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A randomized controlled trial of virtual reality-based distraction for venipuncture-related distress in children

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Complete List of Authors:	Ali, Samina; University of Alberta, Pediatrics Rajagopal, Manasi; University of Alberta, Pediatrics Stinson, Jennifer; Toronto SickKids Ma, Keon; University of Calgary Cumming School of Medicine, Pediatrics Vandermeer, Ben; University of Alberta, Pediatrics Felkar, Bailey; London Health Sciences Centre, Pediatrics Schreiner, Kurt; University of Alberta, Pediatric Parents' Advisory Group Proctor, Amanda; Alberta Health Services Plume, Jennifer; Alberta Health Services Hartling, Lisa; University of Alberta, Pediatrics
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Title: A randomized controlled trial of virtual reality-based distraction for venipuncture-related distress in children

Lay Title: Virtual Reality Based Distraction for Painful Procedures in Children

Authorship: Samina Ali MDCM[1,2,*], Manasi Rajagopal MBT[1], Jennifer Stinson[3], Keon Ma MD[4], Ben Vandermeer MSc[5], Bailey Felkar MS CCLS[6], Kurt Schreiner MPM[7], Amanda Proctor[8], Jennifer Plume BM, MA MTA[9], Lisa Hartling PhD[1,5]

1 Department of Pediatrics, Faculty of Medicine & Dentistry, University of Alberta, Edmonton, Alberta, Canada
2 Women & Children's Health Research Institute, University of Alberta, Edmonton, Alberta, Canada
3 Child Health Evaluative Sciences, Research Institute, The Hospital for Sick Children and the Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada
4 Department of Pediatrics, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada
5 Alberta Research Centre for Health Evidence, Department of Pediatrics, University of Alberta, Edmonton, Alberta, Canada
6 London Health Sciences Centre Children's Hospital, London, Ontario, Canada
7 Pediatric Parents' Advisory Group, University of Alberta, Edmonton, Canada
8 Stollery Youth Advisory Council and Patient and Family Centred Care, Edmonton, Alberta, Canada
9 Stollery Children's Hospital, Edmonton, Alberta, Canada

*denotes corresponding author, and contact for public and scientific inquiries
3-583 Edmonton Clinic Health Academy
11405 – 87 Avenue
Edmonton, AB T6G 1C9
Phone: (780) 248-5574
Fax: (888) 775-8876
Email: sali@ualberta.ca
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ABSTRACT

Introduction. Intravenous (IV) insertions are among the most commonly performed procedures for children seeking medical care; they are often a painful and stressful experience for both children and their caregivers. Pediatric distress and pain that is inadequately treated may lead to a frightened and uncooperative child, repeated IV attempts and overall frustration with care for both the family and clinical team. We hypothesize that distraction via an immersive virtual reality (VR) experience may reduce the associated distress for children undergoing IV insertions.

Methods and analysis.
This two-armed randomized controlled superiority trial will be conducted in a Canadian pediatric emergency department and will aim to enroll 80 children overall. Children will be randomized to receive either departmental standard of care alone or standard of care plus an immersive VR experience. Children 6 to 17 years of age who are undergoing IV insertion and have topical anesthetic application will be considered for inclusion. Our primary objective is to compare the reduction of distress between the two study arms. The primary outcome will be the child's observed distress score as measured by the Observational Signs of Behavioral Distress-Revised (OSBD-R) tool. Secondary outcomes include the child's pain intensity and fear, parental anxiety, satisfaction with the IV procedure, as well as adverse events. Recruitment launched in September 2020 and is expected to end in January 2022.

Ethics and dissemination. This study has been approved by the Health Research Ethics Board (University of Alberta). Informed consent will be obtained from parents or guardians, and assent from children. Study data will be submitted for publication irrespective of results. This study is funded through a Women and Children's Health Research Institute Innovation grant. Purchase of the VR equipment was facilitated through a Stollery Children's Hospital Foundation small equipment grant.

Trial registration number: NCT04291404, First registered March 02, 2020

Words: 300/ 300

Article Summary

Strengths and limitations of this study

1. This randomized controlled trial will assess the effectiveness of immersive virtual reality-based distraction for the reduction of IV insertion-related distress in children.
2. This study measures patient- and family-relevant outcomes including child distress, pain, fear and safety as well as parental anxiety and satisfaction.
3. The study team includes parent and patient partners as co-investigators who will inform study methods and outcomes.
4. The study intervention will be compared to current standard of care; however since there is no consistent standard of care distraction practice, this may create some heterogeneity in the comparison arm of the study.
5. Given the nature of the study intervention, it is not possible to blind patients, parents/caregivers, health care providers, or outcome assessors; the statistician will be blinded to study arms.

INTRODUCTION

Needle procedures, including venipuncture and intravenous (IV) placement, are described by children as some of the most distressing and painful parts of their healthcare visit. [1-5] Untreated distress and pain can lead to a scared and uncooperative child, a need for repeated IV attempts, reduced efficiency and overall dissatisfaction with care for the patient, family and the health care team. [4, 6, 7] Unpleasant medical encounters in childhood can also shape an individual's perception of healthcare and expectations of pain in adulthood. [4, 8-10] This can result in increased anticipatory anxiety and pain for future medical procedures or an avoidance of healthcare services, altogether. [1] As needle procedures form a routine and necessary part of care in the emergency department (ED) [11], it is an important responsibility of health care providers to adequately manage children's distress and pain, wherever possible.[12]

The recommended and responsible approach to managing children's procedural pain incorporates physical, psychological, and pharmacological components. [13-16] While pharmacological interventions such as topical anesthetic creams are available, their effectiveness is limited to *pain*, as they do not address procedure-related *distress and anxiety*. [13] Distraction therapy is a commonly employed psychological strategy which involves engaging children in a cognitive task or activity in order to divert attention away from nociceptive stimuli. [17] An effective distractor provides sensory stimulation and is highly engaging and age-appropriate in order to fully capture the attention of a child. [11] Previous research has indicated that children who use distraction as an active form of coping experience reduced pain and distress during painful procedures. [11, 18, 19] Traditional distraction techniques such as music, video, stories, imagery and focused breathing have been previously explored for children undergoing unpleasant medical procedures and demonstrated mixed results. [20-25] Our team's recently conducted systematic review of digital technologies has suggested that digital distraction techniques appear promising, but require further study to confirm their utility for painful procedures. [26]

Virtual Reality (VR) technology is rapidly emerging as a novel distraction tool for children undergoing various medical procedures. Unlike traditional distraction techniques, VR uses a combination of visual, auditory and tactile stimuli to create the illusion of being fully immersed in an artificial three-dimensional environment. [27] A Head Mounted Display (or 'VR goggles') delivers the VR video and audio to the child, and also serves to block out the view and sounds of the hospital room. [13] This further removes the patient from the chaos of the treatment room and diverts their attention away from surrounding painful and anxiety-evoking stimuli. To date, VR distraction therapy has shown promise for patients undergoing a range of distressing healthcare procedures, including burn wound cleaning, chest radiography, dental interventions and chemotherapy. [28-33] Therapeutic VR has also led to improved health outcomes for patients with anxiety disorders, phobias, post-traumatic stress disorder, and eating disorders. [34-37]

Due to the chaotic, noisy and unpredictable environment of the ED, it is an ideal place to 'stress-test' the ability of VR technology to immerse a child into a distracting and 'safe' space while having a medical procedure. Rapid advances in VR technology over the last few years, and improved cost-effectiveness, offers a unique opportunity to explore its use in the ED setting. While recently published studies from the ED setting suggest that there is a positive impact when VR is used for IV insertion in children, [11, 13] recent systematic reviews have concluded that the current evidence is inconclusive. [38] Furthermore, outcomes such as distress and adverse effects remain poorly studied. [38] Many previous trials utilize proprietary software designed specifically for medical use which may limit widespread accessibility to all centers. This study will evaluate an "off-the-shelf" device with a range of widely accessible software.

This study will evaluate the effectiveness of a VR intervention in reducing IV placement-related distress for children 6-17 years old presenting to the ED. We hypothesize that the use of immersive VR distraction will reduce children's IV related distress when compared with standard of care, and will improve overall satisfaction with the procedure for the patient, family and the health care team.

METHODS AND ANALYSIS

This study is a two-armed, randomized, controlled superiority trial. The study protocol is reported using the SPIRIT-PRO reporting guidelines. [39] (See Table 1.)

Table 1. WHO Trial Registration Data Set

Data Category	Information
Primary Registry and Trial Identifying Number	clinicaltrials.gov NCT04291404
Date of Registration in Primary Registry	March 2, 2020
Secondary Identifying Numbers	University of Alberta Research Ethics Board # Pro00095418
Source(s) of Monetary or Material Support	Stollery Children's Hospital Foundation and the Women and Children Health Research Institute Innovation Grant
Primary Sponsor	University of Alberta
Secondary Sponsor(s)	-
Contact for Public Queries	Dr. Samina Ali 780.248.5575 sali@ualberta.ca
Contact for Scientific Queries	Dr. Samina Ali 780.248.5575 sali@ualberta.ca
Public Title	The Virtual Reality Trial
Scientific Title	A randomized controlled trial of virtual reality-based distraction for venipuncture-related distress in children
Countries of Recruitment	Canada
Health Condition(s) or Problem(s) Studied	Venipuncture-related distress
Intervention(s)	Addition of distraction via an immersive virtual reality experience to departmental standard of care during the intravenous (IV) insertion procedure
Key Inclusion and Exclusion Criteria	To be eligible to participate in this study, an individual must meet all of the following inclusion criteria: **(a)** child aged 6–17 years; **(b)** requires IV placement; and **(c)** will receive topical anesthetic cream for IV placement. Children meeting any of the following criteria will be excluded: **(a)** medically unstable; **(b)** unconscious or not fully alert; **(c)** visual, auditory cognitive, or mental health issues precluding safe interaction with the VR intervention; **(d)** conditions that could be exacerbated by the VR environment, such as *current* symptomatic nausea / vomiting / dizziness/migraine, or a *history* of psychosis/hallucinations/epilepsy; **(e)** presence of an infection/injury which could contaminate the VR intervention equipment such as open wounds/ infections of the head and neck area, or suspected/confirmed methicillin-resistant *Staphylococcus aureus* colonization; **(f)** screens positive for 'influenza-like illness' as per departmental screening criteria; **(g)** language barrier precluding the ability to understand and complete study assessments,

	in the absence of a native language translator; or **(h)** previous enrollment in this study.
Study Type	Randomized Controlled Superiority Trial
Date of First Enrollment	October 5, 2020
Sample Size	80
Recruitment Status	Actively recruiting
Primary Outcome(s)	The primary outcome will be the child's total observed distress score during the IV procedure as measured on the Observational Signs of Behavioral Distress-Revised (OSBD-R) tool.
Key Secondary Outcomes	Secondary outcomes include: **(a)** the child's self-reported pain score during the IV procedure, using an 11-point 0-10 verbal Numerical Rating Scale (vNRS); **(b)** the child's self-reported fear score during the IV insertion as measured by the Children's Fear Scale (CFS); **(c)** parental/caregiver anxiety associated with the procedure, as assessed by the State Trait Anxiety Inventory - State Trait Revised Version (STAI-S, Form Y); **(d)** satisfaction with the procedure for the child, their parent/caregiver and the nurse inserting the IV, as assessed by a 5-point Likert scale; and **(e)** the proportion of children who experience adverse events related to the study intervention.
Ethics Review	University of Alberta Research Ethics Board # Pro00095418
Completion date	-
Summary Results	-
IPD sharing statement	De-identified data can be shared, on a case-by-case basis, upon discussion with the principal investigator.

Setting and Study Period

This study will be conducted in the Stollery Children's Hospital (SCH) emergency department in Edmonton, Alberta, Canada. The SCH is a tertiary care hospital whose annual ED census is typically approximately 60,000. The 2020 ED census for the SCH was reduced to 36,899 due to the COVID-19 pandemic. Study recruitment commenced on September 28, 2020. Based on our team's previous experience conducting research in this setting, and considering the ongoing pandemic-related considerations, we anticipate 18 months of recruitment to meet our overall target of 80 patients.

Eligibility and Exclusion Criteria

Children will be eligible if they are 6 to 17 years, require an IV placement during their ED visit, and have received topical anesthetic cream for their IV placement. This age group was chosen as they are able to reliably self-report pain and are expected to benefit from the virtual reality study intervention, based on prior studies. [40] Due to ethical and pragmatic considerations, we insisted that children must be receiving topical anesthetic cream for IV placement to be eligible for our study, as it is effective and considered standard of care within our hospital. [14] Exclusion criteria are detailed in Table 1.

Study Intervention and Comparison

The intervention will include the use of an immersive VR application that will engage children for the duration of the IV procedure. The VR intervention will be provided *in addition to* standard of care. The child will wear the VR goggles (Oculus Quest, Oculus, Facebook Technologies, LLC; see Figure 1) and small handheld controllers (optional) can be used to interact with the virtual environment and change settings. The VR goggles will occlude the patient's view of the treatment room, and a pair of noise-cancelling headphones (optional) can be used to block out ambient hospital sounds. Together, this will provide the child with a unique vivid experience of being fully immersed or "present" inside the 3D virtual world. The child will be presented with one of two VR menu options, one for novice users and another for more experienced users. The menus will have pre-selected VR applications that are suitable for use during the IV procedure and will include a combination of interactive games and immersive 3D movies designed specifically for a virtual reality experience (see Figure 2). The choice of applications was based on consultation with the Stollery Children's Hospital Youth Advisory Committee prior to commencing the study. The shortlisted applications were then tested by the principal investigators, other team members, and youth. The research assistant (RA), who will be trained in proper equipment use and trouble-shooting, will help the child with selecting and running the VR game/movie. Based on child and nursing preference, children may either sit up or lie in a supine position for the duration of the procedure. The chosen VR games will not require the child to move their torso or both arms, so as to not interfere with the IV placement. The VR goggles can be removed at any time during the procedure, if the child so desires.

