02/2020	Yes	No
Interim results article	pilot study results	10/01/2022	25/10/2022	Yes	No