

BMJ Open Online platform for cardiopulmonary resuscitation and automated external defibrillator training in a rural area: a community clinical trial protocol

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ABSTRACT

Introduction Sudden death resulting from cardiorespiratory arrest carries a high mortality rate and frequently occurs out of hospital. Immediate initiation of cardiopulmonary resuscitation (CPR) by witnesses, combined with automated external defibrillator (AED) use, has proven to double survival rates. Recognising the challenges of timely emergency services in rural areas, the implementation of basic CPR training programmes can improve survival outcomes. This study aims to evaluate the effectiveness of online CPR-AED training among residents in a rural area of Tarragona, Spain.

Methods Quasi-experimental design, comprising two phases. Phase 1 involves assessing the effectiveness of online CPR-AED training in terms of knowledge acquisition. Phase 2 focuses on evaluating participant proficiency in CPR-AED simulation manoeuvres at 1 and 6 months post training. The main variables include the score difference between pre-training and post-training test (phase 1) and the outcomes of the simulated test (pass/fail; phase 2). Continuous variables will be compared using Student's t-test or Mann-Whitney U test, depending on normality. Pearson's χ^2 test will be applied for categorical variables. A multivariate analysis will be conducted to identify independent factors influencing the main variable.

Ethics and dissemination This study adheres to the tenets outlined in the Declaration of Helsinki and of Good Clinical Practice. It operated within the Smartwatch project, approved by the Clinical Research Ethics Committee of the Primary Care Research Institute IDIAP Jordi Gol i Gurina Foundation, code 23/081-P. Data confidentiality aligns with Spanish and European Commission laws for the protection of personal data. The study's findings will be published in peer-reviewed journals and presented at scientific meetings.

Trial registration number NCT05747495.

INTRODUCTION

In Europe, sudden death due to cardiopulmonary arrest (CPA) is a leading cause of mortality, causing about 84/100 000 deaths/year.^{1 2} In Spain, 24500 cases of CPA are estimated to occur each year. In Catalonia, this

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Participants are being recruited from specific primary healthcare centres in 15 municipalities in a rural area of Tarragona, Spain, covering a population of 10 256 individuals.
- ⇒ The intervention, a virtual platform, is accessible 24 hours a day, 7 days a week.
- ⇒ The online training and its evaluation will adhere to the Catalan Resuscitation Council and European Resuscitation Council guidelines.
- ⇒ A significant limitation of the study is the dependence on adequate technology and internet access, particularly in rural settings where these resources may be less available.
- ⇒ Another limitation is that the evaluation is conducted using a mannequin; there can be no direct evidence of benefit on patient outcome.

translates to one CPA-related death every 140 min, with only 20% of people recovering without sequelae.³ This mortality rate increases to 70%–85% when CPA occurs in the extra-hospital setting, where survival in Spain does not exceed 15%.^{4 5}

Ventricular fibrillation is the main cause of CPA, and defibrillation using an automated external defibrillator (AED) is the only measure that allows recovery of an effective heartbeat. However, cardiopulmonary resuscitation (CPR) must be initiated until the AED is applied. Studies have outlined a direct correlation between survival rates and the time elapses between CPA onset and the start of CPR manoeuvres, as well as the quality of these manoeuvres.^{6–9} Immediate bystander-initiated CPR has been demonstrated to double or even triple survival in out-of-hospital cardiac arrest (OHCA).¹⁰ Moreover, a recent study in Japan observed that AED usage by witnesses increased the survival rates of individuals affected by OHCA, resulting

