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PediAppRREST: effectiveness of an interactive cognitive support tablet app in reducing deviations from guidelines in the management of paediatric cardiac arrest: protocol for a simulation-based randomised controlled trial

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ABSTRACT

Introduction Paediatric cardiac arrest (PCA), despite its low incidence, has a high mortality. Its management is complex and deviations from guideline recommendations occur frequently. We developed a new interactive tablet app, named PediAppRREST, to support the management of PCA. The app received a good usability evaluation in a previous pilot trial. The aim of the study is to evaluate the effectiveness of the PediAppRREST app in reducing deviations from guideline recommendations in PCA management.

Methods and analysis This is a multicentre, simulation-based, randomised controlled, three-parallel-arm study. Participants are residents in Paediatric, Emergency Medicine, and Anaesthesiology programmes in Italy. All 105 teams (315 participants) manage the same scenario of in-hospital PCA. Teams are randomised by the study statistician into one of three study arms for the management of the PCA scenario: (1) an intervention group using the PediAppRREST app or (2) a control group Paediatric Advanced Life Support (CtrlPALS+) using the PALS pocket reference card; or (3) a control group (CtrlPALS-) not allowed to use any PALS-related cognitive aid. The primary outcome of the study is the number of deviations (delays and errors) in PCA management from PALS guideline recommendations, according to a novel checklist, named c-DEV15plus. The c-DEV15plus scores will be compared between groups with a one-way analysis of variance model, followed by the Tukey-Kramer multiple comparisons adjustment procedure in case of statistical significance.

Ethics and dissemination The Ethics Committee of the University Hospital of Padova, coordinating centre of the trial, deemed the project to be a negligible risk study and approved it through an expedited review process. The results of the study will be disseminated in peer-reviewed journals, and at national and international scientific conferences. Based on the study results, the PediAppRREST app will be further refined and will be available for download by institutions/healthcare professionals.

Trial registration number NCT04619498; Pre-results.

Strengths and limitations of this study

- The main strengths of this study are the randomised control trial design, the large sample of medical residents who will be recruited, and the presence of two control arms.
- Another strength is that the PediAppRREST app, the innovative intervention being studied to improve the management of paediatric cardiac arrest (PCA), has been previously pilot tested for usability and perceived team leader's workload associated with its use, showing encouraging results.
- Participants in the trial will be exclusively medical residents and therefore this may limit the generalisability of the study findings to more experienced clinicians.
- The simulation-based setting of the study will not provide data on actual patient outcomes, and therefore, future investigations during real-life, in-hospital, PCAs will be necessary to evaluate the actual effectiveness of the PediAppRREST app in clinical practice.

INTRODUCTION

Paediatric cardiac arrest (PCA), despite its low incidence, is associated with high mortality and serious clinical sequelae.[1–5] The need for multiple rapid and complex interventions and the aetiopathogenic differences with adult cardiac arrest, make its management challenging and error prone. International scientific societies periodically release and update evidence-based guidelines outlining the recommended management of in-hospital and out-of-hospital PCA.[6–11] The Paediatric Advanced Life Support (PALS) course has been created by the American Heart

Association (AHA) to train healthcare professionals in the advanced management of PCA.[12] Nevertheless, studies demonstrated that, despite training, deviations from guideline recommendations often occur in PCA management,[13–19] and lead to patients' worse clinical outcomes.[20 21]

Previous studies have assessed multiple strategies and tools to cognitively support providers to deliver optimal resuscitation during CA, as per guideline recommendations, showing variable efficacy.[22–36] Most of these studies focused on adult cardiopulmonary resuscitation (CPR) in an out-of-hospital setting and assessed prerecorded audio/video support or contact by phone with a medical dispatcher.[32] Several studies have so far focused on technology developed to improve the quality of chest compressions through audio/visual feedback.[33–36] Software and apps for mobile phones, and tablets, as well as augmented reality glasses have been developed and used to improve adherence to guidelines.[23–31] However, most of these tools are directed to adult CA and showed to be associated with only partial improvements in the management of simulated CA scenarios. In addition, their usability and associated perceived workload has not been formally assessed before testing their efficacy. Overall, there is very limited experience on the usefulness of interactive cognitive support through an app in the management of PCA.[31]