The control group will receive departmental standard of care which will include topical anesthetic cream (mandatory for inclusion in the study) and may include parent/caregiver support, child life services, nursing support, and other support strategies at the discretion of the ED clinical care team and the family. At present, there is no single established

distraction therapy or routine that is consistently employed for IV procedures within our ED. Thus, for pragmatic and ethical considerations, it is felt that the new study VR intervention should be compared to what is currently already in practice (i.e. standard of care). Generally, VR technology is not employed by the nursing staff for distracting the child. However, other forms of technology (i.e., smart phones, tablets) will *not* be prohibited in the control group if the family chooses to offer them. Use of other devices and distraction techniques will be documented.

Randomization, Allocation Concealment, and Blinding

Randomization will be determined using an online randomization tool hosted on the REDCap [42] (Research Electronic Data Capture) platform. Following documentation of informed consent and assent, the RA will obtain the computer-generated randomized assignment for the child by clicking on the 'Randomize' button within the study-specific REDCap case report form. Allocation will be concealed from the research staff, ED clinical staff and the family until this point. However, due to the nature of the intervention, it is not possible to maintain blinding once the child has been randomized.

Children and their parents/caregivers will be informed that the study will evaluate and compare different forms of distraction, however they will not be made aware of the study hypothesis for the VR intervention. [7] Furthermore, the statistician will be blinded to treatment assignment by using randomization codes until data analysis is complete.

Recruitment and Data Collection

Participant recruitment will occur in the SCH ED when RAs are on-site, from approximately 15:00 to 23:00 daily. Based on our team's previous research, this time frame corresponds with peak ED volume. RAs will screen the electronic ED track board and communicate with on-site clinical staff to identify potentially eligible patients. The RA will then further assess eligibility based on the inclusion/exclusion criteria detailed above. If the child is deemed eligible and the family is willing to participate, the RA will obtain written informed consent from the parent/ caregiver and assent from the child (See Appendix 1). One parent/caregiver for each child will be asked to provide consent and complete all relevant study questionnaires.

Prior to the beginning of the IV procedure, the RA will collect baseline information, including: baseline heart rate, pre-procedure distress, fear, and pain scores from the child, and pre-procedure anxiety score from the parent/caregiver. The RA will then access the randomization tool on REDCap to reveal the child's group assignment (VR intervention or Control).

For the VR intervention group, the RA will set up the VR equipment and spend approximately 5-10 minutes explaining the intervention to the child, including proper use of the goggles and controller. The RA will then help the child put on and secure the goggles and headphones, and hand them the controller. They will document the time required for equipment set up as well as any technical challenges encountered. As per hospital infection control policy, all VR equipment including the goggles, headphones

and controller will be sanitized with disinfectant wipes between participants. A disposable one-time use cover will be placed on the goggles for each participant. For all participants (both study arms), the RA will begin video recording the child five minutes prior to the start of the procedure and continue until 5 minutes post-procedure, to allow for complete coding of OSBD-R distress scores at a later time.

For all participants (both study arms), the staff nurse will insert the IV following institutional protocol. In keeping with the pragmatic design of the trial, no additional or study-specific instructions will be provided to either nurses or parents/caregivers regarding their behaviour during the procedure. For purposes of the study, the start of the IV insertion procedure will be marked by the cleaning of the IV site by the staff nurse. The end of the procedure will be defined by the last point of contact by the staff nurse (i.e., taping cannula in place with or without arm board, wrapping arm with gauze and taping the gauze in place).

During the procedure, the RA will closely monitor the child for any adverse effects. The child will also be asked to let the team know immediately if they are experiencing any adverse events or discomfort related to the VR intervention (i.e., dizziness, nausea, headache). The VR intervention can be discontinued (i.e., the headset can be removed) at any time, at the discretion of the child or clinical team. If an adverse event were to occur, the clinical team will be notified, and details will be logged in the REDCap adverse event log. Additionally, the RA will make a note of any technical failures or issues associated with the VR equipment during enrollment.

Immediately following the first *attempt* at IV placement (regardless of whether it was successful), the RA will collect post-procedure distress, fear and pain scores from the child, and post-procedure anxiety score from the parent/caregiver. A few minutes after completion of the IV placement, satisfaction and acceptability questionnaires will be completed with the child, parent /caregiver as well as the staff nurse responsible for inserting the IV. Five minutes after the procedure is completed, the RA will stop the video recording. The duration of the procedure and total number of IV attempts will be documented. If the first attempt at placement is unsuccessful, any additional attempts will occur after all relevant study questionnaires/measurements have been completed.

Demographic information, previous history and visit details will also be collected from the family and the child's medical chart. See Figure 3 for study flow schematic.

Outcome Measures

Our primary outcome is **distress**. Our secondary outcomes are **(a)** pain; **(b)** fear; **(c)** the parental/caregiver anxiety; and **(d)** parental/caregiver and nurse satisfaction with the procedure in the intervention; and **(e)** safety.

Our primary outcome measure will be the child's total distress score during the IV procedure. Distress associated with the procedure will be assessed using the

Observational Scale of Behavioral Distress-Revised (OSBD-R). The OSBD-R is a validated scale that is widely used to measure pain and distress associated with various medical procedures in children. [43-45] The tool assesses eight specific behaviors that are indicative of distress and are weighted according to intensity: information seeking, crying, screaming, restraint, verbal resistance, emotional support, verbal pain, and flailing. Study participants will be videotaped for the duration of the IV procedure as well as for a few minutes before and after; distress will be scored pre-, during, and post-procedure. Two RAs who are trained in the use of the tool will independently observe the videotapes and record the frequency of each of the eight behaviors during continuous 15-second intervals. To ensure high inter-rater reliability, the first 10% of coded videos will be analyzed for inter-rater reliability and RAs will be provided with feedback and re-training, as needed, prior to coding the remaining videos. [7] The mean OSBD-R scores between the two RAs will be used as the final scores. This standardized procedure for OSBD-R has been successfully used in previous research evaluating distraction. [30, 43, 46-49] This scale demonstrates high inter-rater reliability as well as moderate to high correlations with other behavioral measures of distress. [46, 50, 51]

Our principal secondary outcome measure will be the child's pain score during the IV procedure. Pain will be measured using an 11-point verbal Numerical Rating Scale (vNRS) ranging from 0 (no pain) to 10 (worst possible pain). This scale is a commonly used pain measurement tool in pediatric acute pain studies and is validated for use in children 6-17 years of age. [52-55] Pain scores will be self-reported by children both before and immediately following the IV procedure.

Fear will be measured using the Children's Fear Scale (CFS) [5, 56]. This scale depicts five faces representing increasing levels of anxiety, where the left-most face depicts "not scared at all" (score=0) and the right most-face means "most scared possible" (score=4). The CFS is an adaptation of the adult Faces Anxiety Scale [56] and has been validated to measure fear in children undergoing painful medical procedures. [5] Children will be asked to independently rate their fear both before and immediately following the IV procedure.

Parental/Caregiver anxiety will be measured with the State Trait Anxiety Inventory – State Scale Revised Version (STAI-S, Form Y), a validated and commonly used version of STAI, which has improved psychometric properties. [57] Parents/caregivers will be asked to complete the STAI questionnaire both before and immediately following the IV procedure.

Parent/caregiver and nurse satisfaction with the procedure will be measured using a 5-point Likert scale, ranging from 1 "Very dissatisfied" to 5 "Very satisfied". Child satisfaction with the procedure will be measured using a 5-point Likert scale, ranging from 1 "Not at all happy" to 5 "Very happy". Satisfaction scores will be collected immediately following the IV procedure.

Safety of the VR intervention will be determined by assessing the frequency of adverse events post intervention. Specifically, nausea will be self-rated by children immediately following the intervention, using the Baxter Retching Faces (BARF) scale [58]. This scale consists of 6 faces depicting increasing levels of nausea, with assigned scores ranging from 0 to 10. The BARF scale is widely used in medical research and has demonstrated construct, content and convergent validity as a tool to measure nausea in children. The presence of other adverse events (i.e., dizziness) will also be recorded by the RA. Children who are presenting with nausea, vomiting, dizziness or migraines *prior* to enrollment will be excluded from the study to avoid exacerbating these conditions with the use of the VR equipment.

Sample Size

The sample size for the study is 80 patients overall. Sample size calculations were conducted using a two-tailed, two-sample Mann-Whitney test for the primary outcome of observed behavioral distress based on data from the team's previous trial of digital distraction. To detect a large effect size of 0.6 on the OSBD-R (which was observed in a previous trial), given a Type I error of 0.05 and 80% power, the study will require 35 patients for each of the two study arms. To account for attrition and technical recording failures, the team will plan to over-recruit by 10-15%, for an overall total of 80 patients. This will allow sufficient power to find a difference in the primary outcome, if a difference truly exists.

Statistical Methods

Statistical analyses will be conducted using statistical software SAS (version 9; SAS Institute, Cary, NC). The significance level will be set at 0.05. Baseline variables will be described using appropriate summary statistics for each group. Imbalances between groups for key baseline variables will indicate the need for further adjusted analyses. For the primary outcome of observed behavioral distress, total OSBD-R 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 (the Sidak correction procedure will be used to reduce the probability of a Type I error). Additional model-based analyses (multiple linear regression) will be conducted, as needed, with behavioural distress as the response variable, pre-procedure behavioral distress and group indicators as the explanatory variables along with some possible effect modifiers such as age, sex, and parental/caregiver anxiety levels. Our primary analysis will be based on an intention-to-treat approach where all children who were randomly assigned to a study group will be included in the group to which they were randomized. Where cell sizes are small or data are sparse or 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 if appropriate.

Patient and Public Involvement

The team's parent advisor (KS) has provided ongoing input on the study protocol and design, and has provided valuable feedback on the content, flow and readability of the consent forms and data collection forms. The Stollery Youth Advisory Council, led by team member AP, provided input on the study design, outcomes measures, and types of

virtual reality applications that might be engaging and practical for our study population. AP also reviewed the study protocol and related documents to ensure that the outcomes and tools were patient-relevant and age-appropriate. Following recruitment completion, parent and youth advisors will be further engaged to discuss study results and dissemination plans in the context of patient- and family-centered care.

Data Management and Confidentiality

Data will be entered into a secure online REDCap [42] database hosted by the Women and Children's Health Research Institute (WCHRI). (See Appendix 2 for Case Report Form.) WCHRI's REDCap installation is a validated electronic, web-based data capture system housed in a secure data center at the University of Alberta. Data is entered into REDCap through a web-based interface using 128-bit SSL encryption. Each team member will be granted an individual username/ password and will require additional two factor authentication to log in. All datasets used for statistical analysis will be encrypted and devoid of any patient identifiers. For internal data quality control, a secure master list will be maintained to accurately link study IDs to the patient's medical record.

Selected data elements will be validated electronically throughout the recruitment period and any discrepancies will be assigned to team members for timely resolution. REDCap includes internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

Study data will be entered directly into REDCap in real-time via research iPads or, in some cases (i.e., parent/caregiver indicate a preference to complete paper-based questionnaires), responses may be collected on paper first and then transcribed into REDCap by a trained RA. All paper documents (including study questionnaires, consent/assent forms, and the master list) will be stored in a locked cabinet in a secure location that is only accessible to authorized research staff members. Study videos will be stored electronically in a secure institutional shared drive with restricted access to study staff. Videos will be saved according to their study ID only. The centrally compiled dataset will be stored on a secure server and computers at the University of Alberta. Following completion of the study, all data will continue to be kept in a secure location for five years as dictated by the research ethics board.

ETHICS AND DISSEMINATION

This study has received approval from the Health Research Ethics Board (HREB) at the University of Alberta (HREB identifier: Pro00073476). Any amendments to the study protocol or documents will be submitted for HREB review and will receive approval prior to implementation. Significant protocol amendments will also be reflected online on the clinicaltrials.gov study registration. This study has also received operational approval from the SCH ED.

All children will receive the best possible care for their presenting complaint, regardless of whether they choose to participate. It is possible that patients in the VR intervention group may experience nausea, mild motion sickness or dizziness, however these effects

are rare in children and adolescents, ranging from 0-5%. [59, 60] VR applications have been selected appropriately to minimize these discomforts, and children are monitored closely throughout the study for any adverse effects. Children experiencing nausea, vomiting, dizziness or migraine headaches prior to enrollment will be excluded to avoid potential exacerbation. Study participation is unlikely to prolong the ED length of stay. For infection-control purposes, children screening positive for 'influenza-like illness' (as per ED screening criteria) are excluded to prevent potential contamination of the VR equipment.

Due to resource/logistical constraints, study recruitment will be limited to English-speaking families or those with their own interpreter, at a single recruiting center, and during RA shift hours only. Critically ill children requiring immediate IV insertion will also be excluded to avoid delaying medical care. This may limit the generalizability of the study findings. We will not be controlling for the type of distraction used in the standard of care arm, but we will record what was employed. While this may create some heterogeneity in the comparison arm of the study, it will be a pragmatic reflection of clinical reality. Due to the nature of the intervention, blinding is not possible for the participants or the research personnel, though the statistician will be blind to study group.

The study team plans to publish trial results in a high-impact, peer-reviewed journal and present results at national and international meetings; authorship eligibility will be determined by employing the International Committee of Medical Journal Editors' recommended guidelines. [61] Statistical code and dataset can be made available upon request.

Competing Interests None declared.

Patient Consent After assessing eligibility based on the outlined inclusion/exclusion criteria, research assistants will obtain consent from the parents/caregivers (and assent from children older than 6 years) prior to enrolling the child in the study. The research assistant will provide both a verbal and written explanation of the study to the family. The family will be given an opportunity to review the consent/assent forms in private and can ask the research assistant any questions they might have prior to signing the consent/assent forms. The family is free to withdraw at any point during the study.

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AUTHOR CONTRIBUTIONS

Dr. Samina Ali (SA) is a pediatric emergency clinician-researcher and Professor of Pediatrics & Emergency Medicine at the University of Alberta. She co-developed and revised the protocol and co-drafted the protocol paper. She chose the previously validated tools for measuring the primary outcomes.

Manasi Rajagopal (MR) is the program lead for the Pediatric Emergency Medicine research program at the University of Alberta and co-principal investigator of this study. She co-developed the study protocol, co-drafted the protocol paper, and will operationalize the study.

