ORIGINAL RESEARCH

Simulation-based education for staff managing aggression and high-risk behaviors in children with autism spectrum disorder in the hospital setting: A pilot and feasibility cluster randomized controlled trial

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ABSTRACT

Background and objective: Aggression and high-risk behaviors, which can result in behavioral emergencies, are common in children with autism and can be magnified in the hospital environment. Children with autism, with or without intellectual disability, have complex communication needs which require a sophisticated level of knowledge, understanding and skill from health care professionals. Pediatric acute care nursing staff are often not trained and lack confidence in managing children with autism. The purpose of this study was to conduct a pilot and feasibility cluster randomized controlled trial (RCT) of simulation-based education for staff in managing behavioral emergencies with autism spectrum disorder (ASD) in the hospital setting.

Methods: This study used a mixed method, to explore the acceptability and feasibility of delivering a large-scale cluster RCT and assess trial processes including recruitment, completion rates, contamination, and outcome measures. The simulation-based training format comprised two scenarios involving an adolescent with autism, intellectual disability and aggressive behaviors. Two pediatric wards of similar size and patient complexity were selected to participate in the study and randomized to receive either simulation-based education plus web-based education materials or web-based education materials only.

Results: The RCT design is feasible with recruitment, acceptability and completion rates reaching target. Self-perceived baseline levels of confidence in managing aggression in children were mid-range and lower for children with autism and intellectual disability. Forty to fifty percent of intervention participants rated the training highly in terms of developing skills and knowledge respectively. The mean group score for observer ratings of de-escalation across four simulations was 20 out of a possible 35. Data for ward aggression were not collected.

Conclusions: Simulation-based education is an acceptable training format for acute care pediatric nurses. This study is feasible to conduct as a cluster RCT with some modifications to this protocol including assessment of baseline differences in confidence. Observer ratings of de-escalation skills indicated that more than one episode of training may be required for acute care pediatric staff to successfully de-escalate aggressive incidents. As such, we will use repeated simulation scenario exercises for each intervention group in the next trial.

Key Words: Feasibility studies, Autism spectrum disorder, Intellectual disability, Simulation-based education, Pediatric nursing, Aggression

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1. INTRODUCTION

1.1 Background and rationale

Children and young people with a neurodisability, such as autism spectrum disorder (ASD), often exhibit aggressive and high-risk behaviors which can be magnified in the hospital environment and result in behavioral emergencies.[1,2] Croen et al.[3] reported children with ASD, with or without intellectual disability (ID), to experience more adverse events and more frequent contact with health care providers, including hospital visits, than typically developing children. This includes more baseline anxiety and behavior issues than typically developing children[4,5] which can escalate when under stress and result in sensory overload (noise, foreign smells, equipment) for those in an unfamiliar hospital environment.[6] Children may find the experience of communicating with many more people than usual challenging as they instinctively prefer less social interaction. Intellectual disability, estimated to occur in approximately 50%-70% of individuals with ASD[7] also increases communication difficulties.[8]

Aggressive behavior can be one of the most debilitating comorbidities for children with autism and intellectual disability and is a great source of parental concern when accessing health care. In the hospital environment, the focus is often on managing behavioral emergencies rather than preventing them.[9] Seclusion, restraint and the use of psychotropic medication are often utilized as a short-term solution.[9,10] It is important that research into preventing and managing aggressive and high-risk behaviors in hospital identifies best practice with most benefit, and least physical and emotional harm to the individual.[11]

Behavioral emergencies in hospitals often trigger a team response utilizing staff from a range of clinical areas and roles.[12] Training should ideally replicate the clinical experience through multidisciplinary team training and the opportunity for repetitive practice of de-escalation and restraint skills without patient risk.[13,14] Coupled with this, reflective debriefing and feedback on performance are important adjuncts to promote deeper learning.[15,16] Simulation-based education provides both training opportunities. Simulation-based group training allows participants to practice de-escalation strategies in a risk-free environment and improve their situation awareness, leadership,[17] communication[18,19] and teamwork skills.[20,21]

Aggression management training programs in the psychiatric and mental health settings have been developed and evaluated,[22,23] however, there is a paucity of evidence-based programs for the acute pediatric setting. Studies which include higher levels of evaluation and outcomes that extend beyond perceived self-confidence, self-efficacy, confidence levels, and pre- and post-test evaluations are warranted.[24,25] This pilot cluster randomized trial addresses this need utilizing the Kirkpatrick Model of evaluation.[26,27]

1.2 Need for a trial

The poor quality of simulation research has been acknowledged in the literature.[28] Simulation experts and some journals are recommending that research papers include higher levels of evaluation and outcomes that extend beyond confidence, self-efficacy, and perceived confidence and expand beyond a one-group pre-test, post-test evaluation.[24,28,29] Cook et al.[30] conducted a systematic review of method and reporting quality in medical education research and found that single group pre-/post-test designs may over estimate effect size, recommending the use of two-group studies where possible. The aim of our RCT is to advance the scholarship of simulation education research by providing objective outcome measures which demonstrate learner and patient benefits.

2. METHODS

This study is reported following the checklist from the CONSORT 2010 statement: extension to randomized pilot and feasibility trials.[31] A detailed study protocol has been published.[32] A brief description of those methods follows.

2.1 Study purpose and trial design

This study used mixed methods to explore the acceptability and feasibility of delivering a large-scale cluster RCT and assess trial processes including recruitment, contamination, outcome measures and completion rates. Randomization of two wards was performed with 1:1 sample size per cluster.

2.2 Participants, interventions and outcomes

The study setting was a quaternary, pediatric referral hospital, The Royal Children's Hospital, (RCH) Melbourne, Australia. In this hospital, behavioral emergencies which can include aggression and high-risk behaviors, trigger a hospital emergency response (Code Grey). A Code Grey response is activated by hospital staff when an individual fails to respond to initial de-escalation methods. Clinical nurses who were responsible for providing direct clinical care for patients in either of two general medical or surgical wards, were invited to participate in the study.

