

## **We propose that interaction with a humanoid robot may effectively distract children during IVI thereby reducing their pain and distress” Ali et al (2018).**

### 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.

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Reference:

Ali, S., Sivakumar, M., Beran, T., Scott, S.D., Vandermeer, B., Curtis, S., Jou, H. and Hartling, L. (2018) Study protocol for a randomised controlled trial of humanoid robot-based distraction for venipuncture pain in children. *BMJ Open*. 8(12), p.e023366.

doi: 10.1136/bmjopen-2018-023366.