

Simulation-based education for staff managing aggression and externalising behaviours in children with autism spectrum disorder (ASD) in the hospital setting: Pilot and Feasibility Study Protocol for a cluster Randomised Controlled Trial (RCT).

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Simulation-based education for staff managing aggression and externalising behaviours in children with autism spectrum disorder (ASD) in the hospital setting: Pilot and Feasibility Study Protocol for a cluster Randomised Controlled Trial (RCT).

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Abstract

Background: Children with autism frequently demonstrate aggression and externalising behaviours in the acute care hospital environment. Paediatric acute care nursing staff are often not trained in managing aggression and in particular lack confidence in preventing and managing externalising behaviours in children with autism. High fidelity simulation exercises will be used in this study to provide deliberate practice for acute care paediatric nursing staff in the management of aggressive and externalising behaviours.

Objective: The purpose of this study is to conduct a pilot and feasibility cluster randomised controlled trial (RCT) to evaluate the effectiveness of simulation-based education for staff in managing aggression and externalising behaviours of children with autism spectrum disorder (ASD) in the hospital setting.

Methods: This study is a mixed design, with between group and within participant comparisons to explore the acceptability and feasibility of delivering a large scale cluster RCT. Trial process including recruitment, completion rates, contamination and completion of outcome measures will be assessed and reported as percentages. This study will assess the acceptability of the simulation-based training format for two scenarios involving an adolescent with autism +/- intellectual disability and aggressive and externalising behaviours and the resulting change in confidence in managing clinical aggression. Two paediatric wards of similar size and patient complexity will be selected to participate in the study and randomized to receive either simulation-based education plus web-based education materials or the web-based education materials only. Change in confidence will be assessed using pre- and post-training surveys for bedside nursing staff exposed to the training and the control group who receive who receive the web-based training materials. Knowledge retention three months post-training and continued confidence and exposure to clinical aggression will be assessed via surveys. Changes in confidence and competence will be compared statistically (Chi squared test) using before and after data, to compare the proportion of those who have high confidence at baseline between the two arms and at follow up. The simulation-based education will be recorded with trained assessors reviewing participant ability to de-escalate aggressive behaviours using a validated tool. This data will be analysed using mean values and standard deviations to understand the variation in performance of individuals who undertake the training. Data from each participating ward will be collected each shift for the duration of the study to assess number of aggressive incidents and successful de-escalation for patients with ASD. Total change in Code Grey activations will also be assessed with both data sets analysed using descriptive statistics.

Results: This study gained ethical approval from Research Ethics and Governance, The Royal Children's Hospital Melbourne on 1st November 2019.

Conclusions: We hypothesize that this study is feasible to be conducted as a cluster RCT and that simulation-based training will be acceptable for acute care paediatric nurses. We anticipate the intervention ward will have increased confidence in managing clinical aggression in children with autism immediately and up to 3 months post-training. Clinical Trial: Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12620000139976 <http://www.ANZCTR.org.au/ACTRN12620000139976.aspx>

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Original Paper

Simulation-based education for staff managing aggression and externalising behaviours in children with autism spectrum disorder (ASD) in the hospital setting: Pilot and Feasibility Study Protocol for a cluster Randomised Controlled Trial (RCT).

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Introduction

Background and rationale

Autism spectrum disorder (ASD), a neurodevelopmental disorder identified in childhood, is characterised by persistent deficits in social communication and social interaction across multiple

contexts and restricted, repetitive patterns of behaviour or interests [1]. Children diagnosed with ASD with or without an intellectual disability have an increased risk of hospitalisation [2-5]. They also have longer and more frequent outpatient visits and medications prescribed than children in general [6]. Intellectual disability (ID), one of the most prevalent comorbidities, occurring in approximately 40-70% of individuals with ASD [7-9], has been associated with greater autism symptomology with increased difficulties in communication and social functioning [10].

Exposure to the hospital environment can provide a sensory overload to children with ASD as it is often noisy, brightly lit, with people moving quickly, many unfamiliar people and long wait times [11]. The surroundings are unfamiliar and usual home routines are not able to be maintained. The hospital environment necessitates that children must communicate with many more people, mostly unfamiliar, than usual. This is particularly challenging and stressful for children with ASD as they innately prefer less social interaction and have more difficulty identifying social cues and understanding the expressed emotions of others. Externalising behaviours are common in children with ASD when exposed to these stressors and can result in difficult or delayed treatment, increased anxiety for the parent and child, prolonged procedure times, increased health care costs and poorer health outcomes [2,6,11,12].

The Code Grey procedure is one of a series of Emergency Response Codes used in some Australian hospitals. Code Grey, refers to 'unarmed aggression' and is called when an individual fails to respond to initial defusing mechanisms undertaken by staff [13]. At the Royal Children's Hospital, Melbourne, numbers of Code Grey activations are rising each year. In 2016, there were 611 recorded Code Grey activations, 1050 in 2018 and 1682 in 2019. In 2016-7, 36% of Code Grey activations were due to aggression demonstrated by children and young people with ASD with or without an intellectual disability [14].

Need for a trial

Staff training programs designed to teach best practice principles in the management of clinical aggression in paediatric acute care settings is warranted however evidence on training effects in general hospital settings is scant [15]. There are a number of reviews of aggression management training programs in the psychiatric and mental health settings [16,17] however the results cannot be generalised to the acute setting or further extrapolated to the paediatric setting due to the different types of care provided in each facility and prior training of staff [18,19]. In addition, aggression management training programs designed for nursing staff working with children with neurodisabilities are rarely described in the literature. Simulation training may be an effective educational tool to practice de-escalation skills in a high fidelity situation. The benefit of simulation-based education for communication skills has been shown to improve patient safety in a number of studies [20-22]. There is a paucity of literature in the use of simulation-based education to teach de-escalation communication techniques to staff working with children and young people, particularly those with ASD, in the acute care setting.

Choice of comparator

A purpose designed and built web-based learning package on working with children and young people with ASD and aggression or externalizing behaviours was chosen as the comparator. An online learning package was chosen as it is convenient and flexible in time to complete, yet provides consistent information and allows self-paced learning. The online resource includes an opportunity for learner determined revision of concepts, promotion of active and independent learning and ability

to link to and explore relevant resources.

