

BMJ Open Study protocol for a randomised controlled trial of humanoid robot-based distraction for venipuncture pain in children

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ABSTRACT

Introduction Intravenous insertion (IVI) is a very common procedure in the emergency department (ED). IVI is often painful and stressful for both children and their families. Currently, distraction therapy is not used as a standard of care for IVI in North America. We propose that interaction with a humanoid robot may effectively distract children during IVI thereby reducing their pain and distress.

Methods and analysis This randomised controlled superiority trial will be conducted in a Canadian paediatric ED. We plan to recruit 80 patients. Children will be eligible if they (1) are 6 to 11 years of age, (2) need an IVI, (3) are fully conscious and alert, (4) have sufficient knowledge of the English language to understand and complete the study assessments and (5) are accompanied by a legal guardian. Our primary objective is to compare patient-reported pain and distress with the use of distraction (via a humanoid robot) versus standard care in children. The primary outcomes will be (1) self-reported pain, as measured by the Faces Pain Scale—Revised and (2) observed distress, as measured by the Observational Scale of Behavioural Distress—Revised. Secondary outcomes will include (1) measuring parental anxiety, (2) examining the association between parental anxiety and child outcomes and (3) children's degree of engagement with the humanoid robot via the Intrinsic Motivation Inventory tool. First enrolment occurred in April 2017 and is ongoing.

Ethics and dissemination This study has been approved by the Health Research Ethics Board (University of Alberta). Informed consent to participate will be obtained from all participants' parents/guardian, in conjunction with assent from the participant themselves. This study data will be submitted for publication regardless of results. Purchase of the robot was facilitated through a Stollery Children's Hospital Foundation donation. Recruitment costs are supported by the Women and Children's Health Research Institute.

Trial registration number NCT02997631; Pre-results.

BACKGROUND AND RATIONALE

The WHO and the American Academy of Pediatrics have long mandated that children's pain be addressed as a fundamental human right.^{1,2} Many now consider children's

Strengths and limitations of this study

- This study will be conducted as a randomised controlled trial testing a novel humanoid robot intervention.
- This study supports family-centred care and innovation by measuring patient-level outcomes (pain and distress) as primary outcomes.
- This study tests the effectiveness of a novel distraction technique for children during a painful procedure and may lead to more pain management options in the emergency department.
- It is not possible to blind patients, caregivers, providers and outcome assessors, due to the nature of the intervention.
- The costs of the MEDi robot are higher than other forms of technology-based distraction (eg, iPad), and this may limit its use in lower resource settings.

pain management to be a 'quality assurance' issue, and suboptimal treatment is no longer acceptable to patients, caregivers or health-care providers.^{3–5} There is extensive evidence demonstrating that needle procedures cause significant pain and distress to children.^{6–8} Further, intravenous insertion (IVI) is recognised as the most common painful procedure for ill and injured children.⁶ In fact, hospitalised children describe IVI as the most painful part of their medical experience.^{6,9} The significant pain and distress associated with this procedure can increase hospital stay, slow the healing process and cause suffering which may be perceived as worse than the pain caused by the original injury.^{6,10,11} Left unaddressed, it can result in a scared and uncooperative child, a need for multiple cannulation attempts, needle phobia and dissatisfaction with care for both family and healthcare workers.¹⁰ Untreated pain in children undergoing medical procedures is epidemic.^{12–15} Despite the availability of pharmacological treatments (eg,

anaesthetic creams) for pain reduction, their use and effectiveness can be limited^{16–18} and they have known adverse effects. Psychological interventions are emerging as a newly favoured adjunct to pharmacotherapy due to their demonstrated benefits and safety,¹⁹ although distraction therapy is not currently considered standard of care in North America.^{12–15} Further, in situations where pharmacotherapy might not be possible (ie, time restraints, allergy to drug), it seems safe to assume that isolated distraction techniques are preferable to no pain therapy, at all.

