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Clinical paper

Out-of-Hospital cardiac arrest & SmartphonE RespOndErS trial (HEROES Trial): Methodology and study protocol of a pre-post-design trial of the effect of implementing a smartphone alerting system on survival in out-of-hospital cardiac arrest

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Abstract

Background: Since 2021, international guidelines for cardiopulmonary resuscitation recommend the implementation of so-called "life-saving systems". These systems include smartphone alerting systems (SAS), which enable dispatch centres to alert first responders via smartphone applications, who are in proximity of a suspected out-of-hospital cardiac arrest (OHCA). However, the effect of SAS on survival remains unknown.

Aim: The aim is to assess the rate of survival to hospital discharge in adult patients with OHCA not witnessed by emergency medical services (EMS): before and after SAS implementation.

Design: Multicentre, prospective, observational, intention-to-treat, pre–post design clinical trial.

Population: Adults (aged $\geq$ 18 years), OHCA not witnessed by EMS, no traumatic cause for cardiac arrest, cardiopulmonary resuscitation initiated or continued by EMS.

Setting: Dispatch-centre-based.

Outcomes: Primary: survival to hospital discharge. Secondary: time to first compression, rate of basic life support measures before EMS arrival, rate of patients with shockable rhythm at EMS arrival, Cerebral Performance Category at hospital discharge, and duration of hospital stay.

Sample size: Assuming an absolute difference in survival rates to hospital discharge of 4% in the two groups (11% before implementation of the SAS versus 15% after) and 80% power, and a type 1 error rate of 0.05, the required sample size is $N = 1{,}109$ patients per group (at least $N = 2{,}218$ evaluated patients in total).

Conclusions: The HEROES trial will investigate the effects of a SAS on the survival rate after OHCA.

Trial registration: German Clinical Trials Register (DRKS, ID: DRKS00032920)

Keywords: Cardiopulmonary resuscitation, First responder system, Smartphone alerting system, Out-of-hospital cardiac arrest

Abbreviations: AED, Automated External Defibrillator, BLS, Basic Life Support, CPC, Cerebral Performance Category, CPR, Cardiopulmonary Resuscitation, DNR/DNAR, Do Not (Attempt) Resuscitation order, EMS, Emergency Medical Service, ETE, Estimated Time Enroute, OHCA, Out-of-Hospital Cardiac Arrest, SAS, Smartphone Alerting System

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Introduction

Sudden cardiac arrest is one of the most common causes of death in Germany.[1] The incidence of out-of-hospital cardiac arrest (OHCA) with resuscitation initiated by the emergency medical services (EMS) in Germany is between 57 and 77 per 100,000 inhabitants.[2] This results in approx. 60,000 cases per year. 11% of these patients are discharged alive from the hospital.[2] One of the major contributors to the high mortality rate is the lack of early (high-quality) basic life support. Since 2021, international guidelines for cardiopulmonary resuscitation (CPR) recommend the notification of nearby first responders in the case of a suspected cardiac arrest. Notifications can be carried out via a text message or an app to reduce the time to first compression and shock delivery.[3]

Ringh and colleagues from Sweden were the first researchers who established a text message alerting system and performed a randomised controlled trial.[4] They used a mobile phone positioning system. If responders were within a 500 meters radius and if the patient was randomised to the study group, a text message was sent with location information. In the study group the proportion of patients who received basic life support before the ambulance arrival was 62% whereas in the control group (no alerting of volunteer community responders) BLS was only initiated in 48% of the patients before EMS arrival. There was no significant difference between the groups regarding return of spontaneous circulation or 30-day survival.

In a more recent study, Caputo and colleagues from Switzerland investigated the difference between alerting via SMS or smartphone application. Geo-referenced alerting via a smartphone app was associated with shorter arrival times of first responders as compared to traditional text message alerting.[5]

Currently, various systems for smartphone-based first-aid alerting (Smartphone Alerting Systems, SAS) have become available worldwide and are under constant development. Reviews have shown that these systems differ greatly in terms of concept and technology.[6,7]

Region of Lifesavers alerting system

The smartphone alerting system Region of Lifesavers ("Region der Lebensretter") is based on FirstAED alerting technology, which was established in Denmark in 2012.[8] It is operated by the non-profit organisation Region der Lebensretter e.V. and has been implemented in the region of Freiburg, Germany, in 2018.[9] A continuous process of scientific evaluation and improvements based on the research results[9–12] lead to the development of the third generation of smartphone alerting technology, which is currently in use, and which will be used in all study regions.