Study purpose and trial design

The purpose of this study is to conduct a pilot and feasibility cluster randomised controlled trial (RCT) to evaluate the effectiveness of simulation-based education for staff in managing aggression and externalizing behaviours of children with ASD in the hospital setting.

This study is a mixed design, with between group and within participant comparisons 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. Randomisation of two wards will be performed with 1:1 sample size per cluster.

Study Objectives

Primary objective:

The study objectives are to conduct a pilot and feasibility study and assess features of the acceptability and feasibility of our pilot design.

Population: Clinical nurses working in an acute care paediatric hospital

Intervention: Simulation-based education plus web-based education resources on the management of clinical aggression and externalising behaviours in children with autism spectrum disorder +/- intellectual disability

Comparator: Web-based education material on the management of clinical aggression and externalising behaviours in children with autism.

Outcomes: The following criteria will have to be met to indicate that a RCT is feasible and acceptable as planned:

1. **Randomisation:** more than 10% recruitment rate from ward staff. A total of 160 staff from the two selected wards will be eligible to participate in the study. We aim to recruit 10 staff to each arm of the study.
2. **Completion:** Less than 20% attrition rate with survey completion rate of at least 80%; Focus group participation rate of at least 50% of total participants
3. **Acceptability:** High acceptability of the intervention among participants as indicated by 80% of scores 4 (good) out of 5 or higher in survey data
4. **Data collection:** follow-up survey response rate of at least 30% with acceptability and confidence levels maintained; Ward data collection rate of at least 80% of total shifts during study time in each ward
5. **Low contamination** from intervention participants as evidenced by participant report

Secondary objectives:

Outcomes:

1. **Confidence & Competence:** 80% of participants reporting increased confidence levels and positive qualitative comments
2. **Data collection:** 80% reporting of number of Code Grey activations and the number of successful de-escalation episodes not requiring a Code Grey activation with description of context and outcome for each incident. Participant use of de-escalation skills during simulations using De-escalating Aggressive Behaviours Scale – English modified version (EMDABS).

In summary, the aim of this study is to conduct a pilot and feasibility cluster randomised controlled trial (RCT) to evaluate the effectiveness of simulation-based education for acute care hospital staff in managing aggression and externalising behaviours of children with ASD. We hypothesize that a multisite cluster RCT to evaluate this training format is feasible.

Methods

Participants, Interventions and Outcomes

Study setting

The study setting is a tertiary paediatric hospital, The Royal Children's Hospital, (RCH) Melbourne, Australia. Recruitment will be from nursing staff from one general medical ward and one general surgical ward both of similar size and patient complexity. Hospital data indicates that children and young people with autism+/- intellectual disability are admitted with similar frequency to these wards. The two wards included also experience similar numbers of aggressive incidents per year requiring a hospital Code Grey response.

Eligibility criteria

Clinical nurses who work in two general medical and surgical wards will be invited to participate in the study. Eligible nurses will be those who are responsible for providing direct clinical care for ward patients.

Nurses from these wards are excluded if they are not responsible for direct patient care e.g. care coordinators, advanced practice nurses and nurses in charge of the shift.

Interventions

The training intervention will consist of two components.

1. A web-based learning package, developed using Articulate™ software, about management of aggression and externalising behaviours in children and young people with autism (with and without ID) in the hospital setting as pre-reading.
2. This will be followed by a 1.5 hour simulation-based group education session to manage aggression and externalising behaviours in an adolescent with autism including two separate simulation exercises each followed by a facilitated reflective debrief which explores what the participants did well, what were the challenges and what they will do differently next time. The first scenario involves an adolescent with autism and aggressive and externalising behaviours. The second scenario increases in complexity and involves a non-verbal adolescent who has autism and intellectual disability who also demonstrates aggressive and externalizing behaviours. The training will be conducted in the Simulation Centre, conducted by the Simulation Faculty and Code Grey Coordinator with an actor playing the role of the patient. The parent role in each of the scenarios will be played by a member of the simulation faculty. The simulation exercises will be recorded using Sportstec™ (also known as 'Studiocode') software.

Web-based education (comparator):

A web-based learning package, is being developed using Articulate™ software. Content will be

written by a study investigator with significant experience working with children with autism spectrum disorder and intellectual disability and their families. The content will be reviewed by autism experts within Neurodevelopment & Disability Department, RCH, Murdoch Childrens Research Institute and Department of Paediatrics, University of Melbourne staff. A consumer representative will also review the content. Modifications will be made from the feedback received. The content will be succinct and will be designed for the learner to complete within 30 minutes. A small number of short multi-choice questions will be included in the education package to test understanding and application of knowledge.

Simulation-based education (training intervention):

A 1.5 hour simulation-based education session focusing on managing aggression and externalising behaviours exhibited by a young person with autism, in the inpatient setting is being developed by the study investigators in conjunction with the Simulation Faculty. The RCH Simulation Program curriculum and simulation sessions are designed according to the concepts described by Dieckmann et al [23], utilizing the debriefing framework by Rudolph et al [24]. The simulation scenarios will be reviewed and trialed by members of the Simulation Faculty with modifications to improve the learning experience made prior to conducting the sessions. The training sessions will be delivered by the Simulation Faculty in the Simulation Centre with assistance from the Code Grey Coordinator. Two separate simulation exercises will be delivered within this 1.5 hour simulation training session.

Participants will be required to complete pre-/ post-training surveys and a follow-up survey three months post-training. Each participant will be asked to create a unique identifier for use in all the surveys using first 3 letters of their first street name followed by the first 2 numbers of their mother's birthdate.

Nurses randomised in the ward to receive the training intervention will receive the simulation-based training intervention plus web-based training resources. They will be sent an email with instructions on how to access the surveys and the training and the requirements of the study. Participants in this arm will be instructed to complete the web-based training prior to attending the simulation-based education.

Nurses working in the ward randomised to receive the comparator will receive the web-based training resources only. They also will receive an email outlining the requirements of the study with links to the surveys and the training materials.