We developed and refined a new audio-visual interactive app for tablets, named PediAppRREST, to support the management of PCA.[37] The app was developed based on the results of a multicentre observational simulation-based study, conducted by our research team, evaluating errors and delays in the management of a PCA scenario by paediatric residents.[38] We also tested the app usability in a pilot simulation-based study of non-shockable PCA scenarios, managed by paediatric residents, all PALS certified providers. The app received good usability evaluations and it did not increase the team leader's perceived workload compared with the control group that did not use any cognitive support tool.[37] No app that has previously been tested for usability and associated perceived workload, has so far been evaluated in a large, appropriately powered, randomised clinical trial, involving physicians from different medical specialties, for its efficacy in guiding the management of PCA.

Objectives

The primary objective of this study is to determine, in a multicentre, randomised controlled trial (RCT), whether the use of the PediAppRREST app is associated with a reduction of deviations from international guidelines, in the management of a simulated PCA scenario, compared with the use of the PALS pocket reference card or with the use of no cognitive aid.

The secondary objectives are to further evaluate the usability of the PediAppRREST app and its impact on team members' workload, CPR quality, time to performance of critical resuscitation interventions and overall team performance.

METHODS AND ANALYSIS

Study design and settings

The study is a national, multicentre, superiority, 3-parallel-group, randomised controlled trial conducted in the setting of off-site intermediate-fidelity simulation. The study has been designed following guidelines for healthcare simulation research.[39] The study includes an intervention arm (PediAppRREST arm) and two control arms (CtrlPocketPALS+ and CtrlPocketPALS-). In the intervention arm participants use the novel interactive cognitive support tool, the PediAppRREST tablet app, to manage a standardised simulated scenario of PCA while the teams in the control arms manage the same scenario without the support of the app. Participants in the CtrlPocketPALS+ arm use the current recommended cognitive support tool, the PALS pocket reference card, while in the CtrlPocketPALS- arm no cognitive aid is used. The study design diagram is available in figure 1. All the scenarios are videorecorded and reviewed by two previously trained and independent reviewers who will collect the data in the study case report forms (CRFs).

Participants

Participants are recruited from medical residency programmes in Paediatrics, Emergency Medicine and Anaesthesiology, at the (1) University Hospital of Padua, University of Padua (Padua); (2) Meyer University Hospital, University of Florence (Florence); (3) Maggiore della Carità University Hospital, University of Piemonte Orientale (Novara) and (4) Agostino Gemelli University Hospital, Catholic University of Sacred Heart (Rome).

Eligibility of potential participants is assessed by the study investigators of each participating site. Residents must meet all the following criteria to be enrolled in this trial: (1) to be attending a residency training programme in Paediatrics, Anaesthesiology or Emergency Medicine; (2) to be Basic Life Support (BLS) or Paediatric-BLS (P-BLS) or PALS or ALS or Advanced Cardiac Life Support (ACLS) certified, following the AHA or the European Resuscitation Council (ERC) recommendations and (3) to give consent to participate to the study and to be videorecorded. Additionally, to be eligible for the role of team leader residents must be PALS-certified according to AHA or ERC guidelines. Residents who took part in the pilot study of the PediAppRREST app,[37] or who are unable to attend the simulation sessions because of maternity/paternity leave, sick/personal leave or training abroad are not eligible to participate in the trial.