The SAS is connected to the local dispatch centre via an interface. In case of an emergency call with suspected cardiac arrest (confirmed cardiac arrest or unconscious person) the operations control computer automatically suggests activation of the SAS. If this is confirmed by the dispatch center agent, all relevant data (GPS coordinates, name of the patient, further information needed to find the emergency location, and estimated time enroute [ETE] for the ambulance) are transmitted to the SAS system and the system triggers an alert automatically at the same time as the ambulance and an emergency physician are being alerted. The system is under operation 24 hours per day and 7 days per week. It is not being activated in case of trauma, accident, and in suspected dangerous situations (crime, fire, other potential threads for first responders). Volunteer community responders are alerted to private and public locations, but not to places where healthcare professionals are commonly present (care homes, medical practices, and others).

The alerting algorithm in the third generation of the app aims to (1) achieve the shortest possible time between alert and arrival at the scene and (2) to make sure that an AED arrives at the scene at the earliest possible time but (3) without delaying the arrival of the first volunteer by fetching an AED.

When the SAS server receives the coordinates of a suspected cardiac arrest, the system checks the approximate locations of registered users, who are in close vicinity of the emergency location. Whilst the exact positions are retrieved responders receive a pre-alert through the alerting app (available on Android and iOS). Potential "do-not-disturb" settings are overwritten by the critical alert feature under Android and iOS if the user had allowed this during the installation of the app. Every user is requested to accept or reject the call and select his or her means of transportation (see Fig. 1) Furthermore each responder can specify via the app if they carry an AED. If a responder is invited but does not answer the call, the system assumes after 20 seconds that the responder is not available. After approximately 20 seconds the tasks are distributed, and 4 responders receive the relevant information through their app. The SAS calculates an individual route for every first responder considering their previously stated means of transportation. The two first responders, who will probably arrive first (shortest anticipated travel times) are directed to the emergency site. If none of the four volunteers carries a personal AED, the third responder is directed to an AED, which is publicly available at the specific time of the alert. The fourth responder is directed to the emergency site and instructs the ambulance personnel to make sure they arrive at the patient site at the earliest possible time. If the calculated travel time of a responder is longer than the ETE of the ambulance the volunteer community responder receives a notification that he or she is not needed.

Integration of AEDs

The DEFI-Map database (defi-map.de, Ingenieurbüro Brucklacher, Fellbach, Germany, version 2) is connected to the SAS via an interface and includes location data as well as further information on the availability of AEDs. The information on the AED infrastructure is tactically included in the alarm algorithm and thus ensures an optimal distribution of tasks when alerting first responders. Registered volunteer community responders are encouraged to register AEDs, which are not yet included in the database (and thus not visible in the app).

Registration, qualification, and insurance of first responders

All persons who are trained equivalent to the minimum (48-hours) emergency medical technician training and all health care professionals, who train BLS regularly (minimum once a year) can register through the app. After uploading their certificate and accepting the end-user licence agreement and the terms and conditions including data protection regulations, users are activated by the respective administrators.

In Germany, first responders are generally covered by the statutory accident insurance (SGB VII) during first aid interventions. In addition, first responders registered in the system have subsidiary liability insurance through the region of lifesaver association.