Distraction therapy involves engaging children in cognitive tasks in order to divert attention from painful stimuli and reduce pain and distress. Numerous distractors have been employed with children undergoing medical procedures including audio or video recordings, story books, imagery and focused breathing.^{20–22} The hypothesised mechanism of action of distraction is based on Melzack and Wall's Gate Control Theory of Pain, which suggests that distraction stimulates the brainstem and ultimately inhibits pain perception.²³ A recently updated systematic review of psychological interventions showed a significant reduction in child-reported pain for needle-related procedures.²⁴ Results for other important outcomes, such as observed distress and behavioural measures of pain, had wider confidence intervals, but this does not preclude the possibility of benefit. More rigorous research was recommended to gain a more precise estimate of the impact of distraction therapy.

Children's rapid uptake of technology offers novel forms of distraction. Given children's growing enthusiasm for technological devices, we propose that the use of a technologically enhanced device may effectively distract children and reduce their perceived pain. It is plausible that devices children find actively engaging will provide greater distraction than passive activities such as watching cartoons. Emerging research suggests that mobile robot systems can improve patient care. One recent study of 57 children has demonstrated the effectiveness of child-robot interaction for reducing pain and distress during vaccination.²⁵ A second study has shown reduction in distress, only, for 40 paediatric oncology patients requiring central venous access.²⁶ It is timely to examine whether an interactive, humanoid robot can have an impact on children's pain and distress associated with IVI.

As it is impossible to eliminate procedural pain and distress with single pharmacological interventions, effective pain management via a multimodal approach is crucial. Multimodal analgesic strategies have increasingly been recognised as more effective than traditional single-mode analgesic approaches.^{27–28} Combining child-focused interactions with a humanoid robot and current standard care (eg, topical anaesthetic cream) aligns well with published recommendations to attend to *individual* child preferences and increase *child participation* in healthcare decisions.²⁹

Our proposed study aims to compare the reduction of patient-reported pain and observed distress with the use

of distraction (via a humanoid robot) versus current standard care in children aged 6 to 11 years who are undergoing IVI.

METHODS AND ANALYSIS

This study will be conducted as a two-armed, randomised, superiority trial. The study protocol is reported using the SPIRIT-PRO (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines.³⁰

Study setting

This study will be conducted in the Stollery Children's Hospital (SCH, Edmonton, Alberta) emergency department (ED). The SCH is a tertiary care Canadian paediatric hospital whose annual ED census is >50 000 children. We began recruitment for this study on 20 April 2017, and it is currently ongoing.

Sample size

We conducted sample size calculations using a two-tailed, two-sample Mann-Whitney test for the primary outcome of child-reported pain based on data from our previous trial of music as a distractor for children undergoing IVI.³¹ To detect a difference of 2 points on the Faces Pain Scale—Revised (FPS-R) (which is considered clinically important)³² given a type I error of 0.05% and 80% power, we will require 40 patients per group. We also performed sample size calculations using a two-tailed, two-sample t-test, for our other primary outcome of observed behavioural distress using data from our previous trial (ie, SD=2.77).³¹ To detect a large effect size of 0.6 (which we observed in the previous trial) given a type I error of 0.05% and 80% power, we will require 35 patients per group. We plan to recruit 80 patients with usable data, which will allow sufficient power to find a difference in both primary outcomes if a difference truly exists and account for missing data.

Eligibility and exclusion criteria

Children will be eligible if they (1) are 6 to 11 years of age, (2) need an IVI, (3) are fully conscious and alert, (4) have sufficient knowledge of the English language to understand and complete the study assessments, and (5) are accompanied by a legal guardian. Children will be excluded if they have (1) hearing or visual impairments, (2) neurocognitive delays, (3) sensory impairment to pain (eg, spina bifida), (4) previous enrolment in the same study or (5) at the discretion of the clinical staff. Children will receive topical anaesthetic cream for IVI at the discretion of the ED clinical team (ie, as per standard care). Our age group of focus was carefully chosen, as there is evidence that this age group is able to reliably self-report pain with a single validated pain measurement tool²⁹ and has higher baseline pain and distress levels and, as such, are most likely to benefit from distraction.^{33–35}