The intervention arm will be sent an electronic link to reserve their place in one of two simulation training sessions. Each session will have capacity for 5 participants. The comparator arm will be sent a link to access the web-based training. It is expected that the participants will confirm with their Nurse Unit Manager (NUM) if they are able to be released from ward duties for the duration of the training. Participants will also be instructed via email to complete the pre-training survey prior to commencing the training.

The time commitment to complete the web-based education will be 30 minutes with the simulation education involving a 1.5 hour commitment within working hours.

Staff will complete the simulation training in the double staff time. The principal investigator will liaise with the relevant nurse education team members to ensure that nurses have capacity to complete the simulation-based training and the online training during double staff time. During this time, there are more nurses available to attend training whilst not compromising patient care. This is the time that education is often scheduled for nurses working on wards and this training will be

scheduled to occur in late November 2019, where it is anticipated that ward activity levels are less than during the winter period. Nursing executive and Nurse Unit Managers of the study wards have agreed to support this study as have RCH Simulation and Neurodevelopment & Disability departments.

Training intervention:

A researcher not involved with this study will explain the study design to the participants prior to commencement of the pre-brief to the simulation training. It will be explained that participants will complete a short electronic survey at completion of the simulation education program. The survey will be completed anonymously with no personal details recorded. The researcher will explain that the simulation sessions will be recorded to enable researchers to view the recordings at a later date to assess the impact of the training on participants' performance in de-escalating aggressive situations. Only the study investigators will have access to the recordings which will be deleted once analysed. The assessment of the recordings will not include any participant identification details. Participants in the simulation-based education will be asked to maintain and hold confidential all information regarding the performance of specific individuals and the details of the specific scenarios. The researcher will check that all participants have completed the pre-training survey. For those who haven't, time will be provided to do it in a nearby room with computer access prior to commencing the simulation training.

The Simulation Faculty member facilitating the simulation session will then brief the participants on the objectives of the two simulation exercises. The roles and expectations of both the participants and the instructors are discussed. The structure of the session and the purpose of the post-simulation debrief is explained. The participants are informed that the same professional actor will play the role of the patient in each of the simulation exercises. The second simulation scenario will be more complex than the first, giving the participants the opportunity to extend their skills and build on knowledge learnt from the first scenario. Participants will be asked to volunteer for the different roles in each simulation scenario. The Simulation Faculty Technologist will orientate the participants to the Simulation Centre and simulation equipment prior to commencement of the first simulation scenario.

Outcomes

The primary and secondary outcome measures for assessing the acceptability and feasibility of conducting the training intervention are detailed in Study Objectives.

Two simulation scenarios involving an adolescent with autism, intellectual disability and aggression and externalizing behaviours will be assessed. Study participants will be asked to complete three surveys: a pre-training survey, post-training survey and a follow-up survey.

The purpose of the pre-training survey is to determine participants' self-perception of confidence and competence in managing aggressive and externalising behaviours in a young person with autism. The pre-training survey incorporates the "Confidence in Coping with Patient Aggression Instrument" [25], short answer questions and free text to assess: self-perceived levels of confidence and competence in managing aggression in a young person with autism and intellectual disability and acceptability of the simulation and web-based education. The Confidence in Coping with Patient Aggression Instrument is a one dimensional, 10 item instrument demonstrating a high degree of internal consistency (Cronbach's alpha = 0.92) and precision (standard error = 1.5) [25].

The purpose of the post-training survey is to determine if the training had an impact on participants' self-perception of confidence and competence in managing aggression and externalising behaviours in a young person with autism. The post-training survey also incorporates the "Confidence in Coping with Patient Aggression Instrument" [25], short answer questions and free text to assess: self-perceived levels of confidence and competence in managing aggression and externalizing behaviours in a young person with autism and intellectual disability and acceptability of the simulation and web-based education. The purpose of the follow-up survey is to determine if the training had a continued impact on participants' self-perception of confidence and competence in managing aggression in young people with ASD.

Each of the simulation training scenarios will be recorded. The recordings will be analysed by two clinicians, who are experienced in clinical aggression management, using the De-escalating Aggressive Behaviour Scale – English modified version (EMDABS) to assess the influence the training had on participants' performance in de-escalating aggressive situations. A study investigator will train the clinicians in the use of the tool using the training materials provided by Mavandadi [26] providing a clear definition of terms and items and the scoring system. Both clinicians will use the tool on a recording of a practice simulation involving only members of the Simulation Faculty and the study investigator and discuss decision making processes to ensure consistency and interrater reliability [27].