Dr. Jennifer Stinson (JS) is the Mary Jo Haddad Nursing Chair in Child Health at the Hospital for Sick Children's Research Institute and a nurse practitioner in the Department of Anesthesia's chronic pain program at the hospital. She assisted with the study design and protocol revision.

Dr. Keon Ma is a pediatric trainee at the University of Calgary, with expertise in OSBD-R coding. He assisted with the study design and protocol revision.

Ben Vandermeer (BV) led the statistical analysis planning and contributed to protocol revision.

Bailey Felkar (BF) is a child life specialist at the Stollery ED with expertise in managing children's pain and distress in the ED setting. She assisted with the study design and protocol revision.

Kurt Schreiner (KS) is a family partner who has provided input into study outcomes to ensure family-relevant outcomes are chosen and will inform our knowledge translation efforts to the public.

Amanda Proctor (AP) is the coordinator of the Stollery Youth Advisory Council. Together with the council, she informed programming choices for the virtual reality devices and has reviewed the protocol and related documents to ensure that the outcomes and tools are patient-relevant and age-appropriate.

Jennifer Plume (JP) is the acting director for Stollery child life services with expertise in managing children's pain and distress in the ED. She has informed study methods and will aid and support the development of our knowledge translation plan.

Dr. Lisa Hartling (LH) is a Professor in the Department of Pediatrics at the University of Alberta and Director of the Alberta Research Centre for Health Evidence (Edmonton, Canada). She assisted with the study design and drafting the protocol, and provides expertise in clinical trial methodology and statistical analyses.

All authors have approved this final version of the protocol. None of the authors have financial or other conflicts of interests as they pertain to this study and its involved recruitment sites.

Figures Legend

Figure 1. Child using virtual reality goggles in the emergency department
Figure 2. Virtual Reality Game Menus
Figure 3. Flow Diagram of Study Procedures

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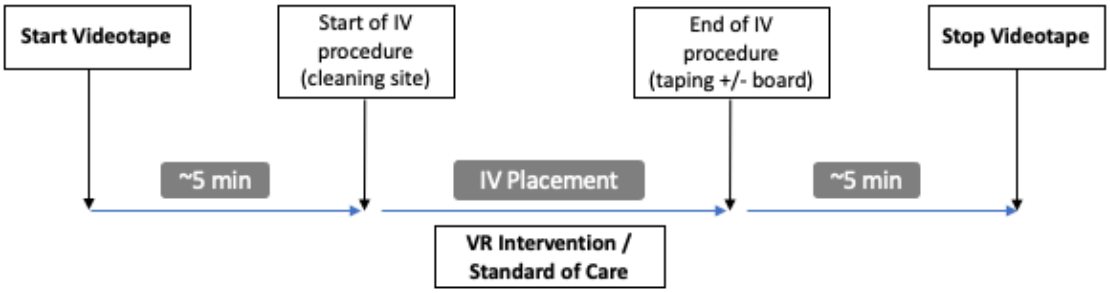
Emergency-UAH
PHILIPS



PRE-Procedure (Baseline)

Child
- Distress score (11-point numerical rating scale)
- Fear score (CFS)
- Pain score (vNRS)
- Baseline HR

Parent
- Anxiety assessment (STAI-S)

POST-Procedure

Child
- Distress score (11-point numerical rating scale)
- Fear score (CFS)
- Pain score (vNRS)
- Nausea rating (BARF)
- Adverse event assessment
- Satisfaction score

Parent
- Anxiety assessment (STAI-S)
- Satisfaction score

Nurse
- Acceptability score
- Satisfaction score

CFS=Children's Fear Scale; vNRS=verbal Numerical Rating Scale; HR=Heart Rate; STAI-S= State Trait Anxiety Inventory – State Scale Revised Version; BARF=Baxter Retching Faces; OSBD-R=Observational Scale of Behavioral Distress-Revised; RA=Research Assistant
Note: OSBD-R coding of videos will be done by RAs post visit

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A randomized controlled trial of virtual reality-based distraction for venipuncture-related distress in children: The VR Study

REB #: Pro00095418	Screening ID	Enrolment Date
PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Pre-Screening

Date and Time of Triage	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Child's Age	_____ years
Child's Sex	☐ Female ☐ Male
Was the family approached for this study?	☐ Yes ☐ No
If NO, specify reason and STOP HERE.	☐ Family refused overall consent to be approached for research ☐ Legal guardian not present ☐ RA busy with another study ☐ Did not meet eligibility criteria, specify _____ ☐ Other, Specify _____
If YES, continue to Eligibility.	

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Eligibility

Was verbal consent for screening obtained from the family? ☐ Yes ☐ No

Inclusion Criteria

1. Child aged 6-17 years	☐ Yes	☐ No
2. Requires IV placement	☐ Yes	☐ No
3. Will receive topical anesthetic cream for IV placement	☐ Yes	☐ No

Exclusion Criteria

1. Medically unstable (i.e. CTAS 1, requires immediate IV insertion)	☐ Yes	☐ No
2. Unconscious or not fully alert	☐ Yes	☐ No
3. Visual, auditory or cognitive or mental health issues precluding safe interaction with the VR intervention	☐ Yes	☐ No
4. Conditions that could be exacerbated by the VR environment (as reported by the family) a. *current* symptomatic nausea / vomiting / dizziness / migraine b. *history* of psychosis / hallucinations / epilepsy	☐ Yes	☐ No
5. Presence of an infection / injury which could contaminate the VR intervention equipment (as determined by the healthcare team) including but not limited to a. open wounds / infections of the head and neck area b. suspected or confirmed methicillin-resistant *Staphylococcus aureus* (MRSA) colonization	☐ Yes	☐ No
6. Screens positive for 'influenza-like illness' (ILI) as per the current SCH ED screening criteria	☐ Yes	☐ No
7. Child or Parental language barrier precluding the ability to understand and complete study assessments, in the absence of a native language translator	☐ Yes	☐ No
8. Previous enrollment (of child OR parent) in this study	☐ Yes	☐ No

Is the family eligible for the study? ☐ Yes ☐ No

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Informed Consent

Has written informed consent been obtained from the **parent/ legal guardian**? ☐ Yes ☐ No

If NO,

Specify reason and STOP HERE.	☐ Declined consent ☐ Declined assent ☐ Other, please specify _____

If YES,

Specify the date and time of Informed Consent:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Has a copy of the signed informed consent been given to the family?	☐ Yes ☐ No; specify: _____
Has written assent been obtained from the **child**?	☐ Yes ☐ No; specify: _____ ☐ No, but verbal assent was obtained and documented ☐ Not required; child < 7y
Has a copy of the signed assent been given to the family?	☐ Yes ☐ No; specify: _____
Has written informed consent been provided by the **clinical nurse**? *Note: Consent only needs to be provided by the clinical nurse once for the entire duration of the study (for all 80-90 participants). If consent has not been previously completed with the clinical nurse, make sure a signed copy is completed before recruitment.*	☐ Yes ☐ No; specify: _____
Clinical Nurse Study ID Number:	_____

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Randomization

If the child satisfies the inclusion/ exclusion criteria and written informed consent has been provided, please RANDOMIZE the participant by clicking on the Randomize button below:

Study Arm	☐ VR Intervention ☐ Standard Care

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Demographics & History

Demographics

Parent/ Caregiver relationship to child	☐ Mother ☐ Father ☐ Other; specify: _____
Parent / Caregiver Age	____ years; or ☐ Prefer not to answer
Parent / Caregiver Sex	☐ Female ☐ Male
Parent / Caregiver Highest level of Education	☐ Elementary School ☐ High School or some High School ☐ Diploma/ Certificate ☐ Some Post-Secondary/ University ☐ University/ Professional Degree ☐ Decline to answer
First three digits of postal code	__ __ __ (1st 3 digits ONLY)
Do you identify your child as a member of an ethnic minority?	☐ Yes ☐ No

Medical History

Was your child born prematurely?	☐ Yes ☐ No
• If yes, at how many weeks gestation?	_____ weeks
Has your child ever been to the Emergency Department before today?	☐ Yes ☐ No
• If yes, how many times:	_____ times
Has your child ever been hospitalized?	☐ Yes ☐ No
• If yes, how many times:	_____ times
Has your child ever had a needle poke in their vein to draw blood or put in an intravenous (IV) line?	☐ Yes ☐ No

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If yes, how distressed was your child during the procedure? *(if more than one occurrence, ask the parent to recall the most recent event)* Choose a number between 1 and 5 that best describes your child's distress where 1 indicates 'no distress at all' and 5 is 'as distressed as possible'	☐ 1 (no distress at all) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (as distressed as possible)

Child Experience with Technology

Has your child played with/ used any of the following devices before to ***play games***?	☐ iPad/ iPod/ iPhone / Tablet *(to play games)* ☐ Gaming console (ex. Xbox, Nintendo, PS4, other) ☐ Virtual Reality (VR) device (ex. Oculus Quest/ Rift, Samsung Gear VR, HTC Vive, PlayStation VR, other) ☐ Robot

If yes, how frequently?

iPad/ iPod/ iPhone / Tablet:	Gaming console	VR device	Robot
☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____	☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____	☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____	☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____

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PRE-Procedure: Child Scores

NOTE: Begin the video recorder (iPad) approximately 5 minutes before the start of the IV procedure, and stop the recording 5 minutes after the end of the procedure.

Baseline Scores: Child

Heart Rate (record from Triage)	____ bpm
Time pre-procedure scores collected	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Pain Score: verbal Numerical Rating Scale (vNRS) "On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"	____ / 10
Distress Score: Numerical Rating Scale "On a scale of 0 to 10, where 0 is no distress and 10 is the most distress you can imagine having, what is your distress level now?"	____ / 10

Fear Score: Children's Fear Scale (CFS)

"These faces are showing different amounts of being scared. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [pint to the last face on the right]. Have a look at these faces and choose the one that shows how scared you are right now."

☐ ☐ ☐ ☐ ☐

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PRE-Procedure: Parent / Caregiver STAI Questionnaire

We would ask that you complete the following questions as they relate to your feelings about your child's upcoming IV procedure, today. A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you feel **right now**, that is, **at this moment**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

1----------2----------3----------4
Not at all Somewhat Moderately so Very much so

1.	I feel calm	1	2	3	4
2.	I feel secure	1	2	3	4
3.	I am tense	1	2	3	4
4.	I feel strained	1	2	3	4
5.	I feel at ease	1	2	3	4
6.	I feel upset	1	2	3	4
7.	I am presently worrying over possible misfortunes	1	2	3	4
8.	I feel satisfied	1	2	3	4
9.	I feel frightened	1	2	3	4
10.	I feel comfortable	1	2	3	4
11.	I feel self-confident	1	2	3	4
12.	I feel nervous	1	2	3	4
13.	I am jittery	1	2	3	4
14.	I feel indecisive	1	2	3	4
15.	I am relaxed	1	2	3	4
16.	I feel content	1	2	3	4
17.	I am worried	1	2	3	4
18.	I feel confused	1	2	3	4
19.	I feel steady	1	2	3	4
20.	I feel pleasant	1	2	3	4

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DURING-Procedure

- Start the iPad video recording approximately 5 minutes prior to the start of the procedure.
- For children randomized to the VR group: Immediately after PRE-procedure scores and STAI are completed, research assistant will set up the VR equipment.
- The staff ED nurse will then begin the IV set-up

Start time of IV procedure: *(Defined as the time the staff nurse begins to clean the IV site)*	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
End time of IV procedure/ attempt: *(Defined as the last point of contact by the staff nurse (ex. taping cannula in place with or without arm board, wrapping arm with gauze and taping the gauze in place)*	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)

Position of Child during IV attempt:	☐ Sitting up ☐ Lying down (supine)
Location of first IV attempt:	☐ Antecubital Fossa – RIGHT ☐ Antecubital Fossa – RIGHT ☐ Dorsum hand – RIGHT ☐ Dorsum hand – LEFT ☐ Other, specify _____
Was the first IV placement attempt successful?	☐ Yes ☐ No
• If NO, how many attempts, in total, were made for the IV during this 'episode'?	_____ attempts
• Was an IV successfully placed during this 'episode'?	☐ Yes ☐ No

Any adverse events or side effects? *Do not suggest any AEs to the participant; Instead, ask more general questions such as "how are you feeling?" or "are you having any side effects?" or "are you feeling any different than before?", and let the child answer spontaneously.*	☐ Yes ☐ No If "**YES**", complete a separate entry for each AE on the AE Form

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

IMMEDIATELY POST-Procedure: Child Scores

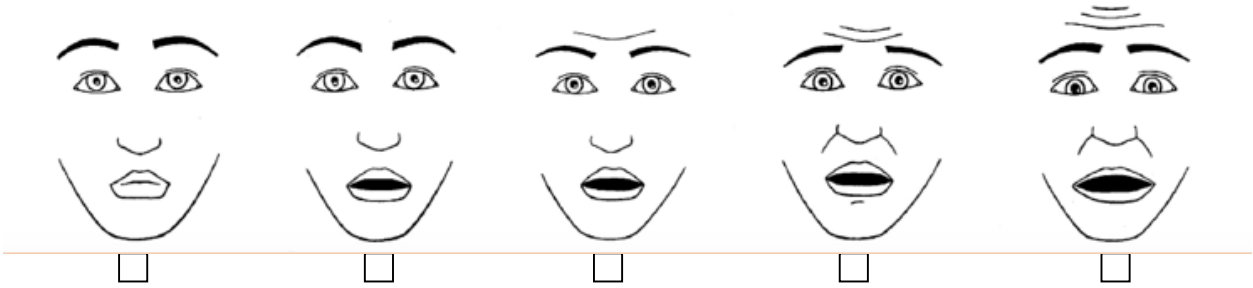
NOTE: Post-procedure scores/ questionnaires should be collected as soon as possible after the procedure is complete:

Post-procedure Scores: Child

Time post-procedure scores collected	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Pain Score: verbal Numerical Rating Scale (vNRS) - Procedure "On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what was your pain level during the needle / IV poke?"	____ / 10
Distress Score: Numerical Rating Scale - Procedure "On a scale of 0 to 10, where 0 is no distress and 10 is the most distress you can imagine having, what was your distress level during the needle / IV poke"	____ / 10

Fear Score: Children's Fear Scale (CFS) - Procedure

"These faces are showing different amounts of being scared. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [pint to the last face on the right]. Have a look at these faces and choose the one that shows how scared you were during the needle / IV poke."