Randomisation, allocation concealment and blinding

Randomisation will be determined using a secure online randomisation tool, through REDCap, and hosted via the



Figure 1 MEDi robot interacting with child.

data management group at the University of Alberta.³⁶ A trained research assistant (RA) will obtain the computer-generated randomised assignment after consent and assent have been obtained. Allocation will be concealed from the research staff, ED staff and participants until after consent has been obtained and randomisation has been assigned. Due to the nature of the intervention, it will not be possible to blind the children, parents, RAs or ED staff. The children and their parents will be informed that the study is to evaluate different forms of distraction but will not know the study hypothesis for the humanoid robot. The RAs coding the videos for OSBD-R scoring cannot be blinded to the intervention, as interaction with the robot is apparent in the child's actions, even though the robot is off-screen. The data analyst will be blind to treatment assignment by using randomisation codes that will not identify groups until analysis is complete.

Study intervention

The intervention will be the use of a humanoid robot, known as MEDi (see [figure 1](#)).

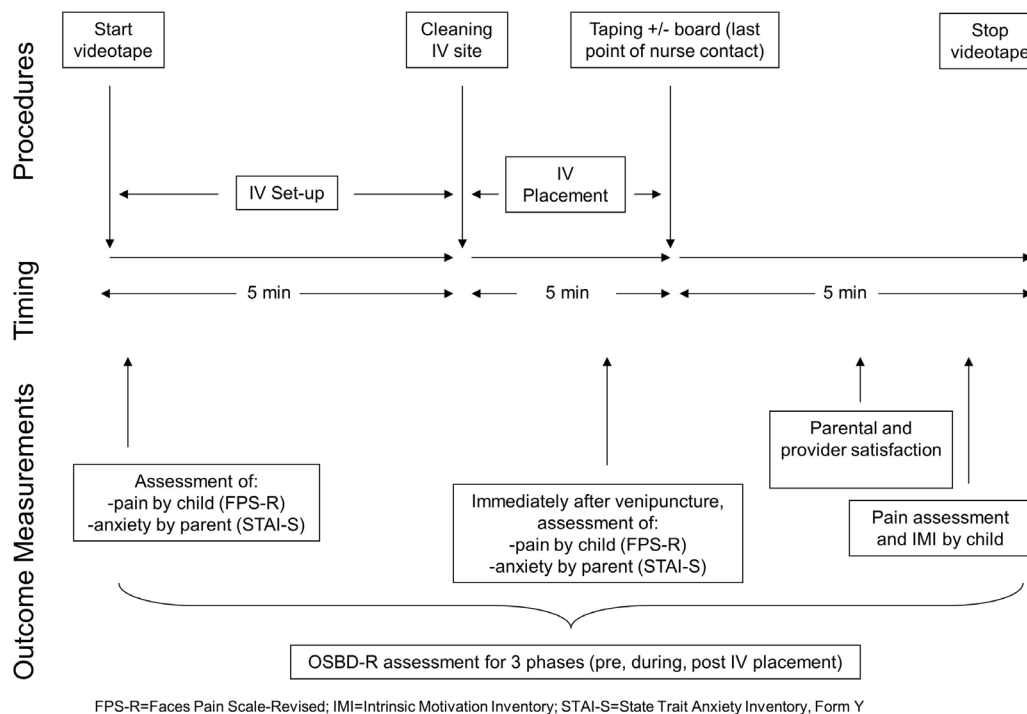
The MEDi robot is a humanoid robot that is programmed with specific, cognitive-behavioural therapy-influenced behaviours to coach children in all kinds of medical procedures. The MEDi robot has been programmed with a unique sequence, developed specifically for this study. The robot can be charged via direct connection to a power outlet, and also has a detachable battery pack for longer operation periods. Once charged, it can operate without a power charge for up to 4 hours, depending on the complexity of the chosen demonstrations. The robot is operated via a tablet device, connected through a wireless connection. Once the operator has started the robot's programmed sequence to be employed for the study, it will run through to completion, unless purposely discontinued by the operator.