Randomisation, allocation concealment and blinding

Participants are randomised by the study statistician in teams of three, stratified by study site and residency programme specialty. Randomisation is conducted assuring that in every team there will be at least one PALS-certified team member assigned to the role of team leader. The same statistician assigns a unique team identification number to each team and prepares the list of participants associated with each team to be sent to the principal investigators. Participants

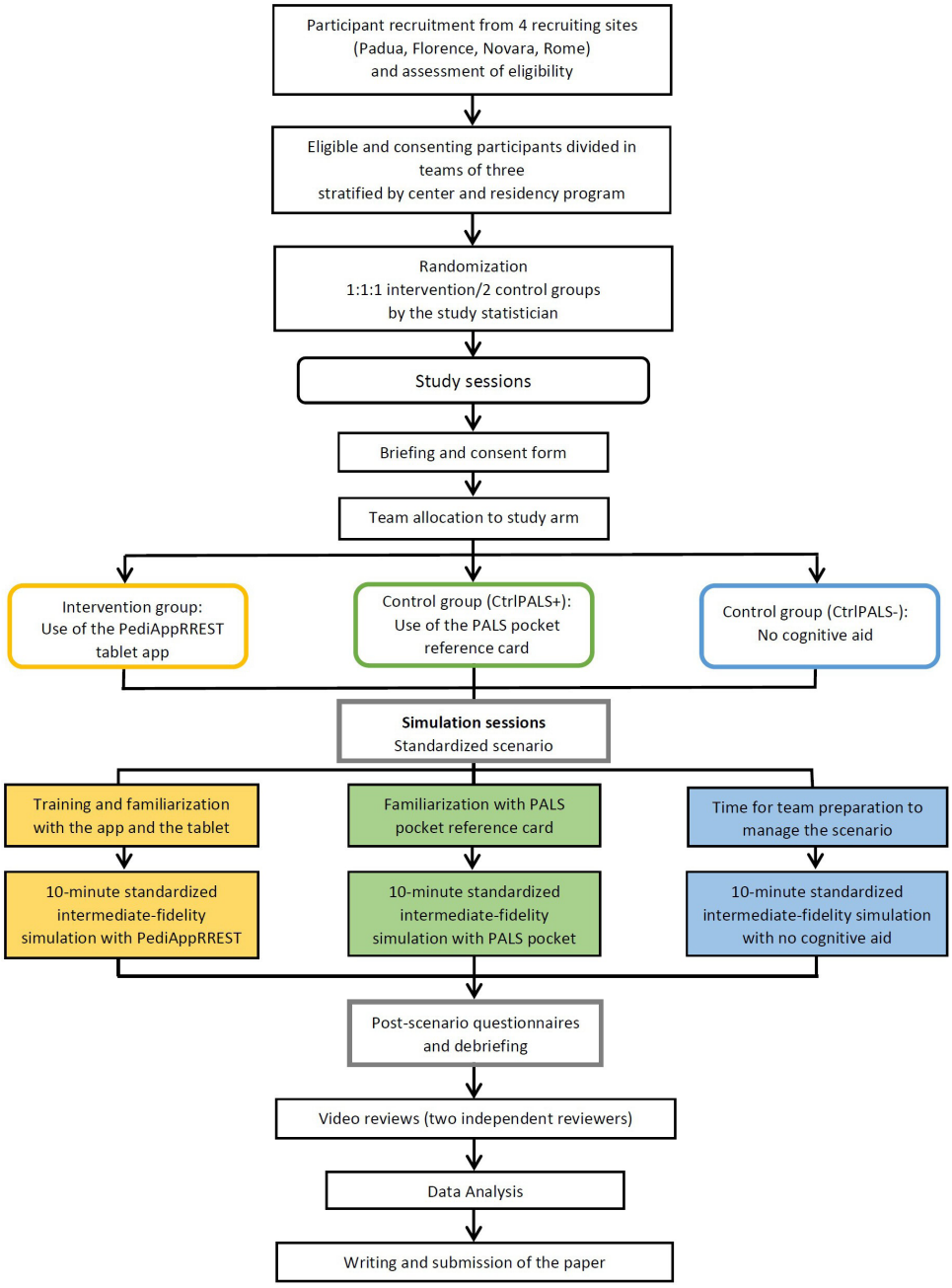

Figure 1 Study design diagram. PALS, Paediatric Advanced Life Support.

are randomly divided in teams of three members per each scenario; the team leader is selected among PALS-certified residents whereas the other two members have to be at least BLS-certified. The teams are randomised with a 1:1:1 ratio in the intervention arm (PediAppRREST arm) and the two control arms.