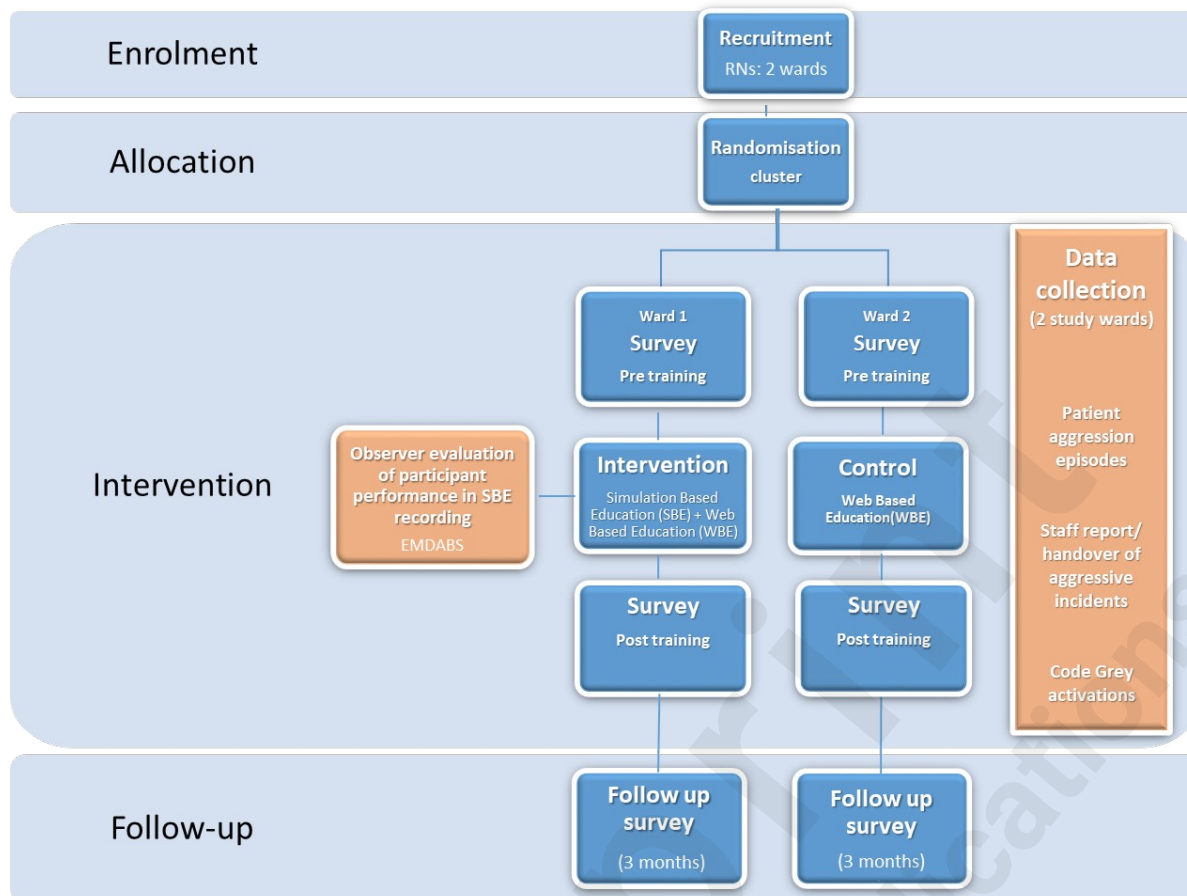
Knowledge retention of study participants three months post-training and continued confidence and exposure to clinical aggression will be assessed via surveys similar in content to the pre-/post surveys. Results from the pre- and post-training and the follow-up surveys will be linked using a unique identifier which the participants created prior to completing the pre-training survey.

Data will be collected at a ward level each shift for the duration of the study to assess number of aggressive incidents and rates of successful de-escalation for patients with ASD. A short survey will be emailed to Associate Unit Managers (AUM) and any additional nurses who acted up in the role of AUM/ in charge of shift, at the completion of the study to explore the enablers and barriers to collecting this data.

Total change in Code Grey activations will also be assessed in total and at a ward level. We will also record rates of data collection.

Participant timeline

Figure 1: Study design flowchart



Sample size

We plan to recruit 10 staff to each arm of the study. This sample size, based on our experiences in Phase 1 of this study, is a good size for a pilot and feasibility study to assess recruitment, contamination and data collection.

Recruitment

A study investigator will provide ward-based education about the study, providing clinical nursing staff with information about the study and an opportunity for questions in the double staff time in each ward 2 times in a 2-3 week period prior to commencement of the study. Hard copies of the study information will also be provided. Following face to face information sharing, study information and request to participate in the study will be forwarded via email to each nurse in the ward by a study investigator. This email will describe the study and outline the participant requirements. It will include a Participant Information Statement and Consent Form. Two reminder emails will be sent 1 week apart to potential participants to remind them to respond.

The first 10 nurses from each ward who agree to participate in the study and return the Consent Form will be accepted into the study. Following randomisation, participants from each arm of the study will be sent an information email (specific to the group to which they have been randomised) with all the information they require to participate in the study. This email will include links to the relevant resources and surveys as well as links to book into the simulation training and the focus group interviews. Three months post-training, all participants will receive an email reminding them to complete the follow-up survey. This email will be re-sent two times as a reminder to participants. At the completion of the study, participants will receive a letter which provides a summary of the main

study findings and thanks them for their participation in the study.

Assignment of interventions

Allocation: Sequence generation:

A researcher not associated with this study and not based at the study site will use coin toss to randomise the wards included in the study to either the training intervention or the comparison group. This will occur once recruitment is complete. A first coin toss will identify which ward is being considered (i.e. heads for one ward and tails for the other). The second coin toss will decide whether the selected ward is the intervention arm or comparator.

Allocation: Concealment mechanism

Once the wards have been allocated the study investigator will be un-blinded and will individually notify participants via email to which arm of the study they have been allocated.

Blinding:

Blinding for the study investigators and participants will not be possible. To reduce bias, once data is exported to Microsoft Excel™, a researcher not involved with the study will code the intervention and comparator groups and remove data columns that relate to the intervention group only so the person conducting the analysis will be blind to group allocation

Data collection, management and analysis

The Kirkpatrick Model will be used to measure the impact of the training. This 4-level model evaluates training according to (1) reaction; (2) learning; (3) behavior and (4) results [28-30].

1. Pre/post simulation training survey (Kirkpatrick Level 1)

A link to a short, electronic REDCap™ survey will be administered to participants' pre- and post-simulation training incorporating the "Confidence in Coping with Patient Aggression Instrument" [25], short answer questions and free text to assess: self-perceived levels of confidence and competence in managing aggression; acceptability of the simulation and web-based training

2. Follow-up survey - 3 months post training (Kirkpatrick Level 1)

A link to a short, electronic REDCap™ survey will be emailed to participants three months post-simulation training incorporating the "Confidence in Coping with Patient Aggression Instrument" [25], short answer questions and free text to assess: self-perceived levels of confidence and competence in managing aggression; acceptability of the simulation and web based training

3. Observer evaluation of use of de-escalation skills within simulation (Kirkpatrick Level 2)

The simulation exercises will be recorded using Sportstec™ software. Sportstec™ is video analysis software designed for use in medical simulation research which allows users to interpret and code the multi-faceted elements of video while identifying patterns that form a comprehensive picture. The video recordings are securely held on RCH servers and the software license includes use for research purposes. Two clinicians with expertise in the management of clinical aggression will assess the participants' recorded performance for each scenario using the English modified version of the De-escalating Aggressive Behaviour Scale (DABS) [27,31]. The DABS is a one-dimensional, 7-item scale combined with a 5-point Likert scale from strongly disagree to strongly agree. Performance

will be represented by the means of the 7 items. The original German language scale was enhanced and validated by [26] to create the English modified version (EMDABS). This tool demonstrated good inter-rater reliability (Intra-class correlation coefficient = 0.752) and strong internal consistency (Cronbach's alpha = 0.901). Training materials have been provided by the authors of the EMDABS tool and will be used to train the clinicians in the use of the tool.

