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Sicher im Ernstfall (Safe in an emergency)

Submission date	Recruitment status	[_] Prospectively registered
04/03/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
In Germany it is recommended for school children to receive basic life support (BLS) training. Even trained people often hesitate to help in cardiac arrest. This study investigates if special training methods are effective at improving school children's preparedness and positive beliefs in their own capability to help in cardiac arrest.

Who can participate?
Students in grade seven and eight at high schools in Hamburg

What does the study involve?
Classes are randomly allocated to either the intervention group or the control group. All classes participate in practical training in BLS. The intervention group receive self-regulated training in peer groups after demonstration and deconstruction of the steps by the trainer. The control group receive Instructor-led training following the four-step approach. Self-efficacy for helping in cardiac arrest is measured immediately after the training and 9 months later.

What are the possible benefits and risks of participating?
Participants receive training in first aid, and no risks are expected.

Where is the study run from?
University Medical Center Hamburg-Eppendorf (Germany)

When is the study starting and how long is it expected to run for?
February 2015 to October 2017

Who is funding the study?
University Medical Center Hamburg-Eppendorf (Germany)

Who is the main contact?
Dr Stefanie Beck
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title
Promotes self-regulated learning in peer- groups self-efficacy for helping in cardiac arrest?

Acronym
Sicher im Ernstfall

Study objectives
Self-regulated learning in peer- groups promotes self-efficacy and long-term retention of practical Basic Life support (BLS) skills in school children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was rated by the head of the local Ethics Committee of the Medical Association of Hamburg as a study with humans but not on humans. Therefore, this educational study does not refer to the statutes of the ethics committee (§ 9 des Hamburgischen Kammergesetzes für Heilberufe) and the study was not appropriate for ethics consultation. This study was conducted with the approval of the Ministry of education of the state of Hamburg (Ministerium für Schule und Weiterbildung des Landes Hamburg).

Primary study design
Interventional

Study design
Prospective randomised controlled interventional trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Helping in cardiac arrest

Interventions
Students were randomised class-wise into the intervention and control arm in a 1:1 allocation ratio. The randomisation was performed in advance by drawing balls of two colours blindly. A cluster was represented by students of one class.

All students participated in a practical training in BLS and an objective structured examination of skills:

Intervention: Basic Life support training with self-regulated training in peer-groups after demonstration and deconstruction of the steps by the trainer
Control: Instructor-led basic life support training following the four-step approach

Intervention Type
Behavioural

Primary outcome(s)
Self-efficacy of school children for helping in cardiac arrest, measured with a four-point Likert scale in three dimensions with two questions for each by adding the values of the two questions. The dimensions were helping in general, helping in cardiac arrest and diminished emotional arousal to cardiac arrest. The questionnaire, based on the general self-efficacy scale of Schwarzer and Jerusalem, was transformed into a special self-efficacy scale following the authors recommendations. Measured immediately after the training and 9 months later.

Key secondary outcome(s)
Pass-rates and means for items in a practical basis life support assessment. The assessment of the practical BLS skills was structured as an OSCE using MiniAnne-mannequins® (LaerdalTM). For assessment, the raters used a structured rating checklist with nine binary items. To pass the practical assessment in total, all nine points had to be rated with yes. Measured immediately after the training and 9 months later.

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Volunteering school children
2. Written informed consent of the parents

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
600

Key exclusion criteria
1. Not able to perform basic life support
2. No written informed consent from the parents

Date of first enrolment
01/07/2016

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center Hamburg-Eppendorf
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Sponsor information

Organisation
University Medical Center Hamburg-Eppendorf

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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 Stefanie Beck (st.beck@uke.de). The final dataset used for analyses could be provided, data are anonymised, consent to publish anonymised result obtained by all participants.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/01/2020	26/10/2020	Yes	No