The robot will be connected via a harness to a cart that is at the child's eye level. It will be programmed to introduce itself and ask for a high five while raising its arm. It will then ask the child to join in some simple distracting activities. Then, the humanoid robot will encourage the child to practice some deep breathing exercises. The robot

will encourage the child to blow as hard as possible three times, while the nurse is inserting the IV. It will then make encouraging comments about how brave he/she was. The robot will then dance to a popular song (Justin Timberlake's *Can't Stop The Feeling*), and then finish with a demonstration of Tai Chi. The duration of its actions will coincide, at minimum, with the length of the procedure (approximately 5–8 min from when the nurse's introduction has ended to when the procedure is complete). This duration of procedure has been confirmed through our previous work.^{31 37} If the procedure runs longer, RAs will be instructed to run another application, which include singing, story-telling and games, and the use of this extra playtime will be noted by the RA. The control group will receive standard care, which generally includes the use of topical anaesthetic cream (Maxilene). This comparison is based on precedent in the literature and is congruent with the pragmatic preferences of physicians at the SCH.^{31 38 39} Overall, it is felt that any new intervention (eg, the humanoid robot) should be compared with what is currently in practice (ie, standard care), as no single form of distraction therapy is consistently and routinely employed in hospitals or EDs at this time.

Recruitment and data collection

RAs will be on-site from approximately 15:00 to 23:00 daily to identify children who require IVI; this period corresponds with peak visits requiring IVIs based on data collected in the ED at the SCH in team members' previous studies. The RA will assess child eligibility based on the inclusion/exclusion criteria outlined above. After obtaining written, informed consent from the parent and assent from the child, the RA will access a secure, online randomisation programme which will assign the child to one of the two study arms (see online supplementary appendix 1A for Consent/Assent forms). The RA will identify one parent/caregiver to participate and complete all relevant questionnaires. The RA will gather information from the parent on baseline demographic variables (eg, sex, age), presenting signs and symptoms (eg, chief complaint), and previous history of ED visits and IVI. The RA will then collect baseline heart rate and preprocedure pain scores from the child, and baseline anxiety scores from the parent. If a child is randomised to the robotic distraction arm of the trial, the RA will bring the robot into the room, set it up and explain how to interact with it. Five minutes prior to the start of the procedure, the RA will begin the video recording. The staff nurse will then perform the routine set up for intravenous placement. For the purposes of our study, cleaning of the injection site by the staff nurse will mark the beginning of the procedure. The end of the procedure will be the last point of contact by the staff nurse (ie, taping cannula in place with or without arm board, wrapping arm with gauze and taping the gauze in place). The RA will record maximum heart rate and pain scores from the child and the parent will complete the anxiety scales immediately after the first attempt at



FPS-R=Faces Pain Scale-Revised; IMI=Intrinsic Motivation Inventory; STAI-S=State Trait Anxiety Inventory, Form Y

Figure 2 Flow diagram of study procedures and timing of main outcome assessments. IV, intravenous.

intravenous placement. Two minutes after completing the IVI, the staff nurse performing the procedure and the parents will complete the satisfaction questionnaire. Five minutes after the procedure is completed, the RA will stop the video recording. A timer will be used to coordinate all steps; this approach has been used successfully in previous trials by our team.^{31 37} If the first attempt at IVI is unsuccessful, additional attempts will occur *after* the study protocol is complete and all measures are administered; completion of study steps post-IVI attempt will not delay IVI reattempt by more than 2–3 min. As outcome measures are all captured within the 5–10 min before and after the ED IVI attempt, we anticipate very little missed data, as families will not be leaving the department during this time. As the outer shell of the robot is made of plastic and no internal components can be accessed by common use and handling, it will be sanitised after each use, in keeping with local infection control policy. See [figure 2](#) for study flow schematic.

Outcomes measures

Our two primary objectives are to compare self-reported pain and observed distress with the use of distraction (via humanoid robot) versus current standard care in children aged 6 to 11 years who are undergoing IVI. Our secondary objectives are (1) to compare parental anxiety related to their child's use of distraction, (2) to examine the association between parental anxiety and child outcomes (ie, pain, distress) and (3) to assess children's degree of engagement with the humanoid robot via a short survey (the Intrinsic Motivation Inventory tool (IMI) tool).