4. Ward patient aggression record (Kirkpatrick Level 3)

Episodes of clinical aggression from patients with ASD will be recorded each shift in participating wards one month prior to and three months post-training intervention. Numbers of successful de-escalation interactions will be recorded. A short, electronic REDCapTM survey will be emailed to Associate Nurse Unit Managers (ANUM) and any additional nurses who acted up in the role of ANUM at the completion of the study to explore the enablers and barriers to collecting this data.

5. Code Grey activations (Kirkpatrick Level 4)

Review of numbers and context of code grey activations in participating wards for one month prior to and three months post-training intervention.

Strategies to be used by the study team to promote participant retention and completion of follow up surveys are described under recruitment.

Data management

Participant confidentiality is strictly held in trust by the study investigators, and the sponsoring institutions.

All surveys are anonymous so no personal details will be stored. The data from the EMDABS will be entered into a password protected REDCapTM account by an administration assistant. All survey data will be entered directly by participants in to the secure REDCapTM web-based application. SportsecTM recordings of the simulation-based education will be deleted once analysis is complete.

All data for this study will be stored on a password protected computer located in department of Neurodevelopment & Disability for five years. After five years, the data will be deleted.

Statistical methods

Primary outcomes: Percentages will be calculated to estimate recruitment, retention, outcomes survey response rate, focus group participation, and the precision of those estimates. We will treat the Likert scores as categories and dichotomise the 11 and 5 point scale responses. Changes in confidence and competence will be compared statistically (Chi squared test) using before and after data, to compare the proportion of those who have high confidence at baseline between the two arms, and at follow-up.

Secondary outcomes: The Code Grey data and daily aggression data will be analysed using descriptive statistics, including descriptions of the clinical journey for children and young people who trigger more than one code grey response. We will report if aggression de-escalation attempts are recorded each shift on each ward as planned. The EMDABS data will be analysed using mean values and standard deviations to understand the variation in performance of individuals who

undertake the training.

Monitoring

Data monitoring

A Data Monitoring Committee is not required as this is a feasibility and pilot study of short duration and minimal risk.

Harms

Due to the realism of simulation-based education, participants could potentially become distressed during, or at the completion of a simulation scenario or the debrief, for many reasons. If a member of the Simulation Faculty observes distress in a participant, they will offer them the option to leave the scenario or debrief, and will support them both at the time they leave, as well as follow-up through the following week. In addition, they will be offered the counsel of the RCH Employees' Assistance Program. In a previous pilot study conducted prior to this work by the authors, distress post simulation-based education was minimal. Immediate support from the Simulation Faculty post-training was sufficient to reassure a small number of participants who verbalised concern about their performance. No participants required referral to the RCH Employees' Assistance Program for continued support or follow-up.

It is not expected that the focus groups will cause participants any anxiety or distress. If participants do not feel comfortable answering any of the questions in the focus group, they do not need to answer them.

Auditing

Auditing of data is not required as this is a feasibility and pilot study of short duration.

Ethics and dissemination

Research ethics approval

The study received ethical approval from The Royal Children's Hospital Melbourne Human Research Ethics Committee (HREC) on 1st November 2019. HREC reference Number: 56684.

Protocol amendments

There are no anticipated amendments to the protocol for this pilot and feasibility study.

Consent

Participation will be voluntary, and consistent with the National Statement on Ethical Conduct of Human Research Section 2.2.9: no coercion or pressure to participate will occur between the study investigators and potential participants [32].

A study investigator will email the Participant Information Statement and Consent to all potential study participants. Nurses in the study wards will be asked in this email to return the Consent Form to the nominated study investigator if they would like to participate in the study.

All participants will be required to read the Participant Information Statement and sign and return the consent form via email before participating in the study.

Participants in both arms of the study will be required to complete the (1) training intervention (2) pre- and post-training surveys; (3) follow-up survey and (4) participate in a one hour focus group interview at completion of the training.

Confidentiality

Participant confidentiality is strictly held in trust by the study investigators, and the sponsoring institutions.

Participants in the simulation-based training will be asked to maintain and hold confidential all information regarding the performance of specific individuals and the details of the specific scenarios.

Surveys: All surveys are anonymous and will be completed electronically using a web link to the REDCap™ survey sent to participants via email. While no personal details will be recorded, it is possible that years of clinical experience may potentially identify some participant responses. Participants will be asked to create their own unique identifier to be used for each survey, so that pre-/post-training and follow-up survey results can be linked. Data stored in the secure database REDCap™ will be deleted following completion of data analysis.

Sportstec™ recordings of the simulation-based education: Confidentiality will be maintained by the assessors, no identifying participant information will be kept and the recordings will be deleted once analysis is complete.

Ward Patient Aggression Record: Completed daily Ward Patient Aggression Records will be stored in a locked filing cabinet in the ward nursing offices and collected daily on week days by a study investigator who will then store the record sheets in a locked filing cabinet in the clinical department of Neurodevelopment & Disability. No patient names will be recorded on these records only the patient Medical Record Number (MRN). This information is re-identifiable however only the study investigator (MM) will have access to the data across the study period. The nurse in charge of the shift who completes the record will have access to the record sheets completed that day and will store them in a locked filing cabinet on the ward until they are collected by a study investigator (MM). This researcher, who is a RCH clinician and works with this population, will access the medical records to locate the aggressive incident. No personal information will be recorded in REDCap™ instead what will be recorded is whether a de-escalation episode was found or not, to check the validity of the reported data as part of the pilot and feasibility study. Data, excluding the patient MRN, will be entered into the secure database REDCap™ and will be deleted following completion of data analysis. Written records will be shredded and disposed of securely once data is entered into REDCap™.