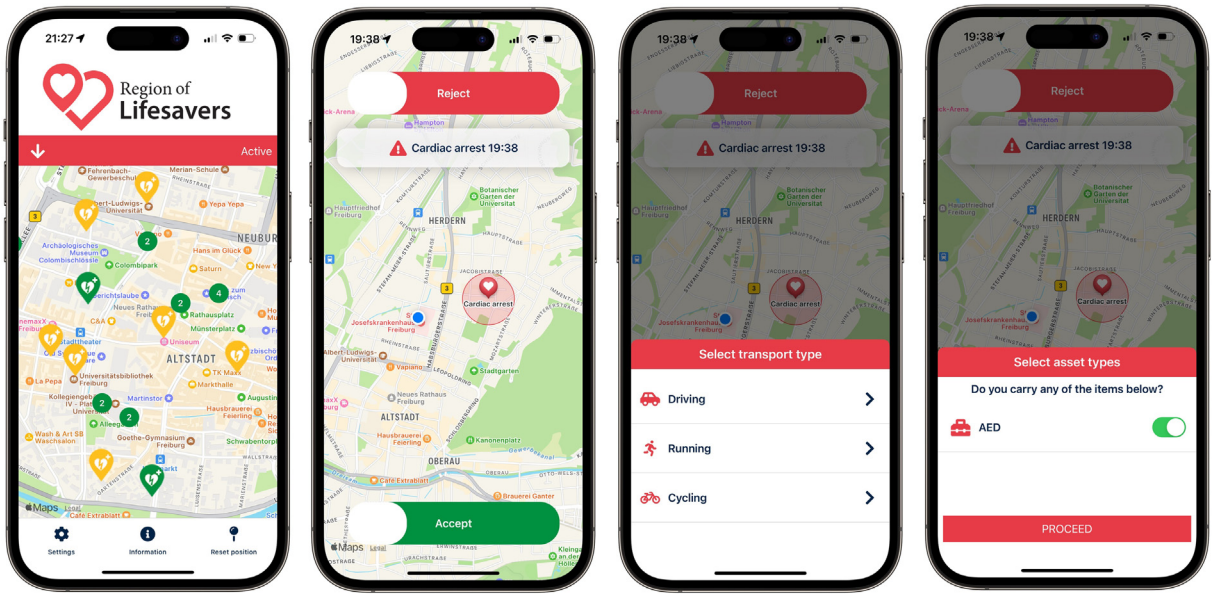

Fig. 1 – Smartphone Application "Region of Lifesavers". From left to right: Home screen without active alarm and display of all time-limited AEDs (yellow) and all AEDs available 24/7 (green). Alarm screen with approximate location. The selected means of transportation must be chosen by the first responder. The first responder is asked whether he is already carrying an AED.

Aim of the study

The out-of-**H**ospital cardiac arrest & smartphon**E** **R**esp**O**nd**E**r**S** **(HEROES)** trial aims to determine whether the implementation of a geo-referenced smartphone alerting system (Region of Lifesavers system) can increase survival to hospital discharge in OHCA. The HEROES trial is a dispatch-centre-based clinical trial using routinely collected data at the participating study sites in Germany.

Methods

Protocol and ethics

The HEROES trial is presented according to SPIRIT guidelines (Appendix 1).[13] The HEROES trial protocol version 1.0 (8 December 2022) has been approved by the Ethics Committee of the Physicians Association of Baden Wurttemberg, Germany (No. F-2023-003). Regions and centres outside of Baden Wurttemberg or with a local ethics committee will obtain ethical approval before study initiation. The trial was prospectively registered with the German Clinical Trials Register (DRKS, ID: DRKS00032920), which is a WHO primary register. Core study information is presented in Appendix 2.

Study design

The trial is designed as a multicentre, prospective, observational, intention-to-treat, pre–post design clinical trial. The trial consists of three phases (see Fig. 2).

Phase I: Observational phase before implementation of the system (8 months)

In the first phase of the trial, data will be collected to assess the baseline without a SAS present. During the 8 months of data collection, a campaign will be planned and conducted to recruit people with medical training to register as first responders in all participating regions. This will be done by the region of lifesaver association in cooperation with the local first aid and EMS organisations, fire brigades and hospitals (social media, local press). Additionally, preparations are carried out to connect the local dispatch centre to the alerting system and publicly accessible AEDs are registered in the system's AED database.

Phase II: Implementation of the system (4 months)

Start of the SAS (Region of Lifesavers system) will be on 1 September 2024 in all participating regions. No data will be collected in this phase of the trial. During these 4 months, optimisations of the system are carried out and the registration of first responders is continued.