The statistician also creates opaque sealed envelopes externally marked with the team identification number and containing a paper slip, which indicates the arm allocation for that specific team. Team group allocation is concealed until the simulation sessions. Randomisation of participants to teams, and teams to the study arms, is performed with SAS V.9.4 (SAS Institute) for Windows.

Due to the nature of the cognitive support tools used in the trial, blinding of participants as well as of research staff involved in the simulation sessions and video reviewers, is not possible. However, blinding of the statistician performing data analysis will be ensured. Data analysis is expected to be finalised by February 2022.

Outcomes

Primary outcome

The primary outcome of the study is the number of deviations from the PALS guidelines made by the teams during the management of a standardised simulated scenario of non-shockable PCA.

Box 1 c-DEV15plus items for non-shockable paediatric cardiac arrest simulation scenario

1. Cardiopulmonary resuscitation (CPR) started within 30 seconds (s) from recognition of pulseless state.
2. CPR board/rigid surface positioned underneath the manikin within 60 s from recognition of pulseless state.
3. Compression/ventilation ratio 15:2.
4. Help called (hospital emergency response system activated) within 60 s from recognition of pulseless state.
5. Compressors switched more than once during CPR.
6. ECG-monitoring started within 60 s from recognition of pulseless state.
7. Intravenous/intraosseous (IO) access called within 60 s from recognition of pulseless state.
8. First epinephrine called within 30 s from recognition of pulseless state.
9. First epinephrine administered at the correct dose and dilution* and by the correct route (intravenous or IO), followed by a normal saline flush, while compressions are being performed, within 300 s (5 minutes) from recognition of pulseless state.
10. Second epinephrine called between 3 and 5 minutes from the first administration of epinephrine.
11. Second epinephrine administered at the correct dose and dilution* and by the correct route, followed by a normal saline flush, while compressions are being performed, within 5 minutes from the first epinephrine.
12. Blood gas called during cardiac arrest.
13. Reversible causes treated.
14. Shock not administered.
15. Medications other than epinephrine (eg, amiodarone, lidocaine, atropine) not administered.†

*Correct dose of epinephrine is defined as 0.01 mg/kg (or a deviation from the correct weight dose of less than 10%); correct dilution of epinephrine is defined as 1:10.000 (0.1 mg/mL).
†Administration of medications to treat identified reversible causes is not considered in this item.

Deviations from PALS guideline recommendations are defined as delays and errors according to a novel checklist we derived from the previously published checklist by Wolfe *et al*,[20] denominated c-DEV, by integrating it with evidence-based guidelines,[6–8 11] previously reported scoring tools[40–43] and checklists.[37 44 45] We named our new modified checklist c-DEV15plus. It includes 15 items, which represent correct critical actions for paediatric resuscitation (box 1).

Each item of the c-DEV15plus is scored either as 0, when the action is performed correctly and timely, as described in the item, or as 1, when the action is not undertaken, undertaken incorrectly, or with wrong timing and, in the event of drug administration, when the dose, duration or route of administration is wrong. The sum of the points attributed to the items represents the c-DEV15plus total score, hence ranging from 0 to 15, with higher scores corresponding to a higher number of deviations from the guidelines. Outcome assessors will score the scenarios through the c-DEV15plus tool using the data registered and coded by the video reviewers.