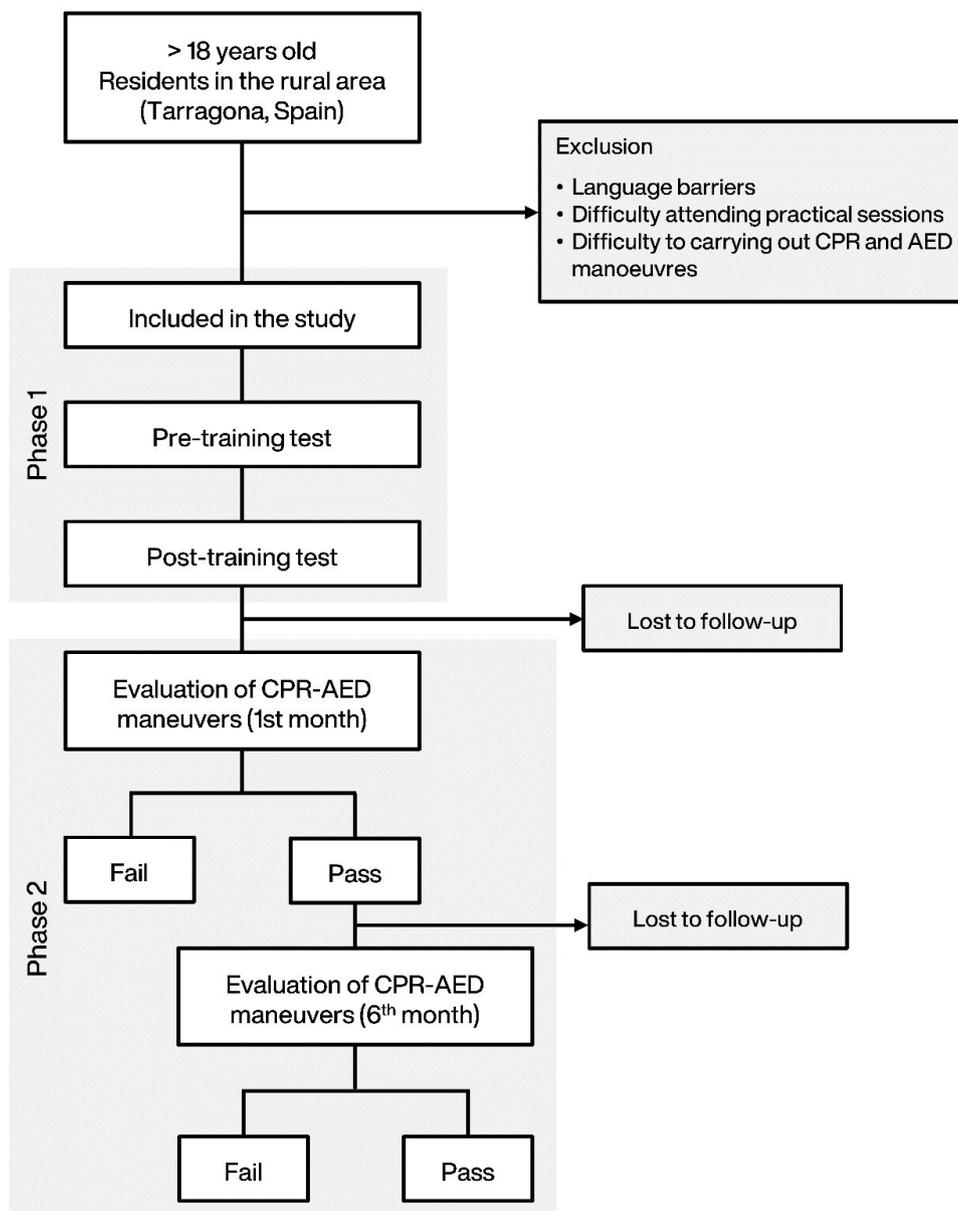


Figure 1 Flowchart of the study: process of selection and follow-up. AED, automated external defibrillator; CPR, cardiopulmonary arrest.

in fewer neurological complications and consequently, enhanced quality of life.¹¹

It is considered that the interval between the call to the emergency medical services (EMS) and the defibrillation should be less than 5 min, as each minute of delay in AED usage reduces survival rates by 10%–12%.^{12 13} In some places, especially in rural areas, this time can exceed 6 min.¹² For this reason, recent recommendations from scientific societies call for telephone operators receiving an alert to encourage people to initiate resuscitation manoeuvres while awaiting the arrival of EMS.¹⁴ While the percentage of the population performing CPR manoeuvres ranges from 20% to 70% in Europe, Spain ranks second to last.^{15 16}

The main limitations in the general public in initiating CPR include fear, difficulty in recognising a CPA and a

lack of knowledge of resuscitation manoeuvres and the use of AED. It has been suggested that training the population in CPR manoeuvres is key for bystanders to have the courage to act.¹⁶ It is crucial that the general population, especially those residing in rural areas, is well informed on how to identify a CPA and respond promptly and accurately.¹⁷

Training the population in CPR and the use of AED

The CPR guidelines of the European Resuscitation Council (ERC) emphasise the need to carry out training in basic life support and the use of AED to enhance the survival of OHCA.¹⁸ Today, these training programmes are effective in improving the survival rates of OHCA cases attended by witnesses.^{18–20}