Phase III: Observational phase after implementation of the system (8 months)

During this phase of the trial, data will be collected to assess the effect of a chain of survival with a SAS present. Now, data of the SAS will also be collected. At the end of this phase (i.e., 20 months after start of the trial) study enrolment will be stopped, and the trial will end after hospital discharge of the last patient of this phase.

Study setting

In Germany, medical emergency calls are handled by local dispatch centres with a two-tiered rescue system with paramedic-staffed ambulances, equipped according to European standard Mobile ICU, DIN EN 1789 (type C) to initiate Advanced Life Support; and a physician staffed emergency response vehicle equipped according to German standard DIN 75079. In response to a confirmed or suspected out-of-hospital cardiac arrest (OHCA) call a paramedic-staffed ambulance and a physician staffed emergency response vehicle are alerted.

Study regions

Table 1 shows the participating regions with inhabitants and area covered by the local dispatch centre. Expected OHCA cases are

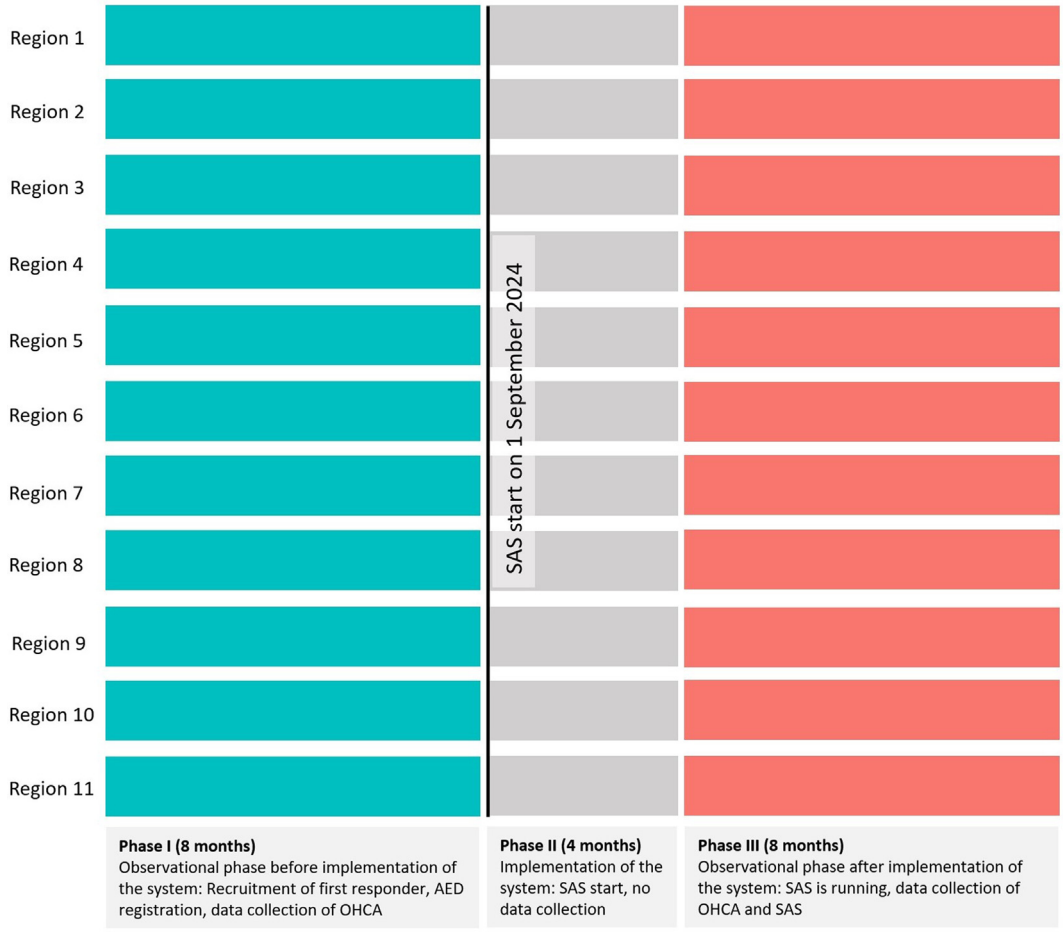

Fig. 2 – Schematic representation of the study programme in three phases.