Secondary outcomes

The following secondary outcome measures will be collected:

- Performance and time to accomplish critical resuscitation interventions recommended by PALS guidelines.[6–11 20] The interventions evaluated will be: (1) CA recognition (pulselessness); (2) start of chest compressions; (3) start of ventilation; (4) use of a CPR board or a rigid surface underneath the manikin; (5) call for emergency team help; (6) start of ECG monitor; (6) first epinephrine administration; (7) second epinephrine administration and (8) treatment of reversible causes of CA. Performance and time to accomplish critical interventions (in seconds) during resuscitation will be assessed and recorded by video reviewers in the study CRFs and will be analysed both as time from the beginning of the scenario and as time from the recognition of pulselessness.
- Usability of the app. To assess the PediAppRREST app usability, the team leaders of the intervention group will be administered one validated questionnaire, the System Usability Scale.[46 47] Further, the team leader will be asked to complete a questionnaire with open-ended questions.
- Team leaders' workload measured by the validated, multidimensional NASA-Task Load Index (NASA-TLX).[48 49] This tool includes six subscale scores that represent independent clusters of variables and different domains of the perceived workload: Mental, Physical and Temporal Demands, Frustration, Effort and Performance.
- CPR quality measured by the Skill Reporter (Laerdal), the internal software of the manikin. CPR quality is defined as: (1) proportion of chest compressions with depth 50–60 mm; (2) chest compression fraction (the percentage of time during CA with chest compressions), (3) mean chest compression depth and (4) mean chest compression rate, according to AHA standards.[7 50]
- Team resuscitation performance as evaluated with the Clinical Performance Tool (CPT).[40 41] The CPT is a validated scoring system designed based on PALS algorithms, through which sequence, timing, and quality of specific actions, during different simulated scenarios, can be assessed. The CPT section for the asystole scenario will be used to evaluate teams' performance.

Intervention

Intervention arm: PediAppRREST app

The PediAppRREST, is an interactive, multimodal (audio-visual), 'checklist' app, sequentially displaying prompts on recommended PCA management interventions.[37] It was specifically designed in 2019 to guide the team leader to perform resuscitation interventions in the sequence/timing and modality reported by the AHA PALS 2015 guidelines.[6–8]

The design and development of the app was guided by the results of a previous study conducted by our research team, which assessed deviations from guidelines in PCA simulation scenarios managed by paediatric residents.[38] The app was further refined following an iterative prototyping development approach with serial testing by our research staff, and according to the feedback provided by paediatric residents involved in a simulation-based pilot study.[37] The PediAppRREST app received a good usability evaluation and did not appear to increase team leaders' workload.[37]

Following the publication of the updated AHA PALS 2020 guidelines,[11] the content and prompts of the app were checked against the guideline updated recommendations. Prompts to administer epinephrine as soon as possible and to guide postarrest management were already provided by the app. The only content that required changing was the recommended ventilation rate for patients with an advanced airway from 1 breath every 6 s to 1 breath every 2–3 s. However, this last parameter is not included in the study outcomes, and it will not affect the results of our study.

Control arm: PALS pocket reference card

The AHA PALS pocket reference card is a 10 × 16.5 cm, full-colour, two-sided, 6-panel card that shows the AHA treatment algorithms.[51] By providing a quick reference tool, it serves as a cognitive aid for healthcare providers who either direct or participate in the management of paediatric respiratory and/or cardiovascular emergencies, including CA. The PALS pocket reference card is used during the PALS course and in a variety of healthcare settings. Although there is no published evidence on its effectiveness, the PALS reference pocket card by summarising the content and sequence of recommended interventions, is the cognitive aid most widely used worldwide. Participants were provided the 2015 AHA PALS reference pocket card[51] until the new 2020 AHA PALS reference pocket card[52] was available and introduced in the study in 2021. Participants in this arm are also allowed to use a pocket calculator to compute medication dosages/dilution and a timepiece.

Control arm: no cognitive aid

Teams who are assigned to the CtrlPALS- group, are not allowed to use neither the PediAppRREST app nor the PALS pocket reference card to manage the simulated scenario. However, they are allowed to use a pocket calculator to work out medication dosages/dilution and a timepiece, but no other cognitive tool.

Study procedures

Participant recruitment and assessment takes place over a 15-month period (September 2020–December 2021). The University Hospital of Padua is the coordinating centre of the trial. Its research team oversees all study procedures and processes during the simulation sessions to assure standardised high-quality procedures are carried out at each participating centre (Padua, Florence, Novara, Rome). At the trial simulation sessions, the research staff meet the residents, illustrate the study, answer any possible questions, reassess eligibility criteria for each participant, and obtain informed consent for study participation and video recording.