Nausea Score: Baxter Retching Faces (BARF) Scale - Procedure

"Have you thrown up or felt like you were going to throw up before? How did your tummy feel then? We call that feeling of being sick to the stomach nausea. These faces show children who feel no nausea at all, who feel a little bit nauseated, who feel even more nauseated, and these are children who have the most nausea it is possible to feel." [Point to each face at the appropriate time.] "Which face is more like how you felt during the needle / IV poke?"

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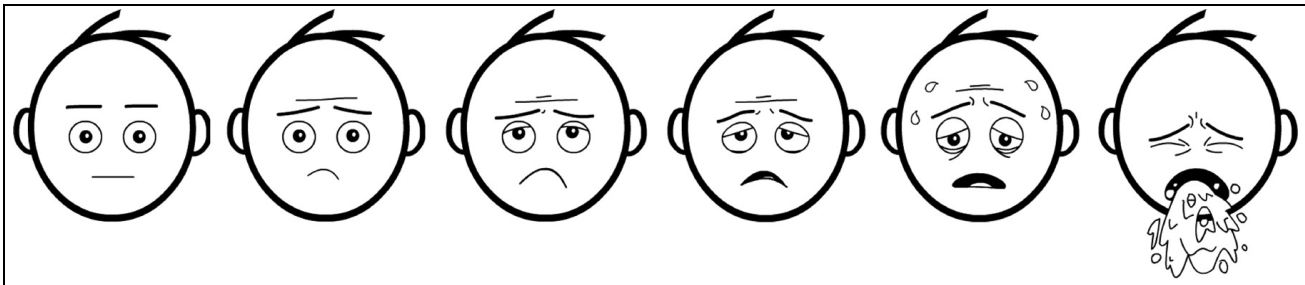

☐ ☐ ☐ ☐ ☐ ☐

Overall, how happy were you with the IV start today, on a scale of 1 to 5, where 1 means "Not at all happy" and 5 means "Very happy"?	☐ 1 "Not at all happy ☐ 2 ☐ 3 ☐ 4 ☐ 5 "Very happy"
On a scale of 1 to 5, where 1 means "Not at all happy" and 5 means "Very happy", how happy were you with the pain treatment for your IV start?	☐ 1 "Not at all happy" ☐ 2 ☐ 3 ☐ 4 ☐ 5 "Very happy"
Did the [distraction / toys / VR goggles] help you today?	☐ Yes, it helped ☐ No, it didn't help ☐ I'm not sure
If you ever had to get an IV or needle poke again, would you want to use the same [distraction / toys / VR goggles] again?	☐ Yes, I would ☐ No, I wouldn't ☐ I'm not sure
Can you tell me why/ why not?	

As soon as possible after completion of procedure, research assistant to give:

1. Post-Procedure Parent STAI and Satisfaction Questionnaire to parent/ caregiver
2. Nurse Satisfaction Questionnaire to staff ED nurse

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

POST-Procedure: Parent / Caregiver STAI Questionnaire

We would ask that you complete the following questions as they relate to your feelings about your child's IV procedure that just happened. A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you feel **right now**, that is, **at this moment**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

1----------2----------3----------4
Not at all Somewhat Moderately so Very much so

1.	I feel calm	1	2	3	4
2.	I feel secure	1	2	3	4
3.	I am tense	1	2	3	4
4.	I feel strained	1	2	3	4
5.	I feel at ease	1	2	3	4
6.	I feel upset	1	2	3	4
7.	I am presently worrying over possible misfortunes	1	2	3	4
8.	I feel satisfied	1	2	3	4
9.	I feel frightened	1	2	3	4
10.	I feel comfortable	1	2	3	4
11.	I feel self-confident	1	2	3	4
12.	I feel nervous	1	2	3	4
13.	I am jittery	1	2	3	4
14.	I feel indecisive	1	2	3	4
15.	I am relaxed	1	2	3	4
16.	I feel content	1	2	3	4
17.	I am worried	1	2	3	4
18.	I feel confused	1	2	3	4
19.	I feel steady	1	2	3	4
20.	I feel pleasant	1	2	3	4

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POST-Procedure: Caregiver Satisfaction Questionnaire

1) Please rate your overall satisfaction with your child's IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

Please Explain: _____

2) Please rate your satisfaction with the management of your child's pain for their IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

Please Explain: _____

3) Would you use the same methods to manage your child's pain from needle pokes in the future?

☐ Yes
☐ No

Why / Why not? _____

Thank you for your participation in our research study, it is very much appreciated!

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ (dd / mmm / yyyy)

Nurse Satisfaction Questionnaire (VR Group)

1) Overall, how easy or difficult was it to perform the IV insertion for this child?

Very Easy	*Easy*	*Neutral*	*Difficult*	*Very Difficult*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

2) Please rate your satisfaction with this child's IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

3) Would you use the same methods (ie. VR device) to manage another child's pain and distress from IV insertion in the future?
- ☐ Yes
- ☐ No

4) Could you please rate the following on a scale of 1-5, where 1= Not at all and 5=Very much

	1	2	3	4	5
Your overall satisfaction with the Virtual Reality (VR) device today	☐	☐	☐	☐	☐
Your willingness to use the VR device to manage another child's IV pain and distress in the future	☐	☐	☐	☐	☐
The degree to which the VR device improved the child's experience	☐	☐	☐	☐	☐
The degree to which the VR **improved** your ability to insert the IV	☐	☐	☐	☐	☐
The degree to which the VR **disrupted** your ability to insert the IV	☐	☐	☐	☐	☐

5) Did the VR device that was used during the procedure increase the time required to insert the IV?
- ☐ Yes (approximately how much time did it increase the procedure by? _____ minutes)
- ☐ No

6) Is there anything else that you would like to tell us, today, about your experience inserting an IV for a child using a VR device?

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

7) How many years of practice do you have as a nurse (all settings)? _____ ☐ N/A

8) How many years of practice do you have as a nurse in the ED? _____ ☐ N/A

9) Please indicate the amount of time spent in the pediatric emergency department (PED):

- ☐ 0-25% of my time is spent in the pediatric ED
- ☐ 26-50% of my time is spent in the pediatric ED
- ☐ 51-75% of my time is spent in the pediatric ED
- ☐ 76-100% of my time is spent in the pediatric ED

10) Please specify your position if other than attending ED nurse (e.g., IV nurse, attending ED physician, resident, physician or nurse from other service [specify], etc):

_____

Thank You!!

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REB #: Pro00095418	Screening ID	Enrolment Date
PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Nurse Satisfaction Questionnaire (Standard Care Group)

1) Overall, how easy or difficult was it to perform the IV insertion for this child?

Very Easy	*Easy*	*Neutral*	*Difficult*	*Very Difficult*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

2) Please rate your satisfaction with this child's IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

3) Would you use the same methods (ie. Standard of Care pain management plan) to manage another child's pain and distress from IV insertion in the future?

☐ Yes
☐ No

4) Could you please rate the following on a scale of 1-5, where 1= Not at all and 5=Very much

	1	**2**	**3**	**4**	**5**
Your overall satisfaction with the pain management plan today	☐	☐	☐	☐	☐
Your willingness to use a similar pain management plan to manage another child's IV pain and distress in the future	☐	☐	☐	☐	☐
The degree to which the pain management plan improved the child's experience	☐	☐	☐	☐	☐
The degree to which the pain management plan **improved** your ability to insert the IV	☐	☐	☐	☐	☐
The degree to which the pain management plan **disrupted** your ability to insert the IV	☐	☐	☐	☐	☐

5) Did the Standard of Care pain management plan that was used during the procedure increase the time required to insert the IV?

☐ Yes (approximately how much time did it increase the procedure by? _____ minutes)
☐ No

6) Is there anything else that you would like to tell us, today, about your experience inserting an IV for a child using a Standard of Care pain management plan?

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

7) How many years of practice do you have as a nurse (all settings)? _____ ☐ N/A

8) How many years of practice do you have as a nurse in the ED? _____ ☐ N/A

9) Please indicate the amount of time spent in the pediatric emergency department (PED):

- ☐ 0-25% of my time is spent in the pediatric ED
- ☐ 26-50% of my time is spent in the pediatric ED
- ☐ 51-75% of my time is spent in the pediatric ED
- ☐ 76-100% of my time is spent in the pediatric ED

10) Please specify your position if other than attending ED nurse (e.g., IV nurse, attending ED physician, resident, physician or nurse from other service [specify], etc):

_____

Thank You!!

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Discharge Information

Disposition	☐ Discharged Home ☐ Admitted ☐ Other, _____
Date & Time of Discharge from the ED	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Length of Stay in ED (calculated field):	____ hours
Discharge Diagnosis	

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

RA Satisfaction Questionnaire *(For Standard Care group, answer Q6 ONLY)*

1) Could you please rate the following on a scale of 1-5, where 1= Not at all and 5=Very much

	1	2	3	4	5
Your overall satisfaction with the Virtual Reality (VR) device today	☐	☐	☐	☐	☐
Ease of set-up of the VR device	☐	☐	☐	☐	☐
Your satisfaction with the amount of time it took to set up the VR device	☐	☐	☐	☐	☐
Your desire to work with the VR device again	☐	☐	☐	☐	☐

2) Approximately how much time was needed to set up the VR device with the child, today? (excluding consent and questionnaire time)

_____ minutes

3) What components of the VR device did the child use during the IV procedure? (check all that apply)

- ☐ VR Goggles / Headset
- ☐ Controller
- ☐ Headphones

4) Were the VR Goggles / Headset kept on for the entire duration of the procedure?

- ☐ Yes
- ☐ No

5) What applications / game(s) did the child play during the procedure?

6) What pain management or distraction tools / resources were used during the procedure? (Check all that apply. If a CLS was involved, ask them to clarify which tools were used.)

- ☐ Virtual Reality
- ☐ iPad / Tablet / Smartphone
- ☐ Toys
- ☐ Music
- ☐ Child Life Specialist (CLS)
- ☐ Other; specify: _____
- ☐ No other techniques were used

7) Did you have any technical or other issues with operating / handing the VR equipment?

- ☐ Yes; specify: _____
- ☐ No

8) Is there anything else that you would like to tell us about your experience with the VR googles today?

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Adverse Events Log

To be filled out by Research Assistant						To be filled out by Site Investigator				
No.	**Description of Adverse Event**	**Onset Date & Time** (dd/mmm/ yyyy HH:MM)	**Action Taken** 1. None 2. Medication 3. New or Prolonged Hospitalization 4. Procedure / Surgery 5. Other, specify	**Outcome** 1. Resolved 2. Resolved with Sequelae 3. Resolving 4. Unresolved 5. Fatal 6. Lost to follow-up	**Date & Time Resolved** (dd/mmm/ yyyy HH:MM)	**Intensity grade:** 1. Mild 2. Moderate 3. Severe	**Expected AE?** Y / N	**Relationship to Study** 1. Unrelated 2. Unlikely 3. Possible 4. Probable 5. Definite	**SAE?** Y / N	**Site PI Initial**
1										
2										
3										

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Early Withdrawal

ONLY fill out this form in the event of an early withdrawal

Date of Discontinuation:	_____/_____/_____ dd mmm yyyy
Reasons for Discontinuation: (check all that apply)	☐ Adverse Event / Serious Adverse Event ☐ Death ☐ Withdrawal of Consent / Assent ☐ Protocol Violation, Specify _____ ☐ Other, Specify _____
If withdrew consent / assent: 1. Permission to use collected data? 2. Permission to conduct Chart Review?	 ☐ Yes ☐ No ☐ Yes ☐ No
Comments:	

Reporting checklist for protocol of a clinical trial.

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	5-7 (Table 1)
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	14
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	15
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	5
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or	N/A

		groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7-8
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	9,13

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8-9 and Figure 3
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9 and Appendix 2 for Case Report Form
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9

Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11

Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14-15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	12-13
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Table 1
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in	13

		results databases, or other data sharing arrangements), including any publication restrictions	
3Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15-16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Table 1
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

A study protocol for a randomized controlled trial of virtual reality-based distraction for intravenous insertion-related distress in children

Journal:	*BMJ Open*
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Keywords:	ACCIDENT & EMERGENCY MEDICINE, Pain management < ANAESTHETICS, Paediatric A&E and ambulatory care < PAEDIATRICS, PAIN MANAGEMENT

Title: A study protocol for a randomized controlled trial of virtual reality-based distraction for intravenous insertion-related distress in children

Lay Title: Virtual Reality Based Distraction for Painful Procedures in Children

Authorship: Samina Ali MDCM[1,2,*], Manasi Rajagopal MBT[1], Jennifer Stinson[3], Keon Ma MD[4], Ben Vandermeer MSc[5], Bailey Felkar MS CCLS[6], Kurt Schreiner MPM[7], Amanda Proctor[8], Jennifer Plume BM, MA MTA[9], Lisa Hartling PhD[1,5]

1 Department of Pediatrics, Faculty of Medicine & Dentistry, University of Alberta, Edmonton, Alberta, Canada
2 Women & Children's Health Research Institute, University of Alberta, Edmonton, Alberta, Canada
3 Child Health Evaluative Sciences, Research Institute, The Hospital for Sick Children and the Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada
4 Department of Pediatrics, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada
5 Alberta Research Centre for Health Evidence, Department of Pediatrics, University of Alberta, Edmonton, Alberta, Canada
6 London Health Sciences Centre Children's Hospital, London, Ontario, Canada
7 Pediatric Parents' Advisory Group, University of Alberta, Edmonton, Canada
8 Stollery Youth Advisory Council and Patient and Family Centred Care, Edmonton, Alberta, Canada
9 Stollery Children's Hospital, Edmonton, Alberta, Canada

*denotes corresponding author, and contact for public and scientific inquiries
3-583 Edmonton Clinic Health Academy
11405 – 87 Avenue
Edmonton, AB T6G 1C9
Phone: (780) 248-5574
Fax: (888) 775-8876
Email: sali@ualberta.ca

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ABSTRACT

Introduction. Intravenous (IV) insertions are among the most performed procedures for children seeking medical care; they are often a painful and stressful experience for both children and their caregivers. Pediatric distress and pain that is inadequately treated may lead to a frightened and uncooperative child, repeated IV attempts and overall frustration with care for both the family and clinical team. We hypothesize that distraction via an immersive virtual reality (VR) experience may reduce the associated distress for children undergoing IV insertions.