Table 1 – Items associated with the first responder system (according to reporting standard for describing first responder systems, smartphone alerting systems and AED networks).[19]

Name of the region (1A1)	Square km covered (1A2)	Inhabitants (1A3)	Expected OHCA cases per year* (1A4)	Expected number of OHCA cases (16 months)
Amberg	2,778	292,268	167	222
Dresden	3,436	1,042,425	594	792
Esslingen	642	533,859	304	406
Konstanz	818	285,325	163	217
Main-Taunus	222	237,735	136	181
Reutlingen	1,094	286,748	163	218
Rhein-Neckar	1,171	707,980	404	538
Rottweil	770	139,455	80	106
Stuttgart	207	634,830	362	482
Trier	2,387	371,843	212	283
Tübingen	519	227.331	130	173
Total	**14,044**	**4,759,799**	**2,715**	**3,619**

* An incidence of 57 per 100,000 inhabitants is assumed.[2]

calculated under the assumption of 57 OHCA cases per 100.000 inhabitants per year.

Case identification and study population

In the participating regions all OHCA cases will be screened. OHCA cases will be identified by screening all emergency doctor and EMS protocols for "resuscitation measures performed", which is a mandatory information in such protocols in Germany. Only OHCA cases which are not observed by the EMS with non-traumatic cause and a patient age $\geq$ 18 years will be included in this trial.

Furthermore, the following exclusion criteria were defined for this trial: Presence of a Do Not (Attempt) Resuscitation order (DNR/

DNAR order), resuscitation is not started/continued by the EMS service, patient age < 18 years, accident, or other traumatic cause of cardiac arrest.

Data collection methods and data management

The variables used and the corresponding data sources of the HEROES trial are listed in Table 2. The emergency doctor or ambulance service protocol, the dispatch centre report, the hospital discharge letter, and information from the Region of Lifesaver backend database are collected for each OHCA case. Study data are collected and managed using REDCap electronic data capture tools hosted at University Medical Centre Freiburg.[14,15] REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources. All data being extracted from the trial database are anonymised.

Consent and data monitoring committee

The data collection of this trial is purely observational for the purpose of scientific evaluation based on data already collected in the context of emergency and clinical care. As the data collection does not cause any changes to the medical procedure in individual cases and it is intended to improve resuscitation care for the entire population, the need to obtain informed consent from patients was waived by the Ethics Committee for this trial. Also, no data monitoring committee will be formed.

Outcome measures

Primary endpoint

The primary outcome of the trial is patient survival to hospital discharge.

Secondary endpoints

The secondary endpoints include: Cerebral Performance Category (CPC) at hospital discharge, survival rate in the Utstein Comparator Group (patients with observed out-of-hospital cardiac arrest and shockable cardiac rhythm [ventricular fibrillation; ventricular tachycardia] in the first derived ECG rhythm), duration of hospital stay, duration between emergency call and arrival of rescuers or emergency medical services at the scene of emergency, Basic Life Support (BLS) before arrival of EMS, application of an AED before arrival of EMS at the scene of the emergency, proportion of patients with shockable heart rhythm on arrival of EMS.

Statistical methods

Sample size calculation

It is assumed that the hospital discharge rate without the Region of Lifesavers system is 11%. An increase to 15% is assumed after the introduction of the system. Sample size calculation was performed by the Institute for Medical Biometry and Statistics at the University Medical Centre Freiburg: given a power of 0.8 at a significance level of 0.05, a case number per group of at least 1,109 is required to detect an increase in the survival rate from 11% to 15%. Therefore, a total of at least 2,218 OHCA cases must be included to be able to detect an increase in survival of 4%.

Data analysis

An independent biostatistician will perform data analyses for the primary and secondary outcomes. Variables that approximate a normal distribution will be summarised as mean ± standard deviation, and groups will be compared using two-sided t-tests. Non-normal variables will be summarised as median and first and third quartiles (Q1, Q3), and groups will be compared using Mann-Whitney rank sum tests. Binomial variables will be expressed as proportions and 95% confidence intervals (exact binomial), and groups will be compared using the chi-squared test. The primary analysis will consider all eligible OHCA cases in the study periods (per-protocol).