Our primary research questions are the following: (1) Does interaction with a humanoid robot (humanoid)

reduce the reported pain of IVI, as measured by the FPS-R? and (2) Does interaction with a humanoid robot (MEDi) reduce the reported distress associated with IVI, as measured by the Observational Scale of Behavioural Distress—Revised (OSBD-R)?

Pain will be measured with the FPS-R and reported directly by the patient. This scale depicts six faces expressing 2-point increases in pain from 0 (no pain) to 10 (maximum pain). The FPS-R will be administered visually, with the child pointing to the face that best represents their pain, as recommended in the literature.^{32 40} Concurrent validity and reliability of scores for this scale are high, and it is the currently recommended pain measurement tool for children aged 4–12 years.^{32 40} These scores will be obtained immediately before and after the intravenous procedure is complete.

Distress will be measured using the OSBD-R. It is the most commonly used outcome measure in procedure-related distress treatment studies.^{41–43} The tool assesses eight behaviours which are weighted according to intensity: information seeking, crying, screaming, restraint, verbal resistance, emotional support, verbal pain and flailing. Two RAs will be trained in the use of the tool and independently observe a videotape of each child while recording the frequency of operationally defined distress-related behaviours during continuous 15s intervals before, during and after the procedure. Inter-rater reliability will be calculated once 10% of videos are coded; retraining and feedback will be provided to the RAs to ensure the highest inter-rater reliability. The average of their two scores will be used for analyses. This protocol for use of the OSBD-R is standardised^{42 44} and has been used

in other trials evaluating distraction.^{31 38 45} The inter-rater reliability of the OSBD-R scores is high, and evidence of validity is shown in moderate to high correlations with other behavioural measures of distress in children aged 2 years and older.^{44 46 47} The RAs coding the videos for OSBD-R scoring cannot be blinded to the intervention, as interaction with the robot is apparent in the child's actions, even though the robot is off-screen.

Parental anxiety will be measured with the State Trait Anxiety Inventory—State Scale Revised Version (STAI-S, Form Y), which has good psychometric properties.⁴⁸ The STAI-S is an introspective psychological inventory of 40 self-report items pertaining to anxiety.⁴⁸ To determine a child's degree of engagement with the robotic technology, children will complete the 18-item version of the IML.⁴⁹ It has been used in the context of sports and games with adolescents; its items were simplified for the age group in our study. It consists of four subscales that measure interest enjoyment in an activity, perceived competence, effort importance and tension pressure. Items are rated on a 7-point scale from 'strongly disagree' to 'strongly agree', and scores provide a reliable and valid representation of these constructs. This scale will be administered immediately after the intravenous procedure.

Statistical methods

Statistical analyses will be conducted using statistical software SASV.9. The significance level is set at 0.05. Baseline variables will be described using appropriate summary statistics for each group. Clinically important imbalances between groups for key baseline variables may indicate the need for further adjusted analysis. For child-reported pain (with the FPS-R) during the procedure, the mean (or median, as appropriate) scores will be compared between the two groups using independent samples t-tests if they are normally distributed or Mann-Whitney U tests if they are skewed. For observed behavioural distress, measured by the OSBD-R, a change score (during procedure minus preprocedure) will be calculated for each child, and the mean change scores will be compared between the study groups using the Mann-Whitney U test.

Additional model-based analyses (multiple linear regression) will be conducted with pain (or behavioural distress) as the response variable, baseline pain (or behavioural distress) and group indicators as the explanatory variables along with some possible effect modifiers, such as age, sex and parental anxiety levels. Our primary analysis will be based on an intention-to-treat approach. Where data are missing, proxy information or appropriate imputation methods will be used as needed. Similar approaches will be used to compare the groups with respect to secondary outcomes (ie, change in parent anxiety pre-post procedure, parent satisfaction post-procedure, provider satisfaction postprocedure). We have planned, a priori, to perform a subgroup analysis excluding children with zero distress (as measured by the OSBD-R) during the procedure, as we rationalise that

there will be minimal potential for effect in this subgroup of children.