During all trial sessions measures to prevent COVID-19 infection spread (physical distancing, hand hygiene, use of personal protective equipment during the scenario, temperature and health checks, contact tracing, surfaces/mannequin/equipment disinfection, etc) are strictly followed for participants and research staff's safety.[53 54]

Before beginning the simulation session, all teams watch the same 20 min briefing video about the study procedures and orientation to the setting, manikin and equipment. This phase has also the aim of increasing participants' adherence to intervention protocols and study procedures.

After the briefing, each team progressively receives and opens its assigned sealed envelope, which contains the arm allocation (PediAppRREST or CtrlPALS+ or CtrlPALS-). Thereafter, all participants wear a sticker with the corresponding team identification number and personal identification code. Ten minutes before their assigned simulated scenario each team is informed that the scenario will be about a PCA case, without specifying any further detail. The teams assigned to the intervention arm (PediAppRREST) watch a 5-minute tutorial video about the app and its use, prepared ad hoc for this study. They are also given 5 minutes to practically familiarise with the tablet and the app. The teams in the CtrlPALS+ arm are given 5 minutes before the scenario to familiarise with the PALS pocket algorithm card, while teams in the CtrlPALS- arm are given 5 minutes to discuss how to manage the scenario without any PALS-related cognitive aid.

Subsequently, each team participates in a 10-minute standardised intermediate-fidelity simulated scenario of non-shockable PCA caused by hypovolaemia and hypoglycaemia. A non-shockable rhythm was chosen for the simulated scenario because it is the most common initial CA rhythm detected in PCA.[55] The setting, the equipment set up, the scenario, and the manikin (Resusci Junior QCPR Laerdal whose head is replaced with the MegaCodeKid Laerdal manikin's head, on which advanced air management can be performed) are the same for all the centres. The scenario is introduced by a standardised video where an actress, playing the patient's (manikin's) mother, provides essential clinical information (further scenario details are included in online supplemental file). The scenarios are conducted off-site, in rooms set up to resemble the Emergency Department Shock room including regularly available equipment. The simulation rooms are set up in a standardised fashion between participating sites. Every team works with one confederate nurse and can call confederate consultants on the phone, who answer based on a standardised script. During the scenario, the team can speak with a facilitator, who is a

member of the research team and answers participants' questions following a predetermined script.

All the scenarios are videorecorded by two different fixed cameras with standardised positions that point to the team and to the monitor. An additional camera captures the actions of the team leaders who use the PediAppRREST app, framing the screen of the tablet. Only the videos from the two fixed cameras will be evaluated by the reviewers. The videos of the team leaders' actions with the tablet will be examined only by the research team to assess potential bugs in the app or challenges with its use.

After the scenario, all participants complete a demographic survey reporting their sex, age, year and type of residency programme, experience in simulation and resuscitation, and time from PALS/P-BLS/BLS/ALS/ACLS certification. In addition, all the team leaders complete the NASA-TLX and the team leaders in the intervention arm also evaluate the app usability, by completing the SUS. Subsequently, all participants participate in a 15-minute debriefing during which they receive feedback about their performance, and the teams in the intervention arm are able to provide feedback about the app. During this phase, the debriefer reports the feedback received on the app in a specific CRF.

The videos of the scenarios will be evaluated by two independent, and previously trained, reviewers expert in paediatric emergency medicine and simulation. Training of the reviewers, on RCT-unrelated PCA simulation videos, will be conducted by the principal investigator (FC), until the reviewers will reach at least 80% inter-rater agreement with the principal investigator. No more than 2weeks will lapse between the training and the assessment of the RCT videos. The reviewers will use a standardised data collection form where actions performed by the team and time to performance will be assessed and recorded. Disagreements between reviewers will be resolved by consensus with a third independent reviewer, expert in paediatric emergency medicine and simulation. Inter-rater reliability between reviewers will be monitored and reported. Data pertaining the CPR quality from the manikin software will be extracted and recorded on a specific CRF. The scores on the c-DEV15plus, and all the secondary outcomes will be calculated by outcome assessors based on the data coded and reported by the video reviewers on the CRFs.