Declaration of interests

None declared.

Access to data

Only study investigators will have access to the trial data.

Ancillary and post-trial care

N/A

Dissemination policy

The results of this study will be disseminated to study participants, staff of the study site and health care professionals through the dissemination plan in Table 1.

Table 1. Dissemination plan

Domain	Activities	Approach	Timeframe	Responsibility	Budget
Dissemination objectives					
	Goal is to present main findings to participants, staff at study site, hospital executive, healthcare professionals and consumers	Dissemination options detailed below for each group	Within 6 months following completion of study	Study investigators	Nil
Identify target audience					
	Study participants	Letter – summary of main findings	1 month following completion of study	Study investigators	Nil
	Staff at study site	Presentation at research forums, department meetings, ward in-service	Within 6 months following completion of study	Study investigators	Nil
	Hospital executive	Face to face meeting with Executive Director of Nursing & Allied Health, written summary of findings	Within 2 months following completion of study	Study investigators	Nil
	Health care professionals	Publication in relevant journals; presentation at relevant local and international	Within 1 year following completion of study	Study investigators	Funding will be sought from relevant scholarships

		conferences; webinar about study and findings for Neurodevelopment & Disability			and funding sources
	Consumers	Blog of main findings presented in plain English on department website	Within 2 months following completion of study	Study investigators	Nil
Key messages					
	Determine key messages for each target group following completion of study	Adapt content as appropriate	1 month following completion of study	Study investigators	Nil
Sensitivities					
	Determine sensitivities for each target group following completion of study	Adapt content as appropriate	1 month following completion of study	Study investigators	Nil
Evaluation plan					
	Evaluate the effect of the different strategies	Analyse click and open rates for web based resources Note implement- ation strategies at study site following dissemination of results	Within 1 year following completion of study	Study investigator	Nil

Results

This study gained ethical approval from Research Ethics and Governance, The Royal Children's Hospital Melbourne on 1st November 2019.

Discussion

Aggression demonstrated by children and young people with autism with or without intellectual disability is increasing in acute care paediatric hospitals. Nursing staff often feel underequipped to successfully de-escalate or prevent aggression or externalising behaviours in this population. It is important that acute care nurses working with children with ASD are confident in managing aggression demonstrated by patients in their workplace. This study aims to develop and pilot test a

simulation-based training program to upskill paediatric nursing staff on working with children and young people with autism and aggression and externalising behaviours.

Abbreviations

ASD: Autism Spectrum Disorder

AUM: Associate Unit Manager

EDONAH: Executive Director of Nursing and Allied Health

EMDABS: De-escalating Aggressive Behaviour Scale – English modified version

ID: Intellectual Disability

MRN: Medical Record Number

RCT: Randomised Controlled Trial

RCH: Royal Children's Hospital

Contributorship

MM developed the training materials for this study with input from all authors. MM wrote the draft of this manuscript. All authors have been involved in revising the manuscript and approved the final version.