Methods and analysis.
This two-armed randomized controlled superiority trial will be conducted in a Canadian pediatric emergency department and will aim to enroll 80 children overall. Children will be randomized to receive either departmental standard of care alone or standard of care plus an immersive VR experience. Children 6 to 17 years of age who are undergoing IV insertion and have topical anesthetic application will be considered for inclusion. Our primary objective is to compare the reduction of distress between the two study arms. The primary outcome will be the child's observed distress score as measured by the Observational Signs of Behavioral Distress-Revised (OSBD-R) tool. Secondary outcomes include the child's pain intensity and fear, parental anxiety, satisfaction with the IV procedure, as well as adverse events. Recruitment launched in September 2020 and is expected to end in March 2022.

Ethics and dissemination. This study has been approved by the Health Research Ethics Board (University of Alberta). Informed consent will be obtained from parents or guardians, and assent from children. Study data will be submitted for publication irrespective of results. This study is funded through a Women and Children's Health Research Institute Innovation grant. Purchase of the VR equipment was facilitated through a Stollery Children's Hospital Foundation small equipment grant.

Trial registration number: NCT04291404, First registered March 02, 2020

Words: 299/ 300

Article Summary

Strengths and limitations of this study

1. This randomized controlled trial will assess the effectiveness of immersive virtual reality-based distraction for the reduction of IV insertion-related distress in children.
2. This study measures patient- and family-relevant outcomes including child distress, pain, fear, and safety as well as parental anxiety and satisfaction.
3. The study team includes parent and patient partners as co-investigators who will inform study methods and outcomes.
4. The study intervention will be compared to current standard of care; however, since there is no consistent standard of care distraction practice, this may create some heterogeneity in the comparison arm of the study.
5. Given the nature of the study intervention, it is not possible to blind patients, parents/caregivers, health care providers, or outcome assessors; the statistician will be blinded to study arms.

INTRODUCTION

Needle procedures, including venipuncture and intravenous (IV) placement, are described by children as some of the most distressing and painful parts of their healthcare visit. [1-4] Untreated distress and pain can lead to a scared and uncooperative child, a need for repeated IV attempts, reduced efficiency and overall dissatisfaction with care for the patient, family and the health care team. [3, 5, 6] Unpleasant medical encounters in childhood can also shape an individual's perception of healthcare and expectations of pain in adulthood. [7-9] This can result in increased anticipatory anxiety and pain for future medical procedures or an avoidance of healthcare services, altogether. [1] As needle procedures form a routine and necessary part of care in the emergency department (ED), it is an important responsibility of health care providers to adequately manage children's distress and pain, wherever possible.[10,11]

The recommended and responsible approach to managing children's procedural pain incorporates physical, psychological, and pharmacological components. [10-15] While pharmacological interventions such as topical anesthetic creams are available, their effectiveness is limited to *pain*, as they do not address procedure-related *distress and anxiety*. [10] Distraction therapy is a commonly employed psychological strategy which involves engaging children in a cognitive task or activity to divert attention away from nociceptive stimuli. [16] An effective distractor provides sensory stimulation and is highly engaging and age-appropriate to fully capture the attention of a child. [12,16] Previous research has indicated that children who use distraction as an active form of coping experience reduced pain and distress during painful procedures. [12, 17, 18] Traditional distraction techniques such as music, video, stories, imagery, and focused breathing have been previously explored for children undergoing unpleasant medical procedures and demonstrated mixed results. [19-24] Our team's recently conducted systematic review of digital technologies has suggested that digital distraction techniques appear promising, but require further study to confirm their utility for painful procedures. [25]

Virtual Reality (VR) technology is rapidly emerging as a novel distraction tool for children undergoing various medical procedures. Unlike traditional distraction techniques, VR uses a combination of visual, auditory, and tactile stimuli to create the illusion of being fully immersed in an artificial three-dimensional environment. [26] A Head Mounted Display (or 'VR goggles') delivers the VR video and audio to the child, and serves to block out the view and sounds of the hospital room. [14] This further removes the patient from the chaos of the treatment room and diverts their attention away from surrounding painful and anxiety-evoking stimuli. To date, VR distraction therapy has shown promise for patients undergoing a range of distressing healthcare procedures, including burn wound cleaning, chest radiography, dental interventions, and chemotherapy. [27-32] Therapeutic VR has also led to improved health outcomes for patients with anxiety disorders, phobias, post-traumatic stress disorder, and eating disorders. [33-36]

The ED presents unique challenges when attempting to distract a child during a painful medical procedure. Due to the chaotic, noisy, and unpredictable environment, it is an ideal place to 'stress-test' the ability of VR technology to immerse a child into a distracting and 'safe' space. Rapid advances in VR technology over the last few years, and improved cost-effectiveness, offers a unique opportunity to explore its use in the ED setting. A few recently published studies from the pediatric ED setting suggest that VR has a positive impact on IV insertion-related pain and satisfaction, [12, 14, 37-40] although outcomes such as distress and adverse effects remain poorly studied. [38] Recent systematic reviews, which have mostly focused on non-ED and in-patient settings, have shown that the current evidence is inconclusive, sometimes contradictory, and have called for further research in larger study groups. [41-42] Furthermore many previous trials utilize proprietary software designed specifically for medical use which may limit widespread accessibility to all centers. This study will evaluate an "off-the-shelf" device with a range of widely accessible software.

This study will evaluate the effectiveness of a VR intervention in reducing IV placement-related distress for children 6-17 years old presenting to the ED. We hypothesize that the use of immersive VR distraction will reduce children's IV related distress when compared with standard of care and will improve overall satisfaction with the procedure for the patient, family, and the health care team.

METHODS AND ANALYSIS

This study is a two-armed, randomized, controlled superiority trial. The study protocol is reported using the SPIRIT-PRO reporting guidelines. [43] (See Table 1.)

Table 1. WHO Trial Registration Data Set

Data Category	Information
Primary Registry and Trial Identifying Number	clinicaltrials.gov NCT04291404
Date of Registration in Primary Registry	March 2, 2020
Secondary Identifying Numbers	University of Alberta Research Ethics Board # Pro00095418
Source(s) of Monetary or Material Support	Stollery Children's Hospital Foundation and the Women and Children Health Research Institute Innovation Grant
Primary Sponsor	University of Alberta
Secondary Sponsor(s)	-
Contact for Public Queries	Dr. Samina Ali 780.248.5575 sali@ualberta.ca
Contact for Scientific Queries	Dr. Samina Ali 780.248.5575 sali@ualberta.ca
Public Title	The Virtual Reality Trial
Scientific Title	A randomized controlled trial of virtual reality-based distraction for intravenous insertion-related distress in children
Countries of Recruitment	Canada
Health Condition(s) or Problem(s) Studied	Intravenous insertion-related distress
Intervention(s)	Addition of distraction via an immersive virtual reality experience to departmental standard of care during the intravenous (IV) insertion procedure
Key Inclusion and Exclusion Criteria	To be eligible to participate in this study, an individual must meet all of the following inclusion criteria: **(a)** child aged 6–17 years; **(b)** requires IV placement; and **(c)** will receive topical anesthetic cream for IV placement. Children meeting any of the following criteria will be excluded: **(a)** medically unstable; **(b)** unconscious or not fully alert; **(c)** visual, auditory cognitive, or mental health issues precluding safe interaction with the VR intervention; **(d)** conditions that could be exacerbated by the VR environment, such as *current* symptomatic nausea / vomiting / dizziness/migraine, or a *history* of psychosis/hallucinations/epilepsy; **(e)** presence of an infection/injury which could contaminate the VR intervention equipment such as open wounds/ infections of the head and neck area, or suspected/confirmed methicillin-resistant

	Staphylococcus aureus colonization; **(f)** screens positive for 'influenza-like illness' as per departmental screening criteria; **(g)** language barrier precluding the ability to understand and complete study assessments, in the absence of a native language translator; or **(h)** previous enrollment in this study.
Study Type	Randomized Controlled Superiority Trial
Date of First Enrollment	October 5, 2020
Sample Size	80
Recruitment Status	Actively recruiting
Primary Outcome(s)	The primary outcome will be the child's total observed distress score during the IV procedure as measured on the Observational Signs of Behavioral Distress-Revised (OSBD-R) tool.
Key Secondary Outcomes	Secondary outcomes include: **(a)** the child's self-reported pain score during the IV procedure, using an 11-point 0-10 verbal Numerical Rating Scale (vNRS); **(b)** the child's self-reported fear score during the IV insertion as measured by the Children's Fear Scale (CFS); **(c)** parental/caregiver anxiety associated with the procedure, as assessed by the State Trait Anxiety Inventory - State Trait Revised Version (STAI-S, Form Y); **(d)** satisfaction with the procedure for the child, their parent/caregiver and the nurse inserting the IV, as assessed by a 5-point Likert scale; and **(e)** the proportion of children who experience adverse events related to the study intervention.
Ethics Review	University of Alberta Research Ethics Board # Pro00095418
Completion date	-
Summary Results	-
IPD sharing statement	De-identified data can be shared, on a case-by-case basis, upon discussion with the principal investigator.

Setting and Study Period

This study will be conducted in the Stollery Children's Hospital (SCH) emergency department in Edmonton, Alberta, Canada. The SCH is a tertiary care hospital whose annual ED census is typically approximately 60,000. The 2020 ED census for the SCH was reduced to 36,899 due to the COVID-19 pandemic. Recruitment launched in September 2020 and is expected to end in March 2022. Based on our team's previous experience conducting research in this setting, and considering the ongoing pandemic-related considerations, we anticipate 18 months of recruitment to meet our overall target of 80 patients.

Eligibility and Exclusion Criteria

Children will be eligible if they are 6 to 17 years, require an IV placement during their ED visit, and have received topical anesthetic cream for their IV placement. This age group was chosen as they can reliably self-report pain and are expected to benefit from the virtual reality study intervention, based on prior studies. [44] Due to ethical and pragmatic considerations, we insisted that children must be receiving topical anesthetic cream for IV placement to be eligible for our study, as it is effective and considered standard of care within our hospital. [10] Exclusion criteria are detailed in Table 1.

Study Intervention and Comparison

The intervention will include the use of an immersive VR application that will engage children for the duration of the IV procedure. The VR intervention will be provided *in addition to* standard of care. The child will wear the VR goggles (Oculus Quest, Oculus, Facebook Technologies, LLC; see Figure 1) and small handheld controllers (optional) can be used to interact with the virtual environment and change settings. The VR goggles will occlude the patient's view of the treatment room, and a pair of noise-cancelling headphones (optional) can be used to block out ambient hospital sounds. Together, this will provide the child with a unique vivid experience of being fully immersed or "present" inside the 3D virtual world. The child will be presented with one of two VR menu options, one for novice users and another for more experienced users. The menus will have pre-selected VR applications that are suitable for use during the IV procedure and will include a combination of interactive games and immersive 3D movies designed specifically for a virtual reality experience (see Figure 2). The choice of applications was based on consultation with the Stollery Children's Hospital Youth Advisory Committee prior to commencing the study. The shortlisted applications were then tested by the principal investigators, other team members, and youth. The research assistant (RA), who will be trained in proper equipment use and troubleshooting, will help the child with selecting and running the VR game/movie. Based on child and nursing preference, children may either sit up or lie in a supine position for the duration of the procedure. The chosen VR games will not require the child to move their torso or both arms, to not interfere with the IV placement. The VR goggles can be removed at any time during the procedure if the child so desires. The game/application selected by the child will be recorded on the case report form.

The control group will receive departmental standard of care which will include topical anesthetic cream (mandatory for inclusion in the study) and may include parent/caregiver support, child life services, nursing support, and other support strategies at the discretion of the ED clinical care team and the family. Child life services include pre-procedural education, distraction and coaching, intra-procedural presence, and post-procedural support and prizes. At present, there is no single established distraction therapy or routine that is consistently employed for IV procedures within our ED. Thus, for pragmatic and ethical considerations, it is felt that the new study VR intervention should be compared to what is currently already in practice (i.e., standard of care). Generally, VR technology is not employed by the nursing staff for distracting the child. However, other forms of technology (i.e., smart phones, tablets) will *not* be prohibited in the control group if the family chooses to offer them. Use of other devices and distraction techniques will be documented.

Randomization, Allocation Concealment, and Blinding

Randomization will be determined using an online randomization tool hosted on the REDCap [45] (Research Electronic Data Capture) platform. Following documentation of informed consent and assent, the RA will obtain the computer-generated randomized assignment for the child by clicking on the 'Randomize' button within the study-specific REDCap case report form. Allocation will be concealed from the research staff, ED clinical staff and the family until this point. However, due to the nature of the intervention, it is not possible to maintain blinding once the child has been randomized.

Children and their parents/caregivers will be informed that the study will evaluate and compare different forms of distraction, however they will not be made aware of the study hypothesis for the VR intervention. Furthermore, the statistician will be blinded to treatment assignment by using randomization codes until data analysis is complete.

Recruitment and Data Collection

Participant recruitment will occur in the SCH ED when RAs are on-site, from approximately 15:00 to 23:00 daily. Based on our team's previous research, this time frame corresponds with peak ED volume. RAs will screen the electronic ED track board and communicate with on-site clinical staff to identify potentially eligible patients. The RA will then further assess eligibility based on the inclusion/exclusion criteria detailed above. If the child is deemed eligible and the family is willing to participate, the RA will obtain written informed consent from the parent/ caregiver and assent from the child (See Appendix 1). One parent/caregiver for each child will be asked to provide consent and complete all relevant study questionnaires.