2.2.1 *Interventions*

The training intervention consisted of two components.

1) Web-based education (comparator)

We designed and built a web-based learning module, as described below. This method was chosen as it provides con-

sistent information, allows self-paced learning and revision of concepts and can be completed by clinicians at a time and location convenient to them.

The module, discussing management of aggression and high-risk behaviors in children and adolescents with autism (with and without ID) in the hospital setting, was developed using Articulate^{TM} software. The module was designed by a study investigator with significant experience working with children with neurodisability, including ASD and ID and their families, and instructional design. The module was designed to be completed within 30 minutes. The content was reviewed by autism experts. A small number of short multi-choice questions were included within the education module to test understanding and application of knowledge.

2) Simulation-based education (SBE) (training intervention) For the intervention arm, the web-based learning was followed by two group simulation exercises (centered around managing aggression and/or high-risk behaviors in an adolescent with autism) of 10 minutes duration, each separated by a 30 minute facilitated debrief. The RCH Simulation Program curriculum and simulation sessions were designed according to concepts described by McGaghie et al. and Dieckmann et al.[29,33] in Table 1, utilizing the debriefing framework by Rudolph et al.[16]

Table 1. Application of medical and simulation features in our SBE design

	Best practices	**Key features of our SBE design**
1) Feedback	Essential Variety of feedback, sources, impact Team debriefing	Team debriefing will occur at the end of each scenario (30-40 minutes) using Rudolph model [16]. Feedback will be provided from peers and facilitators.
2) Deliberate practice	Essential Learner-centered Dose-response relationship	Two scenarios per training session will be conducted allowing focused, repetitive practice.
3) Curriculum integration	Integrate with other learning events. Focus on learning objectives. Complements clinical education.	Lectures/workshops/web-based learning module will be used as pre-learning materials and complement the SBE learning experience.
4) Outcome measurement	Reliable data Methods include observer ratings, learner responses.	Self-report and observer ratings of performance and patient data will be collected.
5) Simulation fidelity	Goals – tools match. Multi-modal simulation. Consideration of learning context.	A simulated patient will be used to maximize fidelity.
6) Skill acquisition and maintenance	Procedural, professional, cognitive and group skills. Maintenance of skill. Aptitude and readiness to learn.	Focus will be on developing non-technical skills and teamwork. Follow-up outcomes will be measured. Participants will sign up to attend the training.
7) Mastery learning	Competency-based education. Mastery of learning goals with little or no outcome variation. Time required varies.	Group competency assessed. Two scenarios will be conducted in each training session. Participants can repeat training yearly.
8) Transfer to practice	Highest level of Kirkpatrick hierarchy. Stretch measurement endpoint from simulation lab to hospital or clinic. Translational science.	Scenarios will replicate clinical practice. Outcome data will be collected from all four levels of Kirkpatrick hierarchy.
9) Team training	Health care team training principles are evidence based.	Team composition will replicate clinical environment. Participants can try different roles in each scenario.
10) High-stakes testing	Research drives new test applications. Highly reliable data.	Pilot and feasibility study will assess outcome measures and test mechanisms.
11) Instructor training	Effective simulation-based medical education (SBME) is not intuitive and requires training. Instructor and learner need not be the same health care profession.	Primary simulation facilitators will be trained simulationists. Additional facilitators will be experts in management of clinical aggression and neurodisability.
12) Educational and professional context	Context authenticity is critical. Context is changing and adaptive.	Simulations will involve children and families with cultural diversity and address commonly experienced clinical issues.

The training was conducted in the Simulation Centre, by the Simulation Faculty and Code Grey Coordinator, with a professional adult actor playing the role of the adolescent. The structure of the session and the purpose of the post-simulation debrief was explained. Participants were informed that the same actor will play the role of the adolescent in both simulation exercises. The second simulation scenario was designed to be more complex than the first, providing participants with opportunity to extend their skills and build on knowledge learnt from the first scenario. Participants were asked to volunteer for different roles in each simulation scenario.

Study design is demonstrated in Figure 1. Study participants were asked to complete pre- and post-training surveys. Continued confidence of study participants in managing aggression three months post-training and exposure to clinical aggression were assessed via surveys similar in content to the pre-/post-training surveys. Participants were also asked to attend a focus group interview following training.

Data were to be collected each shift to record rates of data collection, number of aggressive incidents and rates of successful de-escalation for patients with ASD, on the wards. Enablers and barriers to collecting this data was explored via a survey, emailed to nurses who were regularly in charge of shifts, at the completion of the study. Change in total Code Grey activations during the study period, was also assessed.