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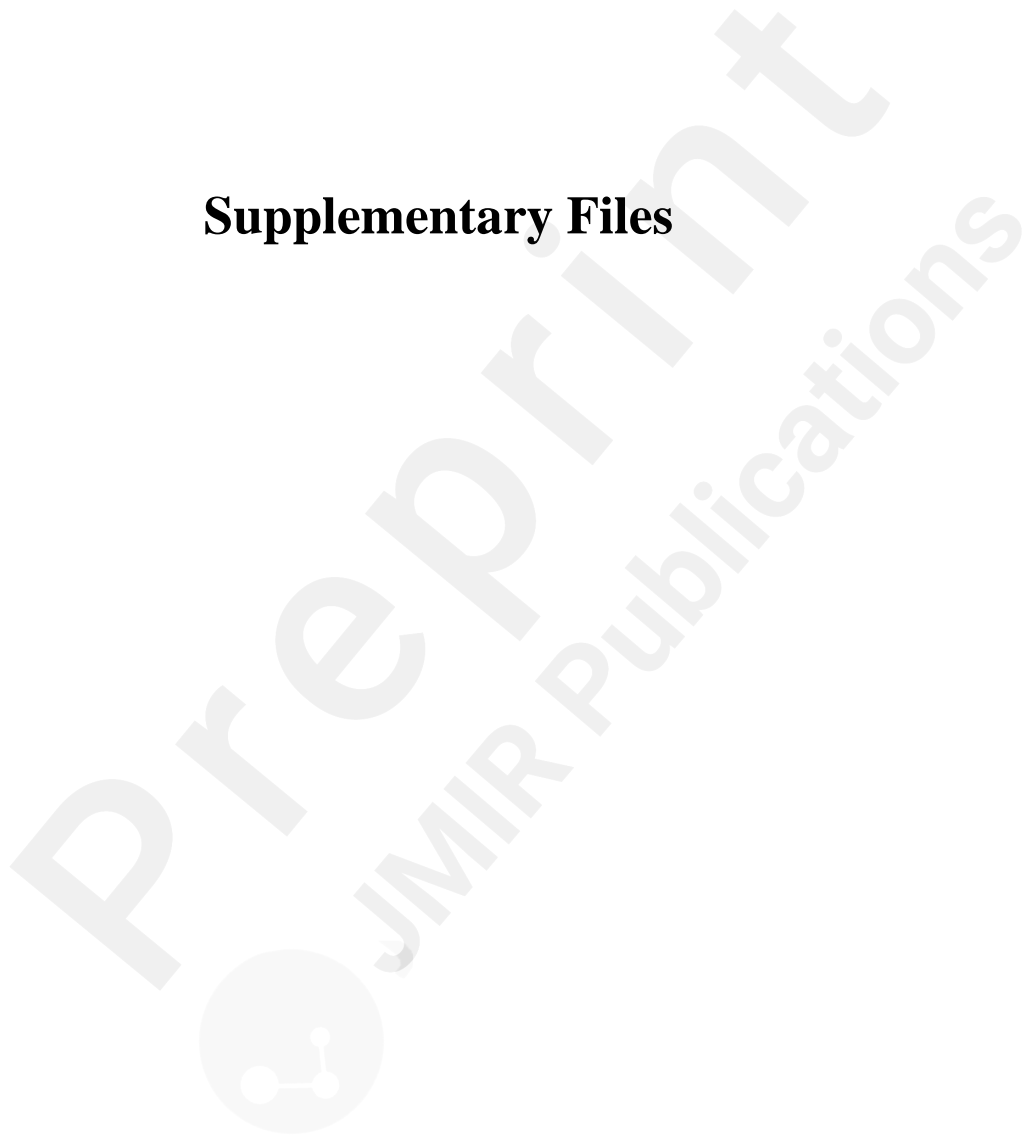
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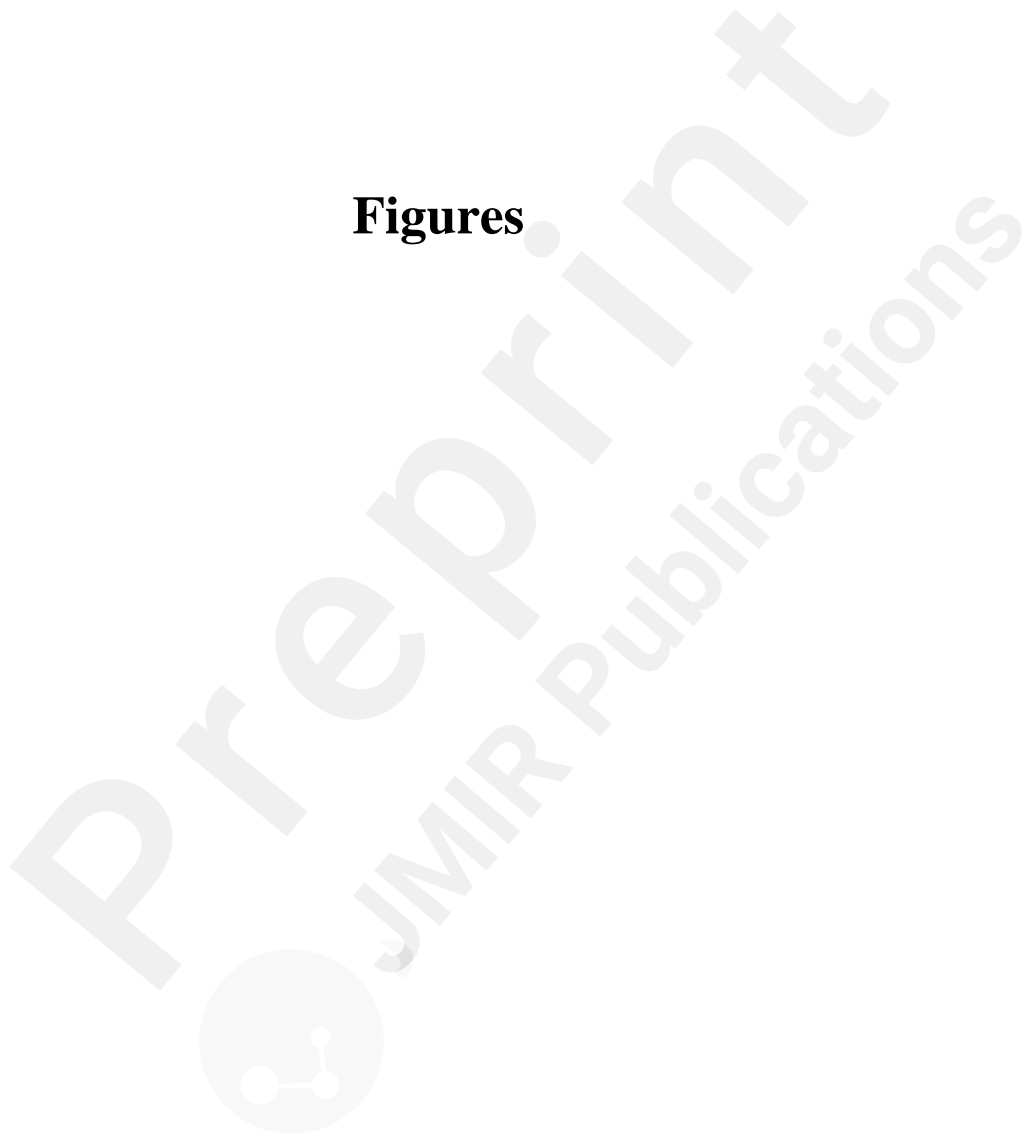
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