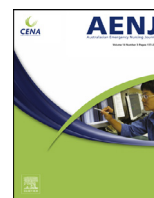




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Research paper

So you want to conduct a randomised trial? Learnings from a 'failed' feasibility study of a Crisis Resource Management prompt during simulated paediatric resuscitation

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ABSTRACT

Background: No study has tested a Crisis Resource Management prompt on resuscitation performance.

Methods: We conducted a feasibility, unblinded, parallel-group, randomised controlled trial at one Australian paediatric hospital (June–September 2014). Eligible participants were any doctor, nurse, or nurse manager who would normally be involved in a Medical Emergency Team simulation. The unit of block randomisation was one of six scenarios (3 control:3 intervention) with or without a verbal prompt. The primary outcomes tested the feasibility and utility of the intervention and data collection tools. The secondary outcomes measured resuscitation quality and team performance.

Results: Data were analysed from six resuscitation scenarios (n = 49 participants); three control groups (n = 25) and three intervention groups (n = 24). The ability to measure all data items on the data collection tools was hindered by problems with the recording devices both in the mannequins and the video camera.

Conclusions: For a pilot study, greater training for the prompt role and pre-briefing participants about assessment of their cardio-pulmonary resuscitation quality should be undertaken. Data could be analysed in real time with independent video analysis to validate findings. Two cameras would strengthen reliability of the methods.

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Introduction

While cardiac arrest in hospitalised paediatric patients is rare, the outcomes are often poor [1]. The survival to hospital discharge rate for these patients is approximately 40%; while 10–30% have unfavourable neurological outcomes [2]. Using early warning tools for signs of clinical deterioration [3], medical emergency teams (METs) [4] and education to improve the efficacy of cardiopulmonary resuscitation (CPR) [5,6] are essential for optimising outcomes [7].

The aim of simulation in healthcare is to replicate some or nearly all of the essential aspects of a clinical situation so that the scenario may be more readily understood and managed when it occurs

in clinical practice [8]. Hence simulated learning is essential for acquiring procedural resuscitation skills [9].

Crisis Resource Management (CRM) skills including communication, leadership, knowledge of environment, teamwork, anticipation and planning, attention allocation, workload distribution and use of cognitive aids are of core importance to the practice of emergency medicine [10]. An effective team leader is identifiable, clinically experienced, communicates effectively and delegates tasks [11,12]. While effective leadership is associated with improved team performance [11,13], poor leadership is associated with the inability to perform the critical interventions required to effectively resuscitate a patient [11,14]. Cognitive aids, such as resuscitation algorithms increase the performance of critical interventions (e.g. timely defibrillation) [15]; and may reduce errors [10]. Therefore, use of cognitive aids (rather than the availability of cognitive aids) is a key component of CRM.

Use of CRM skills is associated with improved resuscitation performance [16–19] in paediatric settings [20]. Over the last decade, CRM training has been incorporated into simulated learning envi-

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ronments [20,21]. While CRM training reduces no-flow time (NFT) (i.e. time without cardiac compressions during CPR) and increases team leader verbalisations (direct orders) [22]; resuscitation teams often deviate from the resuscitation protocol [23,24]. A recent study reported that CPR quality and adherence to the national resuscitation guidelines was poor among paediatric residents [25]. A contributing factor may be that retention of resuscitation knowledge and skills may not persist beyond three [26] to 12 months [27], particularly when used rarely.

A verbal prompt read aloud to trigger the steps of the emergency management algorithm, compared to no verbal prompt, appears to improve the execution of critical actions [23]. A verbal prompt which incorporates prompts for CRM principles (e.g. who is the team leader), as well as steps of the resuscitation protocol (e.g. reading aloud the steps of the algorithm when needed), may improve team performance during real or simulated resuscitation. We found no published studies which tested a verbal CRM prompt and compared to having access to a written algorithm. Therefore we planned to test the feasibility of conducting such a study.