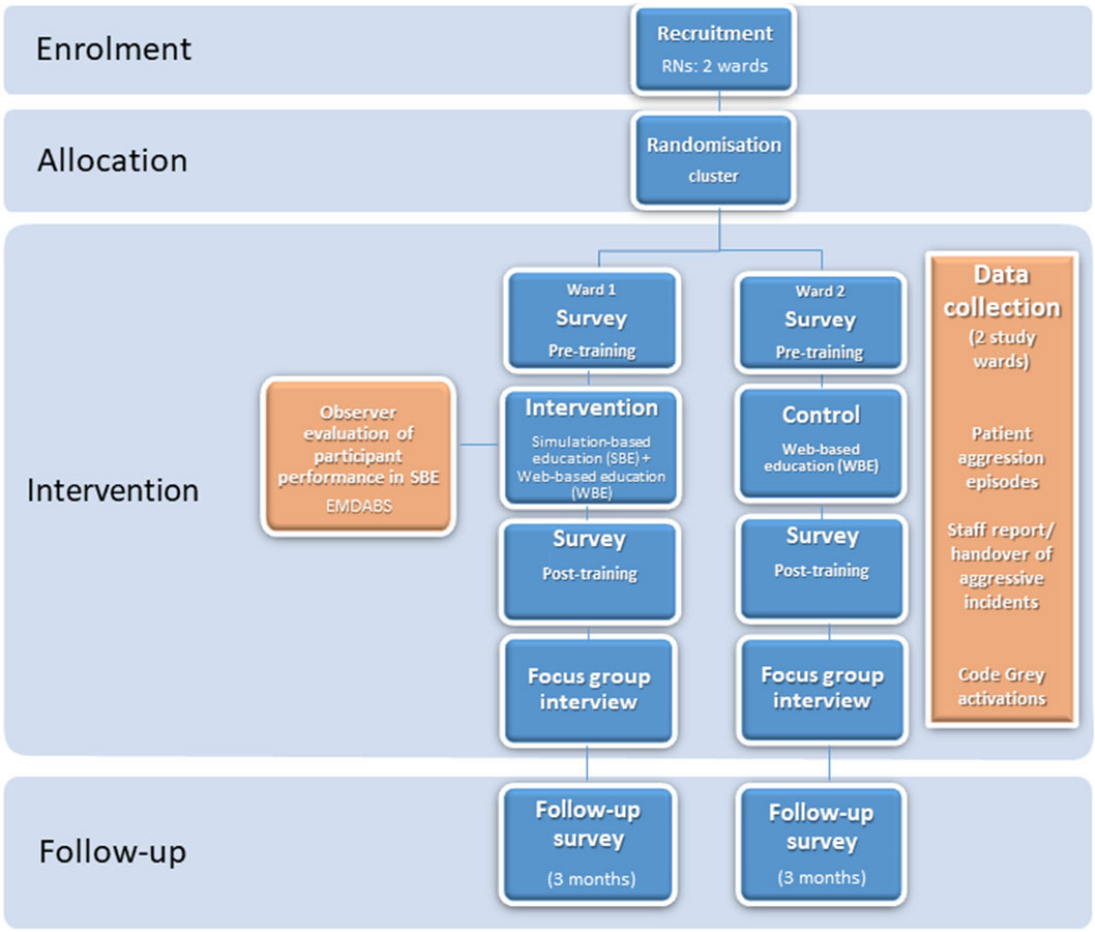

Figure 1. Study design

2.2.2 *Outcomes*

Primary and secondary objectives are outlined in Table 2.

2.2.3 *Study sample and recruitment*

Based on our experiences in an earlier study,[12] recruitment of ten staff to each study arm was deemed to be a suitable size for a pilot and feasibility study to assess recruitment, data collection and contamination. Ward-based education for nursing staff about the study was provided by a study investigator, with opportunity to ask questions prior to commencement of the study. Study information was also provided in hard copy format for the participants. A researcher not associated with this study and not based at the study site, used a coin toss to randomize the wards included in the study to either the training intervention or the comparison group.

Table 2. Study objectives and findings summary

Study Objectives	Findings	Evidence
Primary Objectives		
Randomization: Was there more than 10% recruitment rate from ward staff?	Achieved–recruitment was satisfactory.	20 participants were recruited into the study, 10 in each arm (12% of total eligible).
Completion: a) Was the attrition rate less than 20%? b) Was the pre-/post-survey completion rate at least 80%? Was the focus group participation rate at least 50%?	Achieved–Nil attrition and satisfactory completion rates for pre-/post-surveys and focus groups.	a) 10 participants participated in the training intervention (100%). b) Survey completion rate was Pre-training survey 18/20 (90%); Post-training survey 17/20 (85%); Focus group participation rate was 15/20 (75%).
Acceptability: Was the acceptability of the training at least 80% of scores 4 (good) out of 5 or higher in the survey data?	Achieved – recommendation of training to colleagues; relevance to work. Not achieved – when asked if simulation training was a good method to develop skills and knowledge in managing aggression.	100% of participants would recommend this training to their colleagues; 9/10 (90%) rated the simulation training as a 4 or 5 /5 indicating it was extremely relevant to their work. 4/10 (40%) rated simulation as a good way to develop skills in managing aggression; 5/10 (50%) rated simulation as a good way to develop knowledge in managing clinical aggression.
Data Collection: a) Was the follow-up survey response rate at least 30%? b) Was ward data collection rate at least 80% of total shift during study period?	a) Achieved. b) Not achieved.	a) 13 participants completed the follow-up survey (65%). b) Nil episodes of aggression were recorded on the Aggressive Incidents Record.
Contamination: Was there low contamination from intervention participants as evidenced by participant report?	Achieved – there was no contamination reported.	18/18 (100%) respondents reported that they had not discussed the simulation scenarios with another participant.
Secondary Objectives		
Confidence and Competence: a) Did at least 80% of participants report increased confidence levels b) Did 80% of participants report positive qualitative comments?	a) Part achieved – participants did not accurately record their unique identifier or which arm of the study they were randomized to, so analysis at a group or individual level not possible. b) Achieved.	a) Pre training, total group 1/18 reported confidence as a 4 or 5 /5. b) 9/10 respondents (90%) in the post-survey provided positive comments when asked to describe the training intervention. Focus group comments for the intervention groups were mostly positive.
Data Collection: a) Were 80% of successful de-escalation episodes and Code Grey activations reported? b) Was there demonstrated use of de-escalation skills during the simulations as evidenced by the EMDABS?	a) Part achieved. Code Grey activations documented in appropriate system. Nil documentation of aggressive incidents successfully de-escalated which did not require a Code Grey response. b) Achieved.	a) 14 Code Grey activations documented during study period. Nil de-escalation episodes recorded. b) Average score on EMDABS 20.13 out of 35. Participants scored a 4 or 5 (agree or strongly agree) 16 times out of a total 56 items demonstrating positive de-escalation skills in 28.6% of instances.

