

# Sicher im Ernstfall (Safe in an emergency)

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| <b>Submission date</b><br>04/03/2019   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>07/03/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/10/2020       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data  |

## 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  
st.beck@uke.de

## Contact information

**Type(s)**

Public

**Contact name**

Dr Stefanie Beck

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## 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).

### **Study design**

Prospective randomised controlled interventional trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

Community

### **Study type(s)**

Other

### **Participant information sheet**

not available in web format, please use contact details to request a participant information sheet

### **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 measure**

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.

### **Secondary outcome measures**

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.

**Overall study start date**

04/02/2015

**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

**Age group**

Child

**Sex**

Both

**Target number of participants**

15 classes (clusters) with a mean number of 22 students per class for every group (15 x 22 x 2)

**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**  
Department of Anaesthesiology  
Martini-Str. 52  
Hamburg  
Germany  
20246

## Sponsor information

### Organisation

University Medical Center Hamburg-Eppendorf

### Sponsor details

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### Sponsor type

University/education

### ROR

<https://ror.org/01zgy1s35>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in an open access medical journal.

### Intention to publish date

15/03/2019

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 13/01/2020   | 26/10/2020 | Yes            | No              |