Data collection and management

Participants' data are pseudoanonymised by assigning a unique code to each participant.

Data pertaining the participants' information, video reviews and the outcomes investigated in the trial, is recorded using pseudoanonymised CRFs. Completed CRFs are checked for completeness and accuracy by the principal investigators.

All CRFs data are securely stored in electronic databases created using Research Electronic Data Capture (REDCap), a browser-based, metadata-driven software solution and workflow methodology used to design clinical and translational research secure password-protected databases (REDCap, Vanderbilt University, Nashville, Tennessee, USA).[56] Only the principal investigators and the study statistician will have access to the final trial dataset.

Data will be analysed by the study statistician (ACF) who will be blinded to group allocation coding.

Statistical analysis

Sample size calculation

We calculated sample size on the basis of the results obtained during the previous observational simulation-based study and the pilot study that tested the app usability.[37 38] Based on the preliminary results from these studies, using a single factor analysis of variance (ANOVA) model, 29 scenarios per each of the three groups (PediAppRREST, CtrlPALS+, CtrlPALS-) are necessary to detect a difference of at least 3.00 points on the c-DEV15 plus scale using the Tukey-Kramer (Pairwise) multiple comparison procedure at a 5% significance level and 80% power. The common SD within a group is assumed to be 2.20.

In consideration that some possible technical problems with video-recording or other study procedures could occur, we aim to increase the recruitment of participating teams by 20% per arm, to compensate for loss of statistical power due to a potential insufficient sample size. Hence, we plan to have 35 scenarios per arm, for a total of 105 scenarios, which will include overall 315 residents divided in teams of three.

Data analysis plan

The results will be summarised for each study group with counts and percentages for categorical variables, mean and SD or median and IQR for quantitative variables, as appropriate. The normality of the quantitative variables will be checked with the Shaphiro-Wilk test.

The c-DEV15plus scale, the performance and time to accomplish specific resuscitation interventions, NASA-TLX, CPT and CPR metrics will be compared between groups with one-way ANOVA model, followed by the Tukey-Kramer multiple comparisons adjustment procedure in case of statistical significance.

The outcomes will also be analysed with a linear mixed model considering the team as a cluster to evaluate the influence of participants' characteristics on the outcome. To take into account the correlation of the observations within a team, we will specify an undetermined correlation matrix. In case of a not normal distribution of the model residuals, we will proceed with a transformation in order to normalise the distribution.

Both intention-to-treat and per-protocol analyses will be performed.

Patient and public involvement

No patient involved.

ETHICS AND DISSEMINATION

The design of this study complies with the Declaration of Helsinki ethical principles, Good Clinical Practice

standards and European Union general data protection regulation on scientific research. Participation into the study is on a voluntary basis and bears no academic or professional consequences on the medical residents. A written informed consent to take part into the study is obtained from each participant. The Human Ethics Committee (HEC) of the University Hospital of Padova, coordinating centre of the trial, deemed the trial to be a negligible risk study and approved it through an expedited review process.

The results of the study will be disseminated in peer-reviewed journals, national and international scientific conferences, and medical residency training programmes educational sessions. After publication of the study results, the PediAppRREST app will be released exclusively to institutions/healthcare professionals, on request.

Any adverse event will be communicated to the principal investigators and recorded in the participant CRF. In the extremely unlikely event of a serious adverse event, the principal investigators will be informed immediately and the HEC will be notified within 24–72 hours of occurrence.

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Contributors SB, FC, DS, MA, VS, PLI, MDL, LT, ACF and LDD conceptualised the study. SB and FC designed the study and its procedures, with input from AC. FC and MA wrote the first draft of the protocol and contributed equally to this paper. All authors contributed to the revision of the protocol and editing of the manuscript.

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