2.3 Data collection, management and analysis

The Kirkpatrick Model was used to measure the impact of the training as described in the protocol.[32] This 4-level model evaluates training according to (1) reaction; (2) learning; (3) behavior and (4) results.[26, 27, 34] Outcome measures used in this study are detailed in Table 3. Survey data were entered into REDCap and analyzed using the Stata statistical software package. The surveys incorporated the Con-

fidence in Coping with Patient Aggression Instrument, a one-dimensional, 10-item instrument demonstrating a high degree of internal consistency.[35] The De-escalating Aggressive Behavior Scale – English modified version (EMDABS) consists of 7 questions rated using a 5-point Likert scale.[36] This validated tool provides individual or group ratings of ability to de-escalate aggressive behavior. Data were entered into Microsoft Excel and analyzed using Stata. Focus group interview recordings were transcribed by a research assistant not associated with this study and checked for accuracy by the primary investigator. Transcripts were uploaded to NVivo qualitative data analysis software to classify, sort and arrange information into themes for each interview question.

Table 3. Summary of outcome measures

Data collection Method/Tool	Purpose	Timing of administration	Mode of administration	Kirkpatrick Level
Pre-training survey – incorporates Confidence in Coping with Patient Aggression Instrument****^.	To determine participants' self-perception of confidence and competence in managing aggressive behaviors in an adolescent with autism at baseline.	Prior to training	A link to the electronic REDCap™ survey was emailed to participants after allocation.	Level 1 (Reaction)
Post-training survey– incorporates Confidence in Coping with Patient Aggression Instrument****^.	To determine if the training had an impact on participants' self-perception of confidence and competence in managing aggressive behaviors in an adolescent with autism.	Post-training	A link to the electronic REDCap™ survey was emailed to participants after allocation.	Level 1 (Reaction)
Follow-up survey – incorporates Confidence in Coping with Patient Aggression Instrument****^.	To determine if the training had a continued impact on participants' self-perception of confidence and competence in managing aggression in an adolescent with autism.	3 months post-training	A link to the electronic REDCap™ survey was emailed to participants 3 months after the training.	Level 1 (Reaction)
De-escalating Aggressive Behavior Scale – English modified (EMDABS) ** ^, ^^ & ^^^	To assess the participants' recorded performance for each scenario.	1-week post-training	Two clinicians with expertise in the management of clinical aggression assessed the participants' recorded performance for each scenario using the English modified version of the De-escalating Aggressive Behavior Scale (EMDABS).	Level 2 (Learning)
Ward Patient Aggression Record	To record episodes of clinical aggression from patients with ASD, including episodes of successful de-escalation, each shift in participating wards.	1 month prior to and 3 months post-training intervention.	Written Aggressive Incidents Record available on ward. An electronic REDCap™ survey was emailed to all nurses who were in charge of shifts during the study period	Level 3 (Behavior)
Code Grey Activations	To review numbers and context of Code Grey activations in participating wards.	1 month prior to and 3 months post-training intervention.	Hospital report	Level 4 (Results)

Note. Attributes of validity: *Content validity; **Construct validity; ***Criterion validity; ****validated, attribute not stated. Attributes of reliability: ^Homogeneity (internal consistency); ^^Stability; ^^^Equivalence; ^^^^ reliable, attribute not stated.

Data were stored on a password protected computer and will be deleted after five years. As this was a feasibility and pilot study of short duration, minimal risk was anticipated, therefore a Data Monitoring Committee was not required. Simulation-based education, due to the realism of the scenarios, may cause participants to become distressed during,

or at the completion of the simulation sessions or during the focus group interviews. Strategies to manage distress were developed but not needed. The study received ethical approval from The Royal Children's Hospital Melbourne Human Research Ethics Committee (HREC) on 1st November 2019 (HREC reference number 2019.197). Participation was voluntary with consent processes outlined in the protocol. Participant confidentiality is strictly held in trust by the study investigators, and the sponsoring institutions.

3. RESULTS

Assessment of the study objectives is summarized in Table 2 and described in more detail in the text. Recruitment commenced on 2nd November 2019 with data collection completed on 29th February 2020.

3.1 Primary objectives

3.1.1 *Randomization (see Table 2, Section 1)*

A target of 10 participants per arm of the study was set and achieved from a total of 160 eligible staff. The required recruitment rate (10%) was achieved. For the intervention group, 9/10 had previous simulation training experience with 4 having attended simulation training for the management of clinical aggression. All but one (17/18) participant in the study had been the recipient of clinical aggression.

3.1.2 *Completion (see Table 2, Section 2)*

All participants enrolled in the intervention arm completed the training. The survey completion rate and focus group participation rate were satisfactory.

3.1.3 *Acceptability (see Table 2, Section 3)*

The training intervention was deemed acceptable by all intervention participants indicating they would recommend this training to colleagues. Simulation training was reported to be extremely relevant to the participants' work. Both scenarios and reflective debriefs rated highly in terms of usefulness as a learning resource, with participants rating scenario 1 involving an adolescent with ASD more useful than the more complex scenario 2 involving a non-verbal adolescent with ASD/ID (see Table 4). More focused questions asked participants to rate this simulation training in terms of developing skills and knowledge in managing aggression in a young person with autism (see Table 4). Forty to fifty percent of intervention participants rated the training highly for developing skills and knowledge, respectively.

Focus group data (see Table 5) reinforced the value of the simulation and reflective debrief for learning, trying out communication strategies and reflecting on which strategies were, or were not, beneficial. The positive implications of using a professional actor as the patient were highlighted. Focus group participants also suggested there could be value in adding a face-to-face session on managing aggression after completion of the web-based learning and immediately prior to the simulation training to reinforce the main concepts.

The web-based learning module was rated well by participants as 4.2/5 for developing an understanding of autism and intellectual disability (see Table 4). Participants reported the learning module to be a useful educational resource to develop an understanding on how to work with children and young people with ASD and ID and develop knowledge in managing clinical aggression (see Table 4).

Focus group interview data indicated that participants felt the web-based learning module reinforced and improved knowledge on autism and intellectual disability (see Table 5). A common suggestion for improvement of the module was to include more information on managing behavioral crises. Participants recalled most of the information in the module to be focused on characteristics of autism, triggers for aggressive behavior and prevention of behavioral emergencies (see Table 5).