Table 1 Sections and activities in the CPR-AED online training

Sections	Activities	Description
General space and relationship with the researcher and IT technical support	Notices and news	Publication of the dates of the virtual sessions to the students.
	Questions forum	Space for questions and comments.
	Glossary and terminology	List of key terms in alphabetical order.
Welcome	Student guide	
	Pre-training test	Test with five questions to gauge prior knowledge following the recommendations of the CCR.
Theory	<ol style="list-style-type: none"> 1. Basic life support and CPR 2. Utilisation of AED 3. Management of choking 4. Adaptation of the recommendations to the situation generated by the COVID-19 pandemic 	
Practical	Practical cases	Participants will encounter five situations, presenting several decision-making scenarios. In each case participants must choose course of action, receiving synchronous feedback for their decisions.
	Simulator CPR	Digital tool allowing students to practice cardiac massage rhythm during CPR using the keyboard or mouse.
Evaluation	Final test	Test with 10 questions to evaluate the knowledge acquired following the recommendations of the CCR.
	Satisfaction survey	Participants will be able to evaluate the training experience. A dedicated space for suggestions and observations is also provided.
Certification	Certification	Students who have successfully completed the course can download their corresponding certificate as proof of accomplishment.

AED, automated external defibrillator; CCR, Catalan Resuscitation Council; CPR, cardiopulmonary resuscitation; IT, information technologies.

In addition, initiating this training is recommended to begin at school, as well as a strategy tailored for people close to patients at high risk of sudden death.^{21 22} While some initiatives have been implemented, few results have been presented regarding acceptance, performance, costs and assessment.²³ International studies incorporating mobile technology have shown that its use allows a network of previously trained volunteers to be alerted, reducing the start time of manoeuvres by more than 2 min.^{23 24} A study conducted in Spain showed a reduction in the time spent resuscitating a CPR training mannequin by more than 20 s before and after receiving training, and this improvement was maintained for 6 months.²⁵

In a previous study, we analysed the effectiveness of a network of automatically activated volunteers in reducing the start time of CPR manoeuvres. The aim of that project was to facilitate the automatic activation of a network of resuscitators when an OHCA occurred.^{26 27} Over 86% of the participants significantly increased their knowledge of CPR-AED after receiving the training. In addition, a high percentage of people expressed interest in learning CPR-AED skills, providing further evidence of the programme's impact on the community.²⁷ In 2020, in the context of the COVID-19 pandemic, this in-person training was adapted

into a virtual environment, promoting its dissemination and facilitating access to more people. Since then, 923 people have registered, and 425 (46%) have completed this training (data available from researchers but not reported). However, the effectiveness of this training in a real environment or in a face-to-face simulation remains to be confirmed.

Rural areas pose different challenges for EMS arrival, as the distinctive characteristics and conditions in these environments can prolong the time required to perform CPR manoeuvres in case of OHCA. For instance, a recent study of 1138 OHCA cases in Norway demonstrated lower survival rates among patients in rural settings compared with those in urban settings.²⁸ Similarly, a study in Holland concluded that the volunteer network had a greater impact in rural areas, where the survival rates of patients experiencing OHCA increased by up to 23%.²⁹ Recently, a study indicated a lower probability of successful resuscitation when OHCA occurs in a suburban area, given that EMS headquarters are mostly situated in urban locations.³⁰ Therefore, rural areas could benefit from immediate care in OHCA cases by a witness trained in CPR-AED through this virtual platform. A limitation of online training is the availability of adequate technology

Table 2 Study data collection notebook

Data	Variables
Sociodemographic	Age (years) Gender (male, female, other or prefer not to say) Place of residence (Aleixar, Alforja, Arbolí, Borges del Camp, Capafonts, Cornudella de Montsant, Escaladei, Febró, Maspujols, Morera de Montsant, Poboleda, Prades, Riudecols, Ulldemolins and Vilaplana) Educational level (primary education, secondary education, high school diploma or equivalent, vocational/technical training and college or university: bachelor's, master's and doctorate or professional degree) Socioeconomic level (low, lower middle, middle, upper middle or high)
CPA and related factors	Previous CPR training Family or personal history of heart disease or other risk factors Prior Witnessing of a CPA Past performance in responding to CPA
Course completion	Time taken to complete the course Number of entries Pre-training test score (1–10) Post-training test score (1–10) Number of test attempts
Satisfaction questionnaire	Final overall score Score by dimensions: organisation, methodology, applicability, general assessment and teacher assessment All measured on a Likert scale (1–5)

CPA, cardiopulmonary arrest; CPR, cardiopulmonary resuscitation.

and internet access for the population, especially in rural environments.