Pre-specified sub-groups

We plan to examine the effect of the implementation of the Region of Lifesavers system on the primary outcome especially in the Utstein Comparator Group (patients with witnessed out-of-hospital cardiac arrest and shockable heart rhythm [ventricular fibrillation; ventricular tachycardia] in the first derived ECG rhythm). Additionally, we plan to examine the effect across several subgroups, including age groups, initial arrest rhythm (shockable vs. non-shockable), arrest location (public vs. private), EMS response time, aetiology of cardiac arrest (presumed cardiac vs. other), and witness status (unwitnessed vs. bystander witnessed).

Protocol amendments

Protocol amendments will only occur after approval by the Ethics Committee of the Physicians Association of Baden Württemberg and corresponding local Ethics Committees.

Dissemination of findings

The results from the HEROES trial will be shared as an original manuscript in a peer-reviewed journal. Findings will be presented following the STROBE guidelines.[16]

Discussion

To our knowledge there is only one randomised controlled trial published which had evaluated the effect of a mobile phone alerting system to dispatch lay responders for OHCA.[4] The bystander-initiated CPR rate increased, but the survival rate did not increase. Two major factors may have contributed to the results:(1) The technological development did not yet allow to produce extremely short response times. Recent development from text message systems towards app based alerting including the use of global positioning system (GPS) resulted in reduced response times of volunteer community responders.[5] The advances in algorithm development can further reduce the response times and thus the resuscitation-free interval: One observational study in Freiburg/Germany revealed a median response time of the first volunteer arriving at the emergency site of below 4 minutes; the density of volunteer community responders was only 0.65 responders per km^2. Another study from Sweden (Stockholm and Götaland) found response times of more than 8 minutes although the first responder density was 0.79 (Götaland) and 3.75 (Stockholm) responders per km^2, respectively.[17]

(2) It is unknown which qualification should serve as a minimum standard of volunteer community responders. Lower minimum qualification may lead to higher number of registered volunteers, but higher minimum qualification may result in high quality basic life

Table 2 – Variables and data sources of HEROES trial. Items of the reporting standard[19] are indicated with the respective reference in brackets.

Variable	Definition	Source
Alerting keyword/indication	Cardiac arrest/unconscious/other	Protocol dispatch center
Time emergency call	Time	Protocol dispatch center
Process times of EMS	Time	Protocol dispatch center
T-CPR initiated	YES/NO	Protocol dispatch center
OHCA witnessed	Bystander/EMS/unwitnessed	EMS protocol
OHCA location	Based on Utstein Style protocol	EMS protocol
Pathogenesis of OHCA	Based on Utstein Style protocol	EMS protocol
Bystander CPR	Based on Utstein Style protocol	EMS protocol
First cardiac rhythm	Based on Utstein Style protocol	EMS protocol
Defibrillation data	Based on Utstein Style protocol	EMS protocol
Use of mechanical CPR device	Based on Utstein Style protocol	EMS protocol
Independent life before OHCA	Based on Utstein Style protocol	EMS protocol
Given drugs while ALS	Adrenaline/Noradrenaline/Vasopressin/none given	EMS protocol
Used airway devices	Based on Utstein Style protocol	EMS protocol
ROSC	Based on Utstein Style protocol	EMS protocol
No flow time	If available, based on Utstein Style protocol	EMS protocol
CPR quality measured	Based on Utstein Style protocol	EMS protocol
ECG information	Based on Utstein Style protocol	EMS protocol
Data of first responder system	Reporting Standard Category 1	Region of Lifesavers backend protocol
Data of first responder network	Reporting Standard Category 2	Region of Lifesavers backend protocol
Data of technology, algorithms and strategies	Reporting Standard Category 3	Region of Lifesavers backend protocol
Data collection (as follows)	Reporting Standard Category 4	Region of Lifesavers backend protocol
Data of AED (as follows)	Reporting Standard Category 5	Region of Lifesavers backend protocol DEFI-Map
Process times of first responders	Reporting Standard Category 4, Departing and arrival times of FR	Region of Lifesavers backend protocol
FR arrival before EMS	Reporting Standard (4A6)	Region of Lifesavers First responder survey
Means of transportation used by FR	Reporting Standard (4D2)	Region of Lifesavers First responder survey
FR delivered CPR before EMS arrived	Reporting Standard (4C1)	Region of Lifesavers First responder survey
AED arrival before EMS	Reporting Standard (4A7)	Region of Lifesavers First responder survey EMS protocol
AED attached by FR before EMS arrived and shocks delivered	Reporting Standard (4C2/5D3)	Region of Lifesavers First responder survey
FR delivered stationary AED	Reporting Standard (5B1)	Region of Lifesavers First responder survey
FR delivered mobile AED	Reporting Standard (5B3)	Region of Lifesavers backend protocol
Adverse safety event	Reporting Standard (4D3)	Region of Lifesavers First responder survey
Need for debriefing	Reporting Standard (4D4)	Region of Lifesavers First responder survey
Relevant treatment options	TTM, Reperfusion, ICU	Final medical report (Hospital)
Comorbidities	YES/NO	Final medical report (Hospital)
Survive to hospital discharge	YES/NO	Final medical report (Hospital)
Cerebral Performance Category Score at hospital discharge	CPC 1–5	Final medical report (Hospital)