3.1.4 *Data collection (see Table 2, Section 4)*

The response rate for the follow-up survey reached the target of 30% with 13/20 (65%) of participants in the study completing this survey. Ward data collection of aggressive incidents and their management was unsuccessful. Nil episodes of successful de-escalation were recorded on the study documentation on either the intervention or control wards.

3.1.5 *Contamination (see Table 2, Section 5)*

The intervention group was divided into two. Simulation training was completed on separate days within the same week. Nil contamination of intervention participants occurred with all participants who responded (18/18) indicating that they had not discussed the simulation training nor scenarios with another participant prior to undertaking the training.

3.2 Secondary outcomes

3.2.1 *Confidence and competence (see Table 2, Section 6)*

Self-reported baseline levels of confidence in coping with patient aggression were lower than mid-range for all questions and the total score for this instrument (see Table 6). Changes in confidence at an individual level were not able to be reported in this study as participants did not accurately record their unique identifier on all three surveys. In addition, some (3/18) participants provided inconsistent responses within the pre-survey indicating confusion about whether they had been enrolled in the intervention or the control group. As a result, between group comparisons were not possible.

Table 4. Acceptability of web-based learning module and simulation-based training post-training

Questions	All participants	
	N	Mean (+/-SD)
Did you find the web-based learning module a good way to:		
a) Develop an understanding of autism and intellectual disability?	16	4.2 (0.75)
b) Develop an understanding of how to work with children and young people with autism and intellectual disability?	16	3.9 (0.96)
c) Develop knowledge in managing clinical aggression?	16	3.4 (0.81)
How useful to your learning was the:		
a) Simulation scenario 1 (adolescent with ASD)	10	4.3 (0.82)
b) Debrief scenario 1	10	4.3 (0.82)
c) Simulation scenario 2 (adolescent with ASD/ID, non-verbal)	10	3.7 (1.25)
d) Debrief scenario 2	10	4.1 (0.99)
Did you find the simulation training session a good way to:		
a) Develop skills in managing clinical aggression?	10	3.4 (0.84)
b) Develop knowledge in managing clinical aggression?	10	3.6 (0.70)

Self-perceived baseline levels of confidence in managing aggression specifically in children were also mid-range or lower (see Table 7). Participants rated their confidence in managing aggression in typically developing adolescents and adolescents with autism and intellectual disability. Participants reported feeling more confident in knowing what to do if faced with an aggressive adolescent with autism or ID than actually being able to manage the situation. Self-perceived competence in displaying de-escalation skills, maintaining patient safety, administering restraint and being a group leader were also midrange (see Table 8).

Qualitative responses in the post-training survey were predominately positive in respect to the value of the training. Participants were asked to describe how they would describe the simulation training to colleagues. All but one respondent answered this question with all responses incorporating positive descriptors:

> "The experience was very real and relevant to nursing on the wards."
> "An excellent insight into behaviours and challenges of children with autism and their behaviours."
> "Relevant, clear and useful."

Participants were asked for ideas on how to improve the simulation training. The most frequent suggestion was to increase the length of the training and include a face-to-face skills session immediately prior to the simulation training:

> "Make it a little longer (allocate more time) or make a study day out of it."
> "I feel I did not remember any techniques from the e-learn once in the sim. Perhaps reiterate in a face-to-face session prior to sim."

Participants in the intervention group discussed the value of the simulation and the debrief in the focus group interviews with most comments indicating it was a valuable learning experience, enhanced through the use of a professional actor as the patient (see Table 5). A pre-simulation face-to-face teaching session to revise the concepts discussed in the web-based module was discussed as a useful addition. Both groups commented that the web-based module should include more content on managing a behavioral crisis.

3.2.2 *Data collection (see Table 2, Section 7)*

Code Grey activations for the study wards were recorded in the hospital incident reporting system for the 4-month study period. Nil activations occurred in the month prior to the training in either ward. Ten Code Greys occurred in the intervention ward during the 3 months following training and four in the control ward. One non-verbal patient with ASD and ID triggered four unplanned Code Grey activations in the control ward. The aggressive incidents on the intervention ward were triggered by patients that did not have ASD or ID and 8/10 were planned. Episodes of successful de-escalation that did not trigger a Code Grey activation were not documented during the study period in either ward. Nurses in charge of shifts were surveyed to assess the ease of recording this information. Three nurses completed the survey. All indicated that they would be made aware of any episodes of de-escalation for early aggressive behaviors, 2/3 stated they would document episodes in the patient's medical record, and all indicated it would be possible to record this data for research.

Table 5. Focus group interview themes

Topic	Major Themes	Quotes
Acceptability of the simulation training	Value of the simulation and reflective debrief	"I do feel that it was quite real like I think everyone was committed to making it work and to get the best out of it and the actors were really great. X and I did it together and I think we were both pretty keen on getting what we could get out of it, yeah it was good."
		"I guess that's what we will be able to draw on in future reference, more than the e-learn details but [the simulation] scenario then debriefing after that is really etched into our minds."
		"…also, there were some things that they highlighted like in the debrief it was like 'Oh I didn't pick up on that.' 'Oh, that's really good'...touching on those things were good, yeah."
		"Definitely being able to watch the other scenario….The debrief is sometimes more powerful."
	Value of using a professional actor	"Definitely the actress…was like unreal, she was good aye, she was so good and made it so real. She was able to portray a child with autism so well and really obviously got into her role, so did the mum, she was also very good.…you don't ever get that really so just having that opportunity to act it out, role play it was really beneficial."
		"I think the actor seemed to be quite knowledgeable…she tried to give her perspective of how she felt as the actor during the scenario."
		"That's the perspective that people never get…it very rare you get feedback from a patient or family about a situation unless they were really happy about it and even then, it's probably really unlikely that they will give you their honest opinion as well."
Suggestions to improve the simulation training	Value of including a pre-simulation face-to-face lecture	"…a short classroom session on how to manage actual aggressiveness or prevent it or manage it with an autistic child…and then do the sim."
		"I think what would have been really helpful for me as a learner, would have been to have like a classroom session pre the sim, because I did the e-learn and how much I remembered it or not and then went straight to the sim, kind of couldn't remember what I had learnt in that and did what I naturally do."
Acceptability of the web-based module	Promotion of knowledge and understanding of ASD	"Yes definitely, I though the e-learn and simulation were good. I got an entirely better understanding of autism."
		"I think the training was very useful in that there were certainly some things that I knew but other things particularly around explaining things that I think I didn't really quite understand. Like I knew some about the sensory things but certainly just more around a lot of the fears that comes from the fear of the unknown and just being able to explain more about what's happening…and what the sounds of things mean and that can help to reassure them along too."
Suggestions to improve the web-based learning module	Increase content on managing behavioral crises	"I can't remember there being things about managing aggression in that e-learn at all, was there? Wasn't it just on managing the triggers?"
		"I remember learning about autism but don't remember learning about managing their aggression."