Patient and public involvement

Patients and public were not involved in the development of this study protocol. Family and patient members of our local hospital pain committee will be informed of the results and will be encouraged to share the results within their family-centred care network. Local and national media will be engaged to disseminate results to the public.

Data management

Paper study documents (eg, signed consent and assent forms) will be kept in a locked filing cabinet in the research office which has limited access by the research team only. Once the study is complete, they will be kept in the principal investigator's (PI) office, which is a locked room, in a locked filing cabinet for 5 years. Digital files are stored in a secure REDCap database, hosted by the Women and Children's Health Research Institute Data Coordinating Centre, to which required personnel have individual usernames and passwords.³⁶ REDCap is a programme designed by a consortium of National Institutes of Health-funded institutional partners. It was designed specifically around health data security guidelines and has a proven track record, with over 650 academic clinical research centres hosting the application. All identifying information that is collected will be flagged in the database and removed from data export. Any user who requires access to the dataset but does not need to view identifying information will be assigned 'No Access' to the Contact Information. This study collects the minimum number of identifiers necessary for follow-up contact with participants and analysis. All identifiers are 'flagged' within REDCap. When data need to be exported, they will be exported as a deidentified dataset wherein all fields that have been flagged as identifiers are automatically removed. If an identifier is required for analysis (eg, date of birth), that field will be manually added to the variables that need to be exported. The videos will be stored in a locked Shared Drive with restricted access to research coordinators and PIs only. Videos will only be saved according to their randomised study ID.

ETHICS AND DISSEMINATION

Study participation presents no known risks to the children, will pose no significant inconvenience or cost to the family and will not submit children to any additional pain or suffering. Children will receive standard medical management for their presenting diagnosis. Any protocol amendments will be submitted for Health Research Ethics Board approval prior to implementation and added as an amendment to the ClinicalTrials.gov trial registration. The SCH ED granted operational approval for this study, as well, prior to implementation. The costs of the MEDi robot are higher than other forms

of technology-based distraction (eg, iPad), and this will limit its use in low-resource settings. If the humanoid robot interaction is found to be effective in this study, our team plans to lead a large multiarmed, multicentre randomised controlled trial to compare costs and benefits of various technology-based distraction techniques. Our team plans to publish this trial in a high-impact, peer-reviewed journal and present the results at national and international meetings; authorship eligibility will be determined by employing the International Committee of Medical Journal Editors' recommended guidelines.⁵⁰ Technical online supplementary appendix, statistical code and dataset for this trial can be made available on request.

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Contributors SA developed and revised the protocol, co-drafted the protocol paper, and will operationalise the study. She chose the previously validated tools for measuring both the self-reported, patient-level (FPS-R) and observed (OSBD-R) primary outcomes. MS is a research coordinator and clinical nurse who contributed to study design, co-drafted the protocol paper and will operationalise the study. BV led the statistical analysis planning and contributed to protocol revision. SDS is a nationally recognised knowledge translation expert who has informed our integrated knowledge translation plan and methods. SC is a paediatric emergency physician–researcher who helped adapt the design of the study for implementation in the children's emergency department. HJ is a paediatric emergency physician who brings expertise in the study of non-pharmacological interventions in children. TB is a researcher with expertise in psychology and robotics. TB, SDS, SC and HJ assisted with the study design and protocol revision. LH is the Director of the Alberta Research Centre for Health Evidence (Edmonton, Canada). She codeveloped the study design, assisted in drafting the protocol and provided expertise in clinical trial methodology and statistical analyses.

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Competing interests TB is the founder of the company RxRobots, makers of the robot that we will be using in our study. However, our team purchased the robot at full price, with a Stollery Children's Hospital Foundation Grant. TB (University of Calgary) will not participate in data collection or statistical analysis.

Patient consent for publication Not required.

Ethics approval University of Alberta's Health Research Ethics Board.

Provenance and peer review Not commissioned; externally peer reviewed.

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