Methods

Study design

A feasibility, unblinded, parallel group randomised controlled trial (RCT) was used to answer the question: is it feasible to compare resuscitation performance in METs that use a verbal CRM prompt (*intervention*) compared to no verbal CRM prompt (*control*) through a RCT? The study was justified as the intervention had not been previously tested [28] and would enable investigation of the feasibility of the intervention and the data collection tools; for a larger trial that could assess the outcome of interest (i.e. resuscitation performance) [29,30]. Furthermore, feasibility trials allow for protocol modifications to be conducted prior to the conduct of a statistically powered RCT [31]. Ethical approvals from both the hospital (HREC/13/MHS/183) and the University (2014_155Q) were received.

Research setting

The study was conducted during June to September 2014 in a tertiary paediatric facility in Queensland, which admits over 15,000 children annually. When there is an unexpected clinical deterioration in a patient, within or outside the critical care areas, that meets MET criteria on the early warning tool; a MET code is called [32]. The composition of the MET is an ad-hoc combination of clinical hospital staff who attend an average of 120 calls for medical assistance each year. The MET emergency simulations run on a weekly basis throughout the study hospital.

Participants

The inclusion criterion for the study was any nurse, doctor, or ward-service staff employed at the paediatric tertiary hospital, who would normally be involved in MET events. Exclusions included refusal to participate or not receiving information and providing written informed consent prior to the simulation. Participants were not individually randomised.

Recruitment

The study was advertised on the Paediatric Resuscitation website on the hospital intranet. An email about the study including a link to information sessions was sent to relevant department managers to forward to staff. Participant information and consent forms were distributed at the information sessions and securely collected. Written informed consent remained valid for the entire

study period. Efforts were made to collect individuals' written informed consent prior to simulation events. However, if this was not possible then clinicians were excluded from participating in the scenario. The bed managers, who were responsible for reading out the verbal prompt in the intervention groups; were briefed and consented separately.

Randomisation and blinding

The unit of randomisation was a paediatric resuscitation scenario with or without a verbal CRM prompt. The random allocation sequence for 24 scenarios using block randomisation (blocks of six) was generated by the hospital research facility. Block randomisation was used to ensure even distribution between the control and treatment arms of the study and reduce the chance that the order of randomisation could be predicted [33]. There was no way to blind participants or data analysers to the intervention.

Interventions

Control

Nursing staff were pre-briefed by the simulation coordinator and orientated to the Laerdal® Quality CPR (QCPR) infant manikin's features. The manikin provided key simulation functionalities including spontaneous breathing, electrocardiograph, live defibrillation, intravenous access, blood pressure and stores CPR information electronically. A scenario was provided and nursing staff were prompted to provide clinical care for the patient. At some point in the scenario, MET criteria were reached and staff activated the emergency buzzer. After the MET arrived, one of six simulation scenarios were given, all of which included a loss of cardiac output at four minutes (+/- 30s) after the activation of the emergency alarm. Both control and intervention arms had access to the resuscitation algorithm (Fig. 1). The manikin was pulseless for 8 min +/- 30 s in each simulation. The simulation coordinator terminated the scenario after CPR data had been collected and the group attended a debrief session.

Intervention

The intervention scenario occurred in the same way as the control scenario with the addition of a Nurse Bed Manager using a stop watch and a schedule of timed prompts which focussed on team leadership and use of the resuscitation algorithm (two CRM principles)(Fig. 1).

Outcomes

Primary outcomes (feasibility)

- The number of simulations that are successfully conducted during the study period (n);
- The ability to measure all data items during video analysis (yes/no).

Secondary outcomes

Resuscitation performance

- Proportion of CPR time with hands-on-chest (mean%);
- Compression rate (mean%);
- Compressions with correct hand position (mean%);
- Adequate depth of compressions (mean%);
- Compressions fully released (mean%);
- Ventilation rate (mean%);

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