The COVID-19 pandemic has significantly increased the prevalence of online training in general, with a notable surge in courses focused on CPR and AED usage. Various formats of online training exist, including those incorporating pre-training and post-training assessments, interactive video modules, virtual reality simulations, non-presential practical sessions using mannequins with automated real-time feedback and assessments conducted at 3 and 6 months.^{31–34}

A study conducted in China, exploring knowledge and attitudes towards AED usage, identified key barriers. Lack of proficiency in resuscitation techniques and limited practical skills were identified as significant impediments. Despite the willingness of the population to engage in rescue efforts when necessary, the study concludes that concerted efforts are required to disseminate knowledge and promote the utilisation of AEDs.³⁵

The proposed study aims to assess, through simulated face-to-face evaluation, the effectiveness of online training in CPR and AED use among participants from a rural area, with the potential to extend the programme to other regions also facing limited access to health services.

METHODS AND ANALYSIS

Study objectives

The specific objectives of this study include: (1) assessing participants' improvement in CPR knowledge after the course and (2) assessing participants' CPR skills through

a face-to-face simulation with CPR mannequins at 1 and 6 months post training.

Study design, setting and recruitment

This study constitutes a quasi-experimental community intervention without a control group, see flowchart in figure 1.

The study comprises two phases:

- ▶ Phase 1: Evaluation of the effectiveness of online training in CPR-AED knowledge.
- ▶ Phase 2: Evaluation of the effectiveness of online training in a simulation environment.

Participants recruitment will be carried out at the Borges del Camp and Cornudella de Montsant primary healthcare centres in Tarragona, Spain. The reference population comprises the inhabitants of 15 municipalities in the rural counties of Priorat and Baix Camp, with a total of 10 256 inhabitants.

During a 3-month period prior to the courses, online training will be disseminated to different population groups including the police, firemen, teaching staff, health workers, shopkeepers and pharmacists. In addition, the course will be offered from the primary care centres to everybody but with a focus on the relatives of people with heart disease. Moreover, alliances will be sought with the municipal councils, and informative posters will be distributed.

Participant's selection

The participants will be selected based on the following specific eligibility criteria.

Inclusion criteria include:

- ▶ Resident in the before mentioned areas of Priorat and Baix Camp.
- ▶ Age ≥ 18 years.
- ▶ Availability of devices and internet access that allows online training to be carried out.

Exclusion criteria include:

- ▶ Language barrier (low or no understanding of Catalan).
- ▶ Any disability that impedes participating in the course and/or carrying out CPR and AED manoeuvres.
- ▶ Recognising the potential difficulty to attend simulation sessions for evaluation.

Having previous training in CPR and AED has not been considered as an exclusion criterion.

Patient and public involvement

Patient or the public were not involved in the design, outcome measurement, recruiting plans or implementation of the study. Results obtained in the simulation environment will be delivered to the participant himself through email. Final results will be published by the investigators in academic journals, newspapers and social media.

Description of intervention

The online training has been designed according to the Catalan Resuscitation Council (CCR) and the ERC guidelines. The aim of this training is to provide theoretical and practical knowledge to respond to urgent situations (from unconscious people to drowning, both for adults and children), as well as the use of the AED.

People interested in participating must register on a Moodle environment platform (<https://register.magnore.com/registre-curs-de-reanimacio-cardiopulmonar-dea/?lang=ca>).

The first registration steps will consist of a brief questionnaire with the eligibility criteria and informed consent to participate in the study. A sample of the participant consent form is available in online supplemental material 1. Once registered and during 1 month, they will have free access to complete the course, which requires a dedication of 3–4 hours. The virtual platform is open 24 hours a day, 7 days a week.

Table 1 describes the sections that the platform incorporates.

Evaluation of intervention

Phase 1: evaluation of the effectiveness of online training in CPR-AED knowledge

Participants will complete two knowledge questionnaires: the first, before the training (pre-training test), to assess prior knowledge, and the second, after the training (post-training test), to assess acquired knowledge. This approach is common in research to measure the impact of an educational intervention.³⁶

This questionnaire has been ad hoc designed for the course in accordance with the recommendations of the

CCR and ERC. It includes 10 questions of several formats (including response-based and action-ordering queries). Successful completion of all 10 questions is required to pass the questionnaire, although an unlimited number of attempts are permitted. The qualification will be either pass or fail. To obtain a pass, the result must be 10. If it is lower than 10, the participant will be able to retake the test. Participants who successfully complete the course will obtain a certificate of completion and will be invited for a personal evaluation by staff accredited by the CCR. Those who accept it will be included in phase 2.