Observer ratings of performance in the simulation scenarios were recorded using the De-escalating Aggressive Behavior Scale – English modified version (EMDABS). Two clinicians with extensive experience managing clinical aggression rated the scenarios independently. Four simulation recordings were available for scoring, two from each intervention group. The average group score for each of the four simulations was low (20/35). Participants scored a 4 or 5 (agree or strongly agree) 16 times out of 56 items demonstrating positive de-escalation skills in 29% of items. There was high agreement between raters' scores for all four scenarios. The skills that participants were most proficient in, scoring at least a 4 out of 5 consistently across both groups were 'remaining calm', 'valuing the client' and 'reducing fear.'

Table 6. Confidence in Coping with Patient Aggression Instrument pre-training

Questions	All participants (N = 18) Mean (+/-SD)
a) How comfortable are you working with an aggressive patient?	4.7 (1.84)
b) How good is your current level of training for handling clinical aggression?	4.1 (1.59)
c) How able are you to intervene physically with an aggressive patient?	3.7 (1.91)
d) How self-assured do you feel in the presence of an aggressive patient?	3.9 (1.51)
e) How able are you to intervene psychologically with an aggressive patient?	4.9 (1.8)
f) How good is your present level of training for handling psychological aggression?	4.4 (1.61)
g) How safe do you feel around an aggressive patient?	4.1 (1.60)
h) How effective are the techniques that you know for dealing with aggression?	4.9 (1.35)
i) How able are you to meet the needs of an aggressive patient?	4.9 (1.57)
j) How able are you to protect yourself physically from an aggressive patient?	5.4 (2.17)
Total score (max score 110)	**45 (12.6)**

Table 7. Self-perceived confidence in managing aggression in children pre-training

Questions	All participants (N = 18) Mean (+/-SD)
How confident do you currently feel managing aggression demonstrated by an adolescent right now?	2.6 (0.62)
How confident do you feel managing clinical aggression demonstrated by a young person with autism and intellectual disability right now?	2.6 (0.61)
Would you know what to do right now if faced with clinical aggression demonstrated by a young person with autism and intellectual disability?	2.4 (0.70)
In a situation where you are faced with clinical aggression from a young person with autism and intellectual disability, do you think you will be able to manage it?	1.8 (0.38)

Table 8. Self-perceived competence in managing aggression in a young person with autism and intellectual disability pre-training

How competent to you feel in displaying these skills when faced with clinical aggression demonstrated by a young person with autism and intellectual disability right now?	All participants (N = 18) Mean (+/-SD)
Being a group leader	1.7 (0.75)
De-escalation communication techniques	2.4 (0.62)
Maintaining patient/staff safety	3.1 (0.87)
Hands off restraint	2 (1.14)
Hands on restraint	1.9 (1.11)
Administering chemical restraint	2.1 (0.94)

4. DISCUSSION

We completed a feasibility and pilot study of a novel simulation intervention and found that targets for randomization, completion, acceptability and survey data collection were met. Participants demonstrated use of de-escalation skills in the simulation scenarios. Challenges were experienced in collecting descriptive data of aggressive incidents which occurred in the study wards, and participant survey linkage.

4.1 Recruitment

Nurses in the study wards were receptive to the study which meant recruitment targets were easily met. Pre- and post-training survey response rates were high. The response rate for the follow-up survey was higher than anticipated and more than double the response rate in our previous study, which utilized hardcopy responses.[12] Electronic survey completion rates were comparable to hardcopy surveys administered while attending the training, if participants receive two reminder emails to complete the surveys prior to and following the training.

An important research design issue was highlighted by this study. We asked participants to create their own unique study identifier for all three surveys, to enable linkage and within

group analysis. This proved problematic as only one participant was able to correctly use the same identifier for all three surveys despite clear instructions. This highlights the importance of pilot testing all data collection surveys with a number of volunteers prior to a full scale trial, to identify potential sources of error.[37] We will allocate a unique study identifier to each participant upon recruitment to any future RCT to ensure data can be linked.

4.2 Simulation design and acceptability

Simulation-based education is a resource intensive and costly training intervention. Scholars in SBE have argued that in order to justify the investment in simulation-based training, educators need to ensure that the training is delivered effectively to achieve the desired outcomes and practice changes.[38] McGaghie et al.[29] conducted a critical review of simulation-based medical education (SBME) research published from 2003-2009 to outline twelve features and best practices of SBME. Our study highlights the importance of addressing these key features in our simulation design. Three of these intersecting design concepts require further consideration when reviewing our design: deliberate practice, transfer to practice, and feedback.

Deliberate practice, according to McGaghie et al.,[29] helps to shape, refine and maintain learners' knowledge, skills and attitudes. Key features include focused repetitive practice combined with informative feedback from educational sources. It was an explicit design feature in our SBE to include two scenarios in each training session each with its own reflective group debrief.