Prior to the beginning of the IV procedure, the RA will collect baseline information, including: baseline heart rate, pre-procedure distress, fear, and pain scores from the child, and pre-procedure anxiety score from the parent/caregiver. The RA will then access the randomization tool on REDCap to reveal the child's group assignment (VR intervention or Control).

For the VR intervention group, the RA will set up the VR equipment and spend approximately 5-10 minutes explaining the intervention to the child, including proper use of the goggles and controller. The RA will then help the child put on and secure the goggles and headphones, and hand them the controller. They will document the time required for equipment set up as well as any technical challenges encountered. As per hospital infection control policy, all VR equipment including the goggles, headphones and controller will be sanitized with disinfectant wipes between participants. A disposable one-time use cover will be placed on the goggles for each participant. For all participants (both study arms), the RA will begin video recording the child five minutes prior to the start of the procedure and continue until 5 minutes post-procedure, to allow for complete coding of OSBD-R distress scores at a later time.

For all participants (both study arms), the staff nurse will insert the IV following institutional protocol. In keeping with the pragmatic design of the trial, no additional or study-specific instructions will be provided to either nurses or parents/caregivers regarding their behaviour during the procedure. For purposes of the study, the start of the IV insertion procedure will be marked by the cleaning of the IV site by the staff nurse. The end of the procedure will be defined by the last point of contact by the staff nurse (i.e., taping cannula in place with or without arm board, wrapping arm with gauze and taping the gauze in place).

During the procedure, the RA will closely monitor the child for any adverse effects. The child will also be asked to let the team know immediately if they are experiencing any adverse events or discomfort related to the VR intervention (i.e., dizziness, nausea, headache). The VR intervention can be discontinued (i.e., the headset can be removed) at any time, at the discretion of the child or clinical team. If an adverse event were to occur, the clinical team will be notified, and details will be logged in the REDCap adverse event log. Additionally, the RA will make a note of any technical failures or issues associated with the VR equipment during enrollment.

Immediately following the first *attempt* at IV placement (regardless of whether it was successful), the RA will collect post-procedure distress, fear and pain scores from the child, and post-procedure anxiety score from the parent/caregiver. A few minutes after completion of the IV placement, satisfaction and acceptability questionnaires will be completed with the child, parent /caregiver as well as the staff nurse responsible for inserting the IV. Five minutes after the procedure is completed, the RA will stop the video recording. The duration of the procedure and total number of IV attempts will be documented. If the first attempt at placement is unsuccessful, any additional attempts will occur after all relevant study questionnaires/measurements have been completed.

Demographic information, previous history and visit details will also be collected from the family and the child's medical chart. See Figure 3 for study flow schematic.

Outcome Measures

Our primary outcome is **distress**. Our secondary outcomes are **(a)** pain; **(b)** fear; **(c)** the parental/caregiver anxiety; and **(d)** parental/caregiver and nurse satisfaction with the procedure in the intervention; and **(e)** safety.

Our primary outcome measure will be the child's total distress score during the IV procedure. Distress associated with the procedure will be assessed using the Observational Scale of Behavioral Distress-Revised (OSBD-R). The OSBD-R is a validated scale that is widely used to measure pain and distress associated with various medical procedures in children. [46-48] The tool assesses eight specific behaviors that are indicative of distress and are weighted according to intensity: information seeking, crying, screaming, restraint, verbal resistance, emotional support, verbal pain, and flailing. Study participants will be videotaped for the duration of the IV procedure as well as for a few minutes before and after; distress will be scored pre-, during, and post-procedure. Two RAs who are trained in the use of the tool will independently observe the videotapes and record the frequency of each of the eight behaviors during continuous 15-second intervals. To ensure high inter-rater reliability, the first 10% of coded videos will be analyzed for inter-rater reliability and RAs will be provided with feedback and re-training, as needed, prior to coding the remaining videos. The mean OSBD-R scores between the two RAs will be used as the final scores. This standardized procedure for OSBD-R has been successfully used in previous research evaluating distraction. [29, 49-52] This scale demonstrates high inter-rater reliability as well as moderate to high correlations with other behavioral measures of distress. [49, 53-54]

Our principal secondary outcome measure will be the child's pain score during the IV procedure. Pain will be measured using an 11-point verbal Numerical Rating Scale (vNRS) ranging from 0 (no pain) to 10 (worst possible pain). This scale is a commonly used pain measurement tool in pediatric acute pain studies and is validated for use in children 6-17 years of age. [55-58] Pain scores will be self-reported by children both before and immediately following the IV procedure.

Fear will be measured using the Children's Fear Scale (CFS) [4, 59]. This scale depicts five faces representing increasing levels of anxiety, where the left-most face depicts "not scared at all" (score=0) and the right most-face means "most scared possible" (score=4). The CFS is an adaptation of the adult Faces Anxiety Scale [59] and has been validated to measure fear in children undergoing painful medical procedures. [4] Children will be asked to independently rate their fear both before and immediately following the IV procedure.

Parental/Caregiver anxiety will be measured with the State Trait Anxiety Inventory – State Scale Revised Version (STAI-S, Form Y), a validated and commonly used version of STAI, which has improved psychometric properties. [60] Parents/caregivers will be asked to complete the STAI questionnaire both before and immediately following the IV procedure.

Parent/caregiver and nurse satisfaction with the procedure will be measured using a 5-point Likert scale, ranging from 1 "Very dissatisfied" to 5 "Very satisfied". Child satisfaction with the procedure will be measured using a 5-point Likert scale, ranging from 1 "Not at all happy" to 5 "Very happy". Satisfaction scores will be collected immediately following the IV procedure.

Safety of the VR intervention will be determined by assessing the frequency of adverse events post intervention. Specifically, nausea will be self-rated by children immediately following the intervention, using the Baxter Retching Faces (BARF) scale [61]. This scale consists of 6 faces depicting increasing levels of nausea, with assigned scores ranging from 0 to 10. The BARF scale is widely used in medical research and has demonstrated construct, content, and convergent validity as a tool to measure nausea in children. [61] The presence of other adverse events (i.e., dizziness) will also be recorded by the RA. Children who are presenting with nausea, vomiting, dizziness or migraines *prior* to enrollment will be excluded from the study to avoid exacerbating these conditions with the use of the VR equipment.

Sample Size

The sample size for the study is 80 patients overall. Sample size calculations were conducted using a two-tailed, two-sample Mann-Whitney test for the primary outcome of observed behavioral distress based on data from the team's previous trial of digital distraction. To detect a large effect size of 0.6 on the OSBD-R (which was observed in a previous trial), given a Type I error of 0.05 and 80% power, the study will require 35 patients for each of the two study arms. To account for attrition and technical recording failures, the team will plan to over-recruit by 10-15%, for an overall total of 80 patients. This will allow sufficient power to find a difference in the primary outcome if a difference truly exists.

Statistical Methods

Statistical analyses will be conducted using statistical software SAS (version 9; SAS Institute, Cary, NC). The significance level will be set at 0.05. Baseline variables will be described using appropriate summary statistics for each group. Imbalances between groups for key baseline variables will indicate the need for further adjusted analyses. For the primary outcome of observed behavioral distress, total OSBD-R 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 (the Sidak correction procedure will be used to reduce the probability of a Type I error). Additional model-based analyses (multiple linear regression) will be conducted, as needed, with behavioural distress as the response variable, pre-procedure behavioral distress and group indicators as the explanatory variables along with some possible effect modifiers such as age, sex, and parental/caregiver anxiety levels. Our primary analysis will be based on an intention-to-treat approach where all children who were randomly assigned to a study group will be included in the group to which they were randomized. Where cell sizes are small or data are sparse or 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 if appropriate.

Patient and Public Involvement

The team's parent advisor (KS) has provided ongoing input on the study protocol and design, and has provided valuable feedback on the content, flow and readability of the consent forms and data collection forms. The Stollery Youth Advisory Council, led by team member AP, provided input on the study design, outcomes measures, and types of virtual reality applications that might be engaging and practical for our study population. AP also reviewed the study protocol and related documents to ensure that the outcomes and tools were patient-relevant and age-appropriate. Following recruitment completion, parent and youth advisors will be further engaged to discuss study results and dissemination plans in the context of patient- and family-centered care.

Data Management and Confidentiality

Data will be entered into a secure online REDCap [45] database hosted by the Women and Children's Health Research Institute (WCHRI). (See Appendix 2 for Case Report Form.) WCHRI's REDCap installation is a validated electronic, web-based data capture system housed in a secure data center at the University of Alberta. Data is entered into REDCap through a web-based interface using 128-bit SSL encryption. Each team member will be granted an individual username/ password and will require additional two factor authentication to log in. All datasets used for statistical analysis will be encrypted and devoid of any patient identifiers. For internal data quality control, a secure master list will be maintained to accurately link study IDs to the patient's medical record.

Selected data elements will be validated electronically throughout the recruitment period and any discrepancies will be assigned to team members for timely resolution. REDCap includes internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

Study data will be entered directly into REDCap in real-time via research iPads or, in some cases (i.e., parent/caregiver indicate a preference to complete paper-based questionnaires), responses may be collected on paper first and then transcribed into REDCap by a trained RA. All paper documents (including study questionnaires, consent/assent forms, and the master list) will be stored in a locked cabinet in a secure location that is only accessible to authorized research staff members. Study videos will be stored electronically in a secure institutional shared drive with restricted access to study staff. Videos will be saved according to their study ID only. The centrally compiled dataset will be stored on a secure server and computers at the University of Alberta. Following completion of the study, all data will continue to be kept in a secure location for five years as dictated by the research ethics board.

ETHICS AND DISSEMINATION

This study has received approval from the Health Research Ethics Board (HREB) at the University of Alberta (HREB identifier: Pro00073476). Any amendments to the study protocol or documents will be submitted for HREB review and will receive approval prior to implementation. Significant protocol amendments will also be reflected online on

the clinicaltrials.gov study registration. This study has also received operational approval from the SCH ED.

All children will receive the best possible care for their presenting complaint, regardless of whether they choose to participate. It is possible that patients in the VR intervention group may experience nausea, mild motion sickness or dizziness, however these effects are rare in children and adolescents, ranging from 0-5%. [62, 63] VR applications have been selected appropriately to minimize these discomforts, and children are monitored closely throughout the study for any adverse effects. Children experiencing nausea, vomiting, dizziness or migraine headaches prior to enrollment will be excluded to avoid potential exacerbation. Study participation is unlikely to prolong the ED length of stay. For infection-control purposes, children screening positive for 'influenza-like illness' (as per ED screening criteria) are excluded to prevent potential contamination of the VR equipment.

Due to resource/logistical constraints, study recruitment will be limited to English-speaking families or those with their own interpreter, at a single recruiting center, and during RA shift hours only. Critically ill children requiring immediate IV insertion will also be excluded to avoid delaying medical care. This may limit the generalizability of the study findings. We will not be controlling for the type of distraction used in the standard of care arm, but we will record what was employed. While this may create some heterogeneity in the comparison arm of the study, it will be a pragmatic reflection of clinical reality. Due to the nature of the intervention, blinding is not possible for the participants or the research personnel, though the statistician will be blind to study group.

The study team plans to publish trial results in a high-impact, peer-reviewed journal and present results at national and international meetings; authorship eligibility will be determined by employing the International Committee of Medical Journal Editors' recommended guidelines. [64] Statistical code and dataset can be made available upon request.

Competing Interests None declared.

Patient Consent After assessing eligibility based on the outlined inclusion/exclusion criteria, research assistants will obtain consent from the parents/caregivers (and assent from children older than 6 years) prior to enrolling the child in the study. The research assistant will provide both a verbal and written explanation of the study to the family. The family will be given an opportunity to review the consent/assent forms in private and can ask the research assistant any questions they might have prior to signing the consent/assent forms. The family is free to withdraw at any point during the study.

Acknowledgments The authors would like to thank the members of the Stollery Youth Advisory Council, who provided valuable input on the study design and gaming/application choices for the virtual reality headsets.

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AUTHOR CONTRIBUTIONS

Dr. Samina Ali (SA) is a pediatric emergency clinician-researcher and Professor of Pediatrics & Emergency Medicine at the University of Alberta. She co-developed and revised the protocol and co-drafted the protocol paper. She chose the previously validated tools for measuring the primary outcomes.

Manasi Rajagopal (MR) is the program lead for the Pediatric Emergency Medicine research program at the University of Alberta and co-principal investigator of this study. She co-developed the study protocol, co-drafted the protocol paper, and will operationalize the study.

Dr. Jennifer Stinson (JS) is the Mary Jo Haddad Nursing Chair in Child Health at the Hospital for Sick Children's Research Institute and a nurse practitioner in the Department of Anesthesia's chronic pain program at the hospital. She assisted with the study design and protocol revision.

Dr. Keon Ma is a pediatric trainee at the University of Calgary, with expertise in OSBD-R coding. He assisted with the study design and protocol revision.

Ben Vandermeer (BV) led the statistical analysis planning and contributed to protocol revision.

Bailey Felkar (BF) is a child life specialist at the Stollery ED with expertise in managing children's pain and distress in the ED setting. She assisted with the study design and protocol revision.

Kurt Schreiner (KS) is a family partner who has provided input into study outcomes to ensure family-relevant outcomes are chosen and will inform our knowledge translation efforts to the public.

Amanda Proctor (AP) is the coordinator of the Stollery Youth Advisory Council. Together with the council, she informed programming choices for the virtual reality devices and has reviewed the protocol and related documents to ensure that the outcomes and tools are patient-relevant and age-appropriate.

Jennifer Plume (JP) is the acting director for Stollery child life services with expertise in managing children's pain and distress in the ED. She has informed study methods and will aid and support the development of our knowledge translation plan.

Dr. Lisa Hartling (LH) is a Professor in the Department of Pediatrics at the University of Alberta and Director of the Alberta Research Centre for Health Evidence (Edmonton, Canada). She assisted with the study design and drafting the protocol, and provides expertise in clinical trial methodology and statistical analyses.

All authors have approved this final version of the protocol. None of the authors have financial or other conflicts of interests as they pertain to this study and its involved recruitment sites.