Phase 2: evaluation of the effectiveness of online training in a simulation environment

Volunteers who agree to participate in this second phase will be invited to a face-to-face assessment of CPR skills and the use of the AED in short term (1 month) and medium term (6 months) after training. In the simulated scenario, participants will be exposed to a CPA situation that they must address based on the acquired competence in CPR and AED. The evaluation will be conducted by an external team, independent of the course designers, and will adhere to CCR and ERC recommendations.

Two evaluators will complete a checklist after observing the individual's performance in resolving the situation satisfactorily. The test will be considered successful if 8 out of the 9 actions on the checklist are executed adequately and there is a high level of agreement between the evaluators (>80%). Successful candidates will receive a certified accreditation.

Outcome measures

Primary outcomes measures

- ▶ Effectiveness of the online training in CPR-AED knowledge: The response variable for phase 1 of the study will be the score difference between the pre-training and post-training tests. To successfully pass the course, participants must achieve the maximum score of 10 in the final test. However, the evaluation of online training will focus solely on the score difference between the first attempt at the end of the course and the initial pre-training test. As secondary variables, the number of attempts to obtain the maximum score and the score of the first attempt will also be considered.
- ▶ Effectiveness of the online training in CPR-AED in a simulation environment: The main response variable in phase 2 will be the score obtained in the simulation, defined as a dichotomous variable (pass or fail). The test will be considered successful if 8 out of the 9 actions on the checklist, as proposed by the CCR, are executed adequately, with a high level of agreement between the evaluators (>80%).

It will be considered as secondary outcomes sociodemographic data, CPA and related factors data, course completion data and satisfaction questionnaire (table 2).

Online supplemental material 2 includes the theoretical content test from the online training and a checklist used in the practical evaluation within the simulation

environment, in accordance with the CCR and ERC recommendations.

Data collection

For phase 1, data will be gathered via the online training platform. In phase 2, a healthcare professional will collect data through the CCR questionnaire. These data will be stored in virtual electronic format in a secure environment and under the supervision of the principal investigator. Access to data will be controlled using highly secure credentials. The data obtained will be used solely for this study or a related purpose. A study chronogram is available in online supplemental material 3.

Sample size calculation

For phase 1, the online training course is open access, allowing anyone meeting the study's selection criteria to participate. In phase 2, a representative sample, including participants of different ages and genders, will be obtained from those who completed phase 1. In addition, the population of participants will be selected proportionally based on population density of each municipality.

In order to evaluate the effectiveness of the training in the simulation, the necessary sample size has been calculated using the statistical software GRANMO (vV.7.11; March 2011) using the option of averages observed with respect to a reference sample. Accepting an alpha risk of 0.05 and a beta risk of 0.2 for a bilateral contrast, it is considered that 52 participants are needed to detect a difference equal to or greater than 0.5 points in the face-to-face evaluation of the online training, assuming a common SD of 1.07. The number of subjects is increased by 30% to compensate for potential losses to follow-up.

Statistical analyses

The R Statistics package (R Foundation for Statistical Computing, Vienna, Austria) will serve as statistical software.

Quantitative data in accordance with normal distribution will be expressed as mean and SD. For non-normally distributed quantitative data, median and IQR will be presented. The normality of variables will be assessed using the Kolmogorov test. Categorical data will be described as rates and percentages.

Initially, a descriptive analysis of the study population and a bivariate analysis will be carried out. The paired Student's t-test will be used to compare pre-training and post-training quantitative variables or the Mann-Whitney U test when appropriate. McNemar's test will be employed for categorical variables. Finally, a multivariate analysis using linear regression will be conducted to identify independent factors influencing the main variable, adjusting by all variables of interest described above.

Ethics and dissemination

This study will adhere to the principles of the Declaration of Helsinki, as revised and updated, and Good Clinical Practice. The protocol has received approval from the Clinical Research Ethics Committee of the Primary

Care Research Institute IDIAP Jordi Gol i Gurina Foundation (23/081-P; 15 June 2023).

Only participants who have signed the informed consent form will be included in the study.

Data confidentiality will be protected under Spanish law governing the protection of personal data (*Ley Orgánica de Protección de Datos de Carácter Personal y garantía de los derechos digitales*; 03/2018, 5 December).

The findings of the study will be published open access in peer-reviewed journals and disseminated at national and international conferences and through social media.

Data availability statement

Data from the study will be made available in the future for collaborative research questions. Such requests must be authorised by the principal investigators.

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