Repetitive practice is integral for knowledge and skill improvement.[24,39,40] More than one exposure to the same scenario, may create more knowledge based on discoveries through learner observation or active experimentation. Stocker et al.[41] recommend that an effective simulation structure involves a scenario for concrete experience, a debriefing for abstract conceptualization, followed by a second scenario for active experimentation. We will modify our design for a full-scale trial so that learners experience the same scenario twice in a training session to ensure they experience the benefits of repetitive practice.

Previous exposure to simulation-based education may also influence knowledge and skill acquisition. While most participants in the intervention group had previous simulation training experience, only 4/10 had experienced simulation training for managing clinical aggression in children and adolescents with varying ages and diagnoses. Each time participants experience simulation they learn and reflect upon their performance which in turn influences future actions, consistent with experiential learning.[42] Anderson et al.[42] propose that all learning is relearning so each exposure to simulation builds upon previous learnings. Participants in this study, with prior opportunity to practice skills in the management of clinical aggression in a previous simulation experience, would be adding to and refining their knowledge in this study. As most of the intervention group had not had previous exposure to simulation training for this purpose, it is likely that their learning would be earlier in the integration and adaption continuum than more experienced participants. This may explain to some extent the lower than expected scores in the usefulness of this mode of learning.

Transfer to practice occurs when skills and behaviors acquired during simulation-based education can be utilized in the clinical environment.[29] Measurement of these concepts in clinical practice are difficult to achieve as this pilot study indicates. The intervention group rated the simulation training lower than expected, similar to results from our previous study,[12] and others,[14,43] for its ability to develop skills and knowledge in managing aggression. This may be due to the complexity of the two scenarios which required participants to use multiple strategies to communicate effectively with the adolescent and their parent. Participants commented that the scenarios were challenging, particularly the second scenario. This feedback highlights the difficulties of communicating with a non-verbal adolescent with ASD/ID.

Overhead announcements and equipment alarms caused behavior escalations which interrupted attempts at communication during the simulation. One group demonstrated more skill in developing rapport and de-escalating high-risk behaviors in both scenarios however both groups were unable to complete the scenario objectives. Feelings of inadequacy in managing the situation and not achieving the set task, may have resulted in the participants scoring the effectiveness of the simulation training to develop knowledge and skills less than anticipated. The individual scenarios and reflective debriefs, however, received mean rating scores greater than 3.7/5 indicating value in the learnings.

The range of task difficulty level is an important variable in simulation-based education which may impact transfer of skills.[24,42,44] Once the needs of the learner are identified, manipulation of the environment is required to ensure learner growth. The level of manipulation and complexity of the scenario is an important design consideration. Simulation scenarios which provide a balance between challenge and support will provide the greatest learning.[42] This is challenging to get right as the needs and experience of each group will vary. Whilst participants will feel more comfortable in less challenging scenarios, care must be taken to

not oversimplify the scenarios, and therefore misrepresent the complexity of clinical practice.[45] Stocker et al.[41] recommend that participants are challenged during simulated training to experience failures and difficulties in order to promote reflective observations. Groups which feel they are operating at the edge of their comfort zone will be most motivated to learn.[46] We believe the complexity of the simulation scenarios developed for this study represented real clinical practice, pushed learners out of their comfort zones and provided the opportunity for rich learning in managing aggression in an adolescent with ASD. For this reason, we will maintain a similar level of complexity in the scenarios utilized in a future full-scale trial.

Feedback has been identified as the most important feature of simulation-based education.[24] Those participants with more exposure to simulation training for managing aggression, will have received and processed more feedback than those who are undertaking the training for the first time. Studies have analyzed the value of the reflective debrief post-simulation. A systematic review of the effectiveness of debriefing for simulation-based education reported positive effects on technical and non-technical skills with two studies reporting maintenance of effect months after the simulation experience.[47]

The method of reflective practice is important. We utilized debriefing with good judgement, as described by Rudolph et al.[16] as it combines rigorous reflection with genuine inquiry. This approach creates a psychologically safe environment for learners and encourages understanding of the frames which drive learner behaviors. Good judgement values the expert opinion of the instructor who uses advocacy and inquiry to share expert insights which provide a deeper lever for teaching by using hypotheses to legitimize and explore the learners' interpretations. We felt this approach increases understanding and learning for the participants, which was supported by the participant feedback in our study. The reflective debrief following the simulation scenarios in this study, conducted by content experts in neurodisability and aggression management and a simulation expert, contributed to a significant time proportion of the training and resulted in high mean ratings of usefulness. For scenario two, the reflective debrief scored higher than the simulation component, indicating the value of team reflection and discussion on performance and possible communication approaches. We will continue to use this approach to reflective practice in a future trial.

Enabling and promoting clinician attendance at training is a challenge for education design and delivery. Often the choice is whether staff are released from clinical duties for a full study day or for a 1-hour period within a clinical shift. A previous simulation program we designed and evaluated for managing aggression was embedded into a full day study day and built on concepts discussed in the face-to-face workshops.[12] Attendance was pre-planned but restricted to 1-2 staff members per clinical area. This study required five staff at a time to be released from one ward. We designed this simulation training to include a web-based learning module as pre-learning rather than a face-to-face session to maximize the time participants could spend in the simulation-based training and reduce the time away from their clinical duties. Participants in the intervention group indicated that a pre-simulation face-to-face skills session may have been helpful. The inclusion of a short face-to-face group session reinforcing the de-escalation techniques discussed in the module immediately prior to the simulation training has been used in similar programs and may be a valuable adjunct.[48] In addition, as a result of the participant feedback, the section in the web-based learning module on managing behavioral crises could be expanded with additional resources such as video demonstrations, to supplement this information. We will need to negotiate with hospital managers, prior to commencing a full-scale trial, to ensure release time from clinical duties is adequate to cover the training, and clinical coverage is provided.

Overall, learner attitudes to this training were positive with high levels of acceptability reported. All participants stated they would recommend this training to colleagues, with the simulation training reported to be highly relevant.