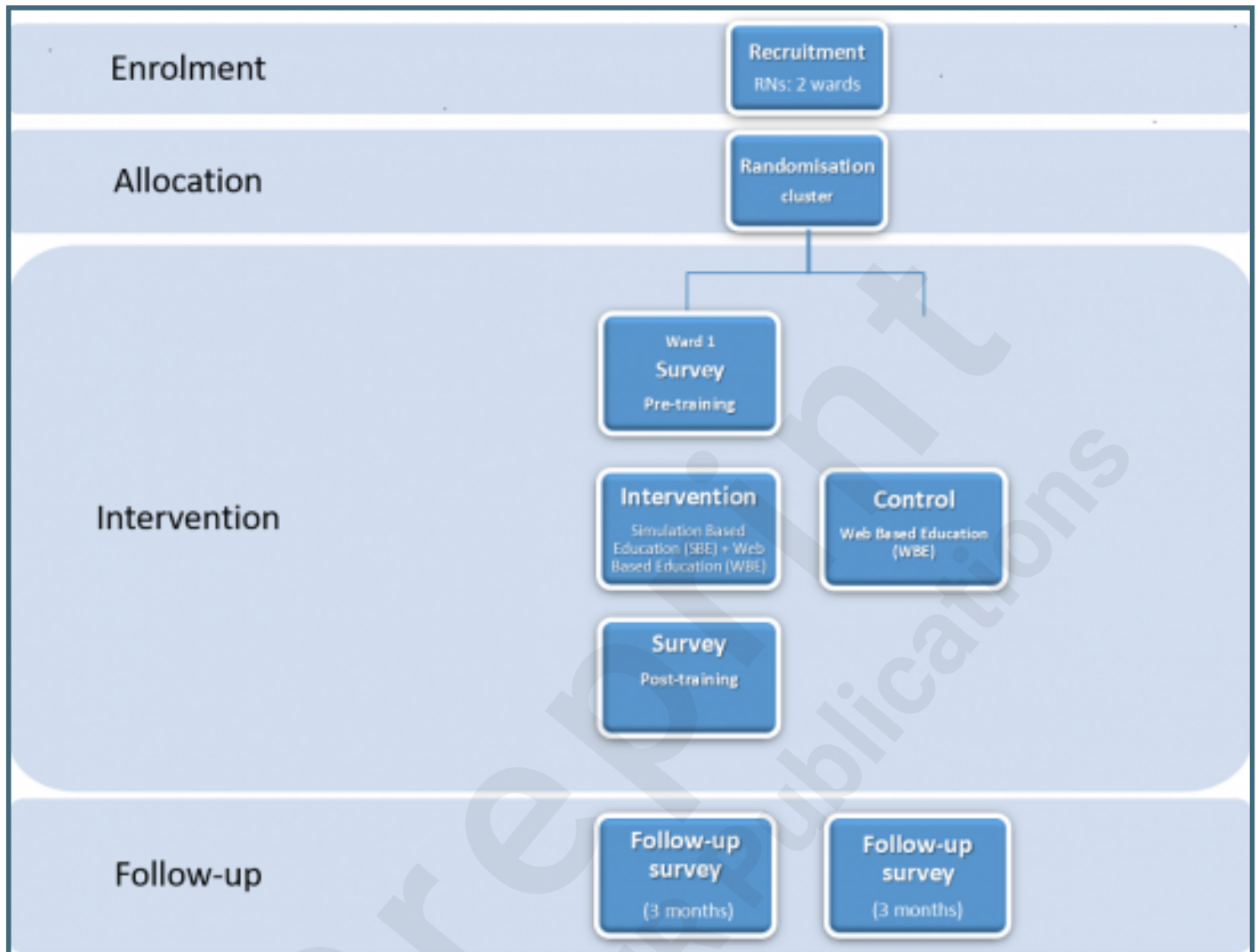
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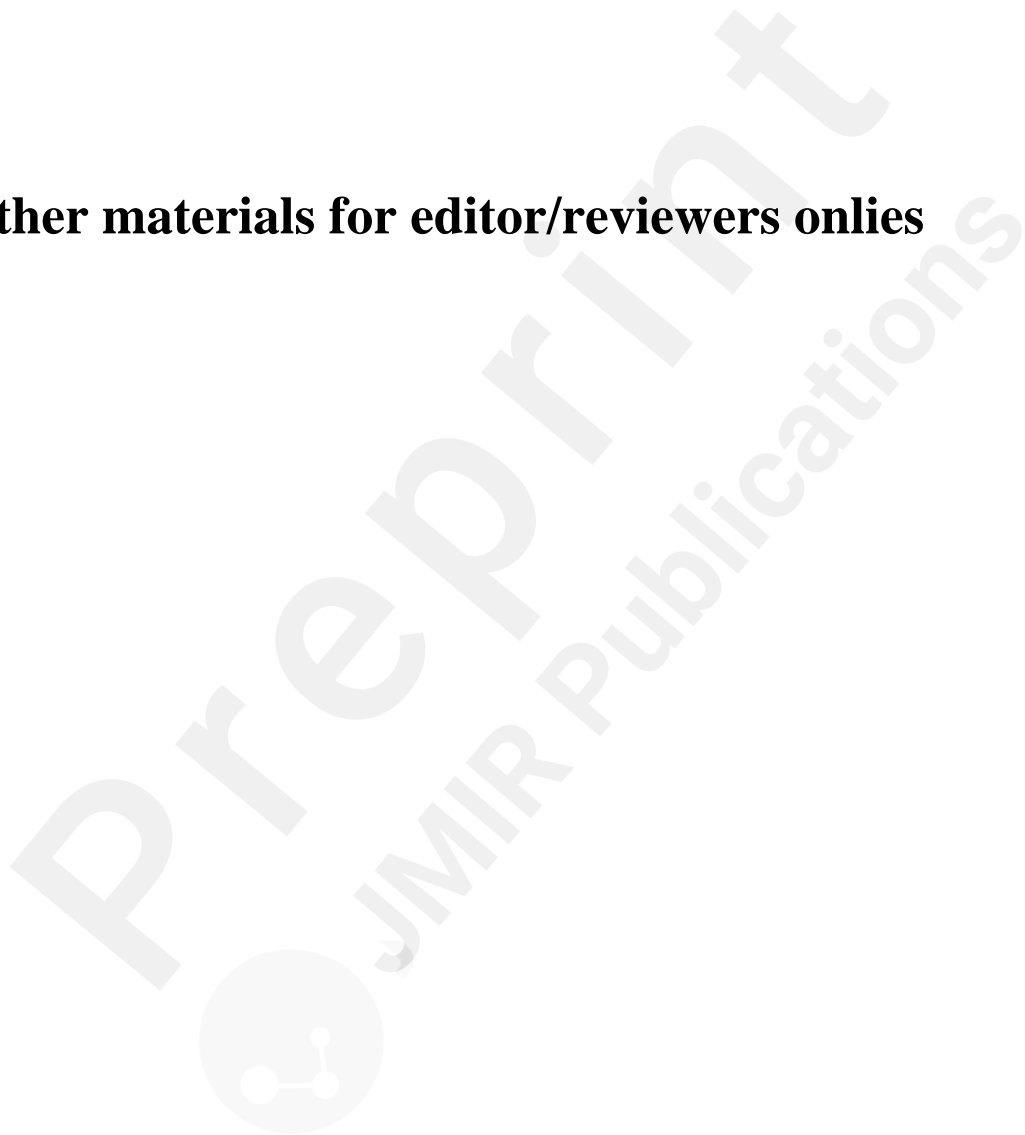
Figures



Study design flowchart.



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