Figures Legend

Figure 1. Child using virtual reality goggles in the emergency department
Figure 2. Virtual Reality Game Menus
Figure 3. Flow Diagram of Study Procedures

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Emergency-UAH
PHILIPS

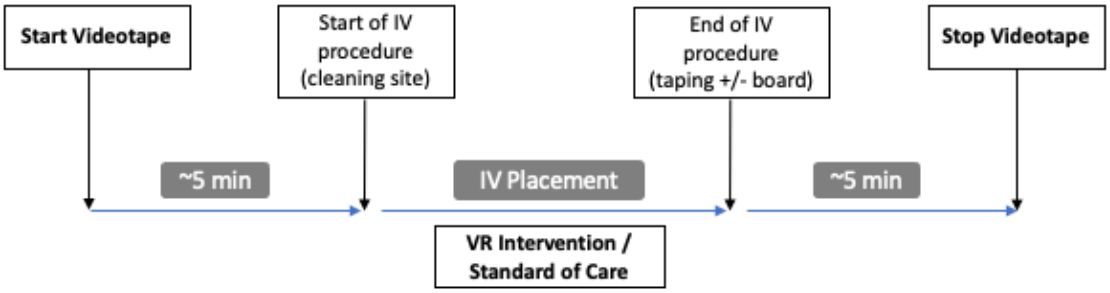
VR Game Menu
Easy/Novice

Title	Category	Content	Controller	Comments
Henry	Immersive 12 min	Henry is the story of a little hedgehog on his birthday.	None	Fun, magical, some movement
YouTube	Immersive Passive	Watch YouTube videos in VR.	Use the front trigger to browse and choose videos	Some videos might not be VR 360 videos can be dizzying
Myth: A Frozen Tale	Immersive 8 min	Watch the elemental spirits of air, fire, water and earth.	None	Some movement, Magical creatures
Color Space	Interactive	A virtual reality coloring book with sound.	- Left controller is the paint pallet - Right controller selects color	Calming, relaxing No movement
Tilt Brush	Interactive	Paint your own 3D world!	- Left controller: art tools - Left joy-stick flips through art tools - Right controller selects tool and draws	Calming, relaxing No movement
Bonfire	Interactive 15 min	You've crash-landed on an alien planet and try to survive.	Front Trigger Right hand joystick	Rated: 10+ Some movement, Fight a giant slug

*Child can be lying down for any of these games

VR Game Menu
Experienced

Title	Category	Content	Controller	Comments
Jurassic World	Immersive 7 min (Blue) 3 min (Apatosarus)	Watch Blue the dinosaur interact with other dinosaurs! * Choose Blue first then Apatosaurus	Front trigger to choose video. Use any button to go back to main menu	Be careful, you will interact with a T-rex! Can be lying down.
Tetris Effects	Interactive	Tetris like you've never seen it, or heard it, or felt it before! * Play Journey Mode	- L hand joy-stick moves block - Right hand A or B to change orientation of the block - Right hand trigger to change block option	Some movement, Lights and music. Can be lying down.
Fruit Ninja	Interactive	Slice through flying fruits! * Only Arcade game can be played	Swipe fruits with dominant hand controller.	Not a lot of movement, Only the flying fruits. Need to be sitting up.
Moss	Interactive *Requires knowledge of VR or gaming*	Action-adventure puzzle game. Help a young mouse explore a magical world. *Hint: Use index trigger to drag blue glowing boxes	Left hand joystick to move Right hand A to jump Right B to hit/attack Right hand A&B to avoid Double B to go back to menu	There will be puzzles you'll have to figure out! Need to be sitting up straight.
Vader Immortal I, II and III	Interactive *Requires knowledge of VR or gaming*	Step into a galaxy far far away! Episode I: hone light saber skills Episode II: Learn to use the force Episode III: Master the skills of the Jedi *Light saber dojo in each episode is very fun!	- Joy stick to hover where to move - Left joy stick when in the dojo. - To use the force: press the grab trigger and hover over the object, you can move it towards you or throw/aim away - Hint: check your belt you may have objects (e.g. light saber)	Need to be sitting up straight Rated: Teen - Star Wars graphics - Fighting with the force - Need to be able to sit up straight - Lots of virtual movement



PRE-Procedure (Baseline)

Child
- Distress score (11-point numerical rating scale)
- Fear score (CFS)
- Pain score (vNRS)
- Baseline HR

Parent
- Anxiety assessment (STAI-S)

POST-Procedure

Child
- Distress score (11-point numerical rating scale)
- Fear score (CFS)
- Pain score (vNRS)
- Nausea rating (BARF)
- Adverse event assessment
- Satisfaction score

Parent
- Anxiety assessment (STAI-S)
- Satisfaction score

Nurse
- Acceptability score
- Satisfaction score

CFS=Children's Fear Scale; vNRS=verbal Numerical Rating Scale; HR=Heart Rate; STAI-S= State Trait Anxiety Inventory – State Scale Revised Version; BARF=Baxter Retching Faces; OSBD-R=Observational Scale of Behavioral Distress-Revised; RA=Research Assistant
Note: OSBD-R coding of videos will be done by RAs post visit

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A randomized controlled trial of virtual reality-based distraction for venipuncture-related distress in children: The VR Study

REB #: Pro00095418	Screening ID	Enrolment Date
PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Pre-Screening

Date and Time of Triage	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Child's Age	_____ years
Child's Sex	☐ Female ☐ Male
Was the family approached for this study?	☐ Yes ☐ No
If NO, specify reason and STOP HERE.	☐ Family refused overall consent to be approached for research ☐ Legal guardian not present ☐ RA busy with another study ☐ Did not meet eligibility criteria, specify _____ ☐ Other, Specify _____
If YES, continue to Eligibility.	

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Eligibility

Was verbal consent for screening obtained from the family? ☐ Yes ☐ No

Inclusion Criteria

1. Child aged 6-17 years	☐ Yes	☐ No
2. Requires IV placement	☐ Yes	☐ No
3. Will receive topical anesthetic cream for IV placement	☐ Yes	☐ No

Exclusion Criteria

1. Medically unstable (i.e. CTAS 1, requires immediate IV insertion)	☐ Yes	☐ No
2. Unconscious or not fully alert	☐ Yes	☐ No
3. Visual, auditory or cognitive or mental health issues precluding safe interaction with the VR intervention	☐ Yes	☐ No
4. Conditions that could be exacerbated by the VR environment (as reported by the family) a. *current* symptomatic nausea / vomiting / dizziness / migraine b. *history* of psychosis / hallucinations / epilepsy	☐ Yes	☐ No
5. Presence of an infection / injury which could contaminate the VR intervention equipment (as determined by the healthcare team) including but not limited to a. open wounds / infections of the head and neck area b. suspected or confirmed methicillin-resistant *Staphylococcus aureus* (MRSA) colonization	☐ Yes	☐ No
6. Screens positive for 'influenza-like illness' (ILI) as per the current SCH ED screening criteria	☐ Yes	☐ No
7. Child or Parental language barrier precluding the ability to understand and complete study assessments, in the absence of a native language translator	☐ Yes	☐ No
8. Previous enrollment (of child OR parent) in this study	☐ Yes	☐ No

Is the family eligible for the study? ☐ Yes ☐ No

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Informed Consent

Has written informed consent been obtained from the **parent/ legal guardian**? ☐ Yes ☐ No

If NO,

Specify reason and STOP HERE.	☐ Declined consent ☐ Declined assent ☐ Other, please specify _____

If YES,

Specify the date and time of Informed Consent:	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Has a copy of the signed informed consent been given to the family?	☐ Yes ☐ No; specify: _____
Has written assent been obtained from the **child**?	☐ Yes ☐ No; specify: _____ ☐ No, but verbal assent was obtained and documented ☐ Not required; child < 7y
Has a copy of the signed assent been given to the family?	☐ Yes ☐ No; specify: _____
Has written informed consent been provided by the **clinical nurse**? *Note: Consent only needs to be provided by the clinical nurse once for the entire duration of the study (for all 80-90 participants). If consent has not been previously completed with the clinical nurse, make sure a signed copy is completed before recruitment.*	☐ Yes ☐ No; specify: _____
Clinical Nurse Study ID Number:	_____

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Randomization

If the child satisfies the inclusion/ exclusion criteria and written informed consent has been provided, please RANDOMIZE the participant by clicking on the Randomize button below:

Study Arm	☐ **VR Intervention** ☐ **Standard Care**

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Demographics & History

Demographics

Parent/ Caregiver relationship to child	☐ Mother ☐ Father ☐ Other; specify: _____
Parent / Caregiver Age	____ years; or ☐ Prefer not to answer
Parent / Caregiver Sex	☐ Female ☐ Male
Parent / Caregiver Highest level of Education	☐ Elementary School ☐ High School or some High School ☐ Diploma/ Certificate ☐ Some Post-Secondary/ University ☐ University/ Professional Degree ☐ Decline to answer
First three digits of postal code	__ __ __ (1st 3 digits ONLY)
Do you identify your child as a member of an ethnic minority?	☐ Yes ☐ No

Medical History

Was your child born prematurely?	☐ Yes ☐ No
• If yes, at how many weeks gestation?	_____ weeks
Has your child ever been to the Emergency Department before today?	☐ Yes ☐ No
• If yes, how many times:	_____ times
Has your child ever been hospitalized?	☐ Yes ☐ No
• If yes, how many times:	_____ times
Has your child ever had a needle poke in their vein to draw blood or put in an intravenous (IV) line?	☐ Yes ☐ No

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If yes, how distressed was your child during the procedure? *(if more than one occurrence, ask the parent to recall the most recent event)* Choose a number between 1 and 5 that best describes your child's distress where 1 indicates 'no distress at all' and 5 is 'as distressed as possible'	☐ 1 (no distress at all) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (as distressed as possible)

Child Experience with Technology

Has your child played with/ used any of the following devices before to ***play games***?	☐ iPad/ iPod/ iPhone / Tablet *(to play games)* ☐ Gaming console (ex. Xbox, Nintendo, PS4, other) ☐ Virtual Reality (VR) device (ex. Oculus Quest/ Rift, Samsung Gear VR, HTC Vive, PlayStation VR, other) ☐ Robot

If yes, how frequently?

iPad/ iPod/ iPhone / Tablet:	Gaming console	VR device	Robot
☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____	☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____	☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____	☐ _____ hours/ week ☐ Less than Once per week ☐ Less than 5 times in total ☐ Other, specify _____

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PRE-Procedure: Child Scores

NOTE: Begin the video recorder (iPad) approximately 5 minutes before the start of the IV procedure, and stop the recording 5 minutes after the end of the procedure.

Baseline Scores: Child

Heart Rate (record from Triage)	____ bpm
Time pre-procedure scores collected	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Pain Score: verbal Numerical Rating Scale (vNRS) "On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what is your pain level now?"	____ / 10
Distress Score: Numerical Rating Scale "On a scale of 0 to 10, where 0 is no distress and 10 is the most distress you can imagine having, what is your distress level now?"	____ / 10

Fear Score: Children's Fear Scale (CFS)

"These faces are showing different amounts of being scared. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [pint to the last face on the right]. Have a look at these faces and choose the one that shows how scared you are right now."

☐ ☐ ☐ ☐ ☐

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PRE-Procedure: Parent / Caregiver STAI Questionnaire

We would ask that you complete the following questions as they relate to your feelings about your child's upcoming IV procedure, today. A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you feel **right now**, that is, **at this moment**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

1----------2----------3----------4
Not at all Somewhat Moderately so Very much so

1.	I feel calm	1	2	3	4
2.	I feel secure	1	2	3	4
3.	I am tense	1	2	3	4
4.	I feel strained	1	2	3	4
5.	I feel at ease	1	2	3	4
6.	I feel upset	1	2	3	4
7.	I am presently worrying over possible misfortunes	1	2	3	4
8.	I feel satisfied	1	2	3	4
9.	I feel frightened	1	2	3	4
10.	I feel comfortable	1	2	3	4
11.	I feel self-confident	1	2	3	4
12.	I feel nervous	1	2	3	4
13.	I am jittery	1	2	3	4
14.	I feel indecisive	1	2	3	4
15.	I am relaxed	1	2	3	4
16.	I feel content	1	2	3	4
17.	I am worried	1	2	3	4
18.	I feel confused	1	2	3	4
19.	I feel steady	1	2	3	4
20.	I feel pleasant	1	2	3	4

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

DURING-Procedure

- Start the iPad video recording approximately 5 minutes prior to the start of the procedure.
- For children randomized to the VR group: Immediately after PRE-procedure scores and STAI are completed, research assistant will set up the VR equipment.
- The staff ED nurse will then begin the IV set-up

Start time of IV procedure: *(Defined as the time the staff nurse begins to clean the IV site)*	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
End time of IV procedure/ attempt: *(Defined as the last point of contact by the staff nurse (ex. taping cannula in place with or without arm board, wrapping arm with gauze and taping the gauze in place)*	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)

Position of Child during IV attempt:	☐ Sitting up ☐ Lying down (supine)
Location of first IV attempt:	☐ Antecubital Fossa – RIGHT ☐ Antecubital Fossa – RIGHT ☐ Dorsum hand – RIGHT ☐ Dorsum hand – LEFT ☐ Other, specify _____
Was the first IV placement attempt successful?	☐ Yes ☐ No
• If NO, how many attempts, in total, were made for the IV during this 'episode'?	_____ attempts
• Was an IV successfully placed during this 'episode'?	☐ Yes ☐ No

Any adverse events or side effects? *Do not suggest any AEs to the participant; Instead, ask more general questions such as "how are you feeling?" or "are you having any side effects?" or "are you feeling any different than before?", and let the child answer spontaneously.*	☐ Yes ☐ No If "**YES**", complete a separate entry for each AE on the AE Form

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IMMEDIATELY POST-Procedure: Child Scores

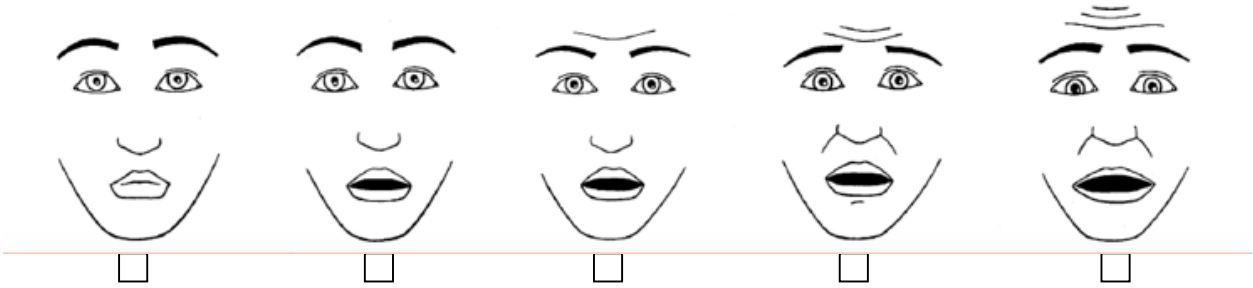
NOTE: Post-procedure scores/ questionnaires should be collected as soon as possible after the procedure is complete:

Post-procedure Scores: Child

Time post-procedure scores collected	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Pain Score: verbal Numerical Rating Scale (vNRS) - Procedure "On a scale of 0 to 10, where 0 is no pain and 10 is the worst pain you can imagine, what was your pain level during the needle / IV poke?"	____ / 10
Distress Score: Numerical Rating Scale - Procedure "On a scale of 0 to 10, where 0 is no distress and 10 is the most distress you can imagine having, what was your distress level during the needle / IV poke"	____ / 10

Fear Score: Children's Fear Scale (CFS) - Procedure

"These faces are showing different amounts of being scared. This face [point to the left-most face] is not scared at all, this face is a little bit more scared [point to the second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [pint to the last face on the right]. Have a look at these faces and choose the one that shows how scared you were during the needle / IV poke."