4.3 Data collection

We were unable to collect ward data on successful de-escalation of aggressive behavior in patients with autism and or intellectual disability. Senior nurses indicated collection of data around de-escalation events should be possible, but this did not occur during the study, despite education and a number of reminders by a study investigator. It is possible that there were not any successful attempts at de-escalation to record or it may have been time-consuming and inconvenient to access the folder containing the ward aggressive incident record, whilst providing clinical care. Other studies have also found similar data difficult to collect.[49,50] There is a paucity of training studies which utilize Kirkpatrick level 3 and above data and the aim of this study was to collect data which addressed all four Kirkpatrick levels.[51] Strategies would need to be developed with ward staff to promote and enable collection of this data so that in a future trial, outcomes addressing all of Kirkpatrick's levels are evaluated.

4.4 Confidence and competence

In addition to self-reported measures of confidence managing aggression, the EMDABS tool was used to rate group performance in the simulations. Results indicated that participant ability to successfully de-escalate aggressive behavior in these simulations was low. Repetitive practice in managing aggression is required to support ongoing skill development and reduce skill decline. It is common in simulation research to use self-reported levels of competence and confidence to assess the effect of the training intervention. Studies have reported variability between observer ratings of competence and self-attributed ratings of confidence levels.[46,52,53] It is important that studies incorporate objective outcome measures and do not solely rely on self-reported confidence and competence levels as they may not be a reliable indicator of skill development. In order to accurately assess changes in performance, deliberate practice using the same simulation scenario should be used at baseline, post-training and follow-up assessments to support skill acquisition.[40] Objective assessment of performance could then be used to evaluate performance at each phase.

4.5 Strengths and limitations of this study

The major strength of this study design is the use of multiple outcome measures that address all levels of evaluation.[51] Simulation-based education with deliberate practice is thought to be superior to traditional teaching formats in medical clinical education.[40] Studies have demonstrated simulation-based education to increase team performance and communication skills when managing aggression in an acute health care setting.[48,54] It is considered a sophisticated training option and when paired with an evidence-based online training module, may effectively address adult learning principles providing goal and task orientated, practical, relevant, experiential training.[55]

The main limitations of this study design relate to data collection. Strategies to improve ward data collection and capture aggressive episodes that do not activate a hospital emergency response, need to be explored and developed.[37] Built in processes within the survey collection system need to be refined to ensure participants utilize study identifiers consistently and correctly to enable within group and between group analysis.

We hypothesized that simulation-based education would be a more effective training format for teaching non-technical skills than web-based learning. It was surprising that simulation-based education, which was used by the intervention arm in this study, was not more effective than web-based learning alone for promoting confidence in managing aggression in young people with ASD. This may be due to several factors. This was a pilot and feasibility study with a small number of participants. Participants in the intervention arm completed one simulation-based education event (with two different scenarios). For simulation to be effective, it needs to be repetitive, like any other skill acquisition. Not every participant had the opportunity to actively participate in both scenarios. Whilst there is evidence for observers to learn from participating in the debrief,[56,57] learning could be improved if multiple simulation sessions occurred and each participant had the opportunity to have an active role in each simulation. Also, if this was the first and only time they participated in simulation, they may not gain the full benefits of simulation. Repetitive practice may improve performance as it allows repeated practice and reduced cognitive overload, promoting deeper processing of information into memory.[58] Repetition after initial learning also stimulates retrieval of information learnt in previous simulations.

Simulation scenarios are regularly refined and improved in practice as design issues emerge each time they are conducted. Scenario 2 was complex involving a non-verbal adolescent with ASD and ID. At times participants felt the amount of environment distractions interrupted their interventions and thought processes. This scenario could be streamlined to introduce environmental distraction at different stages, allowing participants the opportunity to learn how to successfully achieve objectives. Scenario design should focus on the benefits of simple versus complex simulation scenarios.[45] More accurate assessments of competence may result from repeating the same scenario rather than using two scenarios of escalating difficulty involving different patients. A pre-simulation face-to-face classroom session, revisiting de-escalation communication principles, may be of value.[48] Change from baseline levels of confidence should also be reported as a way of adjusting for baseline variation.

4.6 Recommendations for RCT protocol amendments

Based on this pilot and feasibility trial, our recommendations for amendments to the RCT protocol include:

1) Repetitive practice of the same simulation scenarios (pre-training, post-training and at follow-up).

2) Embed a pre-simulation face-to-face skills session prior to simulation-based education.

3) Report change from baseline levels of confidence as a way of adjusting for baseline variation.

4) Generate larger amount of objective data on participant skill in de-escalation of aggressive events through utilization of more assessors to score simulation recordings.

5) Utilize data collection system functionality to ensure generation of unique participant identifiers and mandatory completion of all survey questions.

6) Explore strategies to promote collection of ward aggressive incidents which are managed without triggering a hospital emergency response.

In addition, careful selection of study wards to avoid contamination due to previous training and ensure the training content is relevant to the study participants is required. It is important that future research in this area captures benefits at Kirkpatrick level 3 and above to add value to the wider body of evidence on the benefits of simulation-based education for aggression management.[51]

5. Conclusion

It is feasible to conduct a cluster RCT to evaluate the effectiveness of simulation-based education for staff in managing behavioral emergencies of children with autism spectrum disorder in the hospital setting. Adjustments to the RCT design and simulation content will be made based on this study's findings including reporting change to baseline levels of confidence, greater emphasis on prevention strategies and exposure to repetitive practice. Observer ratings of de-escalation skills indicated that more than one episode of training may be required for acute care pediatric staff to successfully de-escalate aggressive incidents. As such, we will use repeated simulation scenario exercises over time for each intervention group in the next trial. It is important that acute care nurses working with children with ASD are confident in managing aggression demonstrated by patients in their workplace and have access to evidence-based training programs.

Trial Registration

Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12620000139976; http://www.ANZCTR.org.au/ACTRN12620000139976.aspx

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Conflicts of Interest Disclosure

The authors declare that there is no conflict of interest.

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