support. After many technological improvements of the alerting app and with a sophisticated algorithm resulting in very short response times, we believe that the effects of the system should be evaluated in a large multicentre trial.

The international guidelines recommend activating volunteer community responders in case of suspected cardiac arrest, and a recently published retrospective study demonstrated increased rate of favourable survival after implementation of a text message sys-

tem.[18] The authors found it inadequate to perform a randomised controlled trial. A pre-post study design is appropriate as establishing our SAS requires commonly several months of preparation: Fundraising is needed as the system is not funded by health insurances or government. A campaign is necessary to recruit as many volunteers as possible, who register in the app. Finding 11 regions which wanted to establish our SAS and coordinating a synchronised start at the same day in each region took some effort. However, this setup enables the authors to include enough patients with an observation period of only 8 months before activation of the system.

Conclusion

Despite a strong recommendation by international guidelines for cardiopulmonary resuscitation to implement SAS, there is still the need for prospective studies to investigate the effect on the survival rate. The HEROES trial is a multicentre, prospective, observational pre–post design clinical trial that aims to improve survival rates to hospital discharge in OHCA by implementing a SAS (Region of Lifesavers system).

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CRediT authorship contribution statement

Michael P. Müller: Investigation, Data curation. **Julian Ganter:** Project administration, Methodology, Investigation, Data curation, Conceptualization. **Hans-Jörg Busch:** Resources, Project administration, Investigation, Funding acquisition. **Georg Trummer:** Resources, Project administration, Investigation. **Jörg Sahlmann:** Methodology, Formal analysis, Conceptualization. **Florian Brettner:** Writing – review & editing, Validation, Data curation. **Maria Reden:** Investigation, Data curation. **Daniel Elschenbroich:** Investigation, Data curation. **Michael Preusch:** Investigation, Data curation. **Jonas Rusnak:** Investigation, Data curation. **Stephan Katzenschlager:** Investigation, Data curation. **Dirk Nauheimer:** Investigation, Data curation. **Robert Wunderlich:** Investigation, Data curation. **Jan-Steffen Pooth:** Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: 'MPM is chair of Region der Lebensretter e.V. (non-profit organisation), member of the executive committee of the German Resuscitation Council (GRC), shareholder of SmartResQ ApS, Denmark, and received speaker honoraria by Stryker. JG is board member of Region der Lebensretter e.V. HJB is vice chair of Region der Lebensretter e.V. GT is board member of Region der Lebensretter e.V., secretary of the GRC, and shareholder of Resuscitec GmbH, Freiburg, Germany. JSP is member of Region der Lebensretter e.V. and member of the executive committee of the GRC. All other authors have no conflicts of interest to declare'.

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Appendix A. Supplementary material

Supplementary material to this article can be found online at https://doi.org/10.1016/j.resplu.2024.100564.

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