Nausea Score: Baxter Retching Faces (BARF) Scale - Procedure

"Have you thrown up or felt like you were going to throw up before? How did your tummy feel then? We call that feeling of being sick to the stomach nausea. These faces show children who feel no nausea at all, who feel a little bit nauseated, who feel even more nauseated, and these are children who have the most nausea it is possible to feel." [Point to each face at the appropriate time.] "Which face is more like how you felt during the needle / IV poke?"

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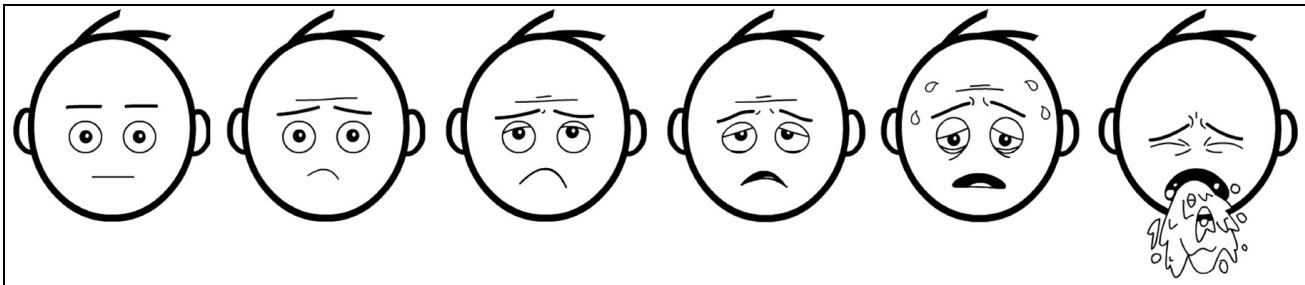

☐ ☐ ☐ ☐ ☐ ☐

Overall, how happy were you with the IV start today, on a scale of 1 to 5, where 1 means "Not at all happy" and 5 means "Very happy"?	☐ 1 "Not at all happy ☐ 2 ☐ 3 ☐ 4 ☐ 5 "Very happy"
On a scale of 1 to 5, where 1 means "Not at all happy" and 5 means "Very happy", how happy were you with the pain treatment for your IV start?	☐ 1 "Not at all happy" ☐ 2 ☐ 3 ☐ 4 ☐ 5 "Very happy"
Did the [distraction / toys / VR goggles] help you today?	☐ Yes, it helped ☐ No, it didn't help ☐ I'm not sure
If you ever had to get an IV or needle poke again, would you want to use the same [distraction / toys / VR goggles] again?	☐ Yes, I would ☐ No, I wouldn't ☐ I'm not sure
Can you tell me why/ why not?	

As soon as possible after completion of procedure, research assistant to give:

1. Post-Procedure Parent STAI and Satisfaction Questionnaire to parent/ caregiver
2. Nurse Satisfaction Questionnaire to staff ED nurse

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POST-Procedure: Parent / Caregiver STAI Questionnaire

We would ask that you complete the following questions as they relate to your feelings about your child's IV procedure that just happened. A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you feel **right now**, that is, **at this moment**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

1----------2----------3----------4
Not at all Somewhat Moderately so Very much so

1.	I feel calm	1	2	3	4
2.	I feel secure	1	2	3	4
3.	I am tense	1	2	3	4
4.	I feel strained	1	2	3	4
5.	I feel at ease	1	2	3	4
6.	I feel upset	1	2	3	4
7.	I am presently worrying over possible misfortunes	1	2	3	4
8.	I feel satisfied	1	2	3	4
9.	I feel frightened	1	2	3	4
10.	I feel comfortable	1	2	3	4
11.	I feel self-confident	1	2	3	4
12.	I feel nervous	1	2	3	4
13.	I am jittery	1	2	3	4
14.	I feel indecisive	1	2	3	4
15.	I am relaxed	1	2	3	4
16.	I feel content	1	2	3	4
17.	I am worried	1	2	3	4
18.	I feel confused	1	2	3	4
19.	I feel steady	1	2	3	4
20.	I feel pleasant	1	2	3	4

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POST-Procedure: Caregiver Satisfaction Questionnaire

1) Please rate your overall satisfaction with your child's IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

Please Explain: _____

2) Please rate your satisfaction with the management of your child's pain for their IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

Please Explain: _____

3) Would you use the same methods to manage your child's pain from needle pokes in the future?

☐ Yes
☐ No

Why / Why not? _____

Thank you for your participation in our research study, it is very much appreciated!

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REB #: Pro00095418	Screening ID	Enrolment Date
PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ (dd / mmm / yyyy)

Nurse Satisfaction Questionnaire (VR Group)

1) Overall, how easy or difficult was it to perform the IV insertion for this child?

Very Easy	*Easy*	*Neutral*	*Difficult*	*Very Difficult*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

2) Please rate your satisfaction with this child's IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

3) Would you use the same methods (ie. VR device) to manage another child's pain and distress from IV insertion in the future?
- ☐ Yes
- ☐ No

4) Could you please rate the following on a scale of 1-5, where 1= Not at all and 5=Very much

	1	2	3	4	5
Your overall satisfaction with the Virtual Reality (VR) device today	☐	☐	☐	☐	☐
Your willingness to use the VR device to manage another child's IV pain and distress in the future	☐	☐	☐	☐	☐
The degree to which the VR device improved the child's experience	☐	☐	☐	☐	☐
The degree to which the VR **improved** your ability to insert the IV	☐	☐	☐	☐	☐
The degree to which the VR **disrupted** your ability to insert the IV	☐	☐	☐	☐	☐

5) Did the VR device that was used during the procedure increase the time required to insert the IV?
- ☐ Yes (approximately how much time did it increase the procedure by? _____ minutes)
- ☐ No

6) Is there anything else that you would like to tell us, today, about your experience inserting an IV for a child using a VR device?

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

7) How many years of practice do you have as a nurse (all settings)? _____ ☐ N/A

8) How many years of practice do you have as a nurse in the ED? _____ ☐ N/A

9) Please indicate the amount of time spent in the pediatric emergency department (PED):

- ☐ 0-25% of my time is spent in the pediatric ED
- ☐ 26-50% of my time is spent in the pediatric ED
- ☐ 51-75% of my time is spent in the pediatric ED
- ☐ 76-100% of my time is spent in the pediatric ED

10) Please specify your position if other than attending ED nurse (e.g., IV nurse, attending ED physician, resident, physician or nurse from other service [specify], etc):

_____

Thank You!!

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REB #: Pro00095418	Screening ID	Enrolment Date
PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Nurse Satisfaction Questionnaire (Standard Care Group)

1) Overall, how easy or difficult was it to perform the IV insertion for this child?

Very Easy	*Easy*	*Neutral*	*Difficult*	*Very Difficult*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

2) Please rate your satisfaction with this child's IV start:

Very Dissatisfied	*Dissatisfied*	*Neutral*	*Satisfied*	*Very Satisfied*
1 ☐	**2** ☐	**3** ☐	**4** ☐	***5*** ☐

3) Would you use the same methods (ie. Standard of Care pain management plan) to manage another child's pain and distress from IV insertion in the future?

☐ Yes
☐ No

4) Could you please rate the following on a scale of 1-5, where 1= Not at all and 5=Very much

	1	**2**	**3**	**4**	**5**
Your overall satisfaction with the pain management plan today	☐	☐	☐	☐	☐
Your willingness to use a similar pain management plan to manage another child's IV pain and distress in the future	☐	☐	☐	☐	☐
The degree to which the pain management plan improved the child's experience	☐	☐	☐	☐	☐
The degree to which the pain management plan **improved** your ability to insert the IV	☐	☐	☐	☐	☐
The degree to which the pain management plan **disrupted** your ability to insert the IV	☐	☐	☐	☐	☐

5) Did the Standard of Care pain management plan that was used during the procedure increase the time required to insert the IV?

☐ Yes (approximately how much time did it increase the procedure by? _____ minutes)
☐ No

6) Is there anything else that you would like to tell us, today, about your experience inserting an IV for a child using a Standard of Care pain management plan?

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

7) How many years of practice do you have as a nurse (all settings)? _____ ☐ N/A

8) How many years of practice do you have as a nurse in the ED? _____ ☐ N/A

9) Please indicate the amount of time spent in the pediatric emergency department (PED):

- ☐ 0-25% of my time is spent in the pediatric ED
- ☐ 26-50% of my time is spent in the pediatric ED
- ☐ 51-75% of my time is spent in the pediatric ED
- ☐ 76-100% of my time is spent in the pediatric ED

10) Please specify your position if other than attending ED nurse (e.g., IV nurse, attending ED physician, resident, physician or nurse from other service [specify], etc):

_____

Thank You!!

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Discharge Information

Disposition	☐ Discharged Home ☐ Admitted ☐ Other, _____
Date & Time of Discharge from the ED	_____/_____/_____ dd mmm yyyy _____:_____ (24 hour clock)
Length of Stay in ED (calculated field):	____ hours
Discharge Diagnosis	

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PI: Dr. Samina Ali	**VR - ___ ___ ___**	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

RA Satisfaction Questionnaire *(For Standard Care group, answer Q6 ONLY)*

1) Could you please rate the following on a scale of 1-5, where 1= Not at all and 5=Very much

	1	2	3	4	5
Your overall satisfaction with the Virtual Reality (VR) device today	☐	☐	☐	☐	☐
Ease of set-up of the VR device	☐	☐	☐	☐	☐
Your satisfaction with the amount of time it took to set up the VR device	☐	☐	☐	☐	☐
Your desire to work with the VR device again	☐	☐	☐	☐	☐

2) Approximately how much time was needed to set up the VR device with the child, today? (excluding consent and questionnaire time)

_____ minutes

3) What components of the VR device did the child use during the IV procedure? (check all that apply)

- ☐ VR Goggles / Headset
- ☐ Controller
- ☐ Headphones

4) Were the VR Goggles / Headset kept on for the entire duration of the procedure?

- ☐ Yes
- ☐ No

5) What applications / game(s) did the child play during the procedure?

6) What pain management or distraction tools / resources were used during the procedure? (Check all that apply. If a CLS was involved, ask them to clarify which tools were used.)

- ☐ Virtual Reality
- ☐ iPad / Tablet / Smartphone
- ☐ Toys
- ☐ Music
- ☐ Child Life Specialist (CLS)
- ☐ Other; specify: _____
- ☐ No other techniques were used

7) Did you have any technical or other issues with operating / handing the VR equipment?

- ☐ Yes; specify: _____
- ☐ No

8) Is there anything else that you would like to tell us about your experience with the VR googles today?

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PI: Dr. Samina Ali	VR - ___ ___ ___	__ __ / __ __ __ / 2 0 __ __ dd mmm yyyy

Adverse Events Log

To be filled out by Research Assistant						To be filled out by Site Investigator				
No.	**Description of Adverse Event**	**Onset Date & Time** (dd/mmm/ yyyy HH:MM)	**Action Taken** 1. None 2. Medication 3. New or Prolonged Hospitalization 4. Procedure / Surgery 5. Other, specify	**Outcome** 1. Resolved 2. Resolved with Sequelae 3. Resolving 4. Unresolved 5. Fatal 6. Lost to follow-up	**Date & Time Resolved** (dd/mmm/ yyyy HH:MM)	**Intensity grade:** 1. Mild 2. Moderate 3. Severe	**Expected AE?** Y / N	**Relationship to Study** 1. Unrelated 2. Unlikely 3. Possible 4. Probable 5. Definite	**SAE?** Y / N	**Site PI Initial**
1										
2										
3										

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Early Withdrawal

ONLY fill out this form in the event of an early withdrawal

Date of Discontinuation:	_____/_____/_____ dd mmm yyyy
Reasons for Discontinuation: (check all that apply)	☐ Adverse Event / Serious Adverse Event ☐ Death ☐ Withdrawal of Consent / Assent ☐ Protocol Violation, Specify _____ ☐ Other, Specify _____
If withdrew consent / assent: 1. Permission to use collected data? 2. Permission to conduct Chart Review?	 ☐ Yes ☐ No ☐ Yes ☐ No
Comments:	

Reporting checklist for protocol of a clinical trial.

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	5-7 (Table 1)
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	14
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	15
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	5
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or	N/A

		groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7-8
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	9,13

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8-9 and Figure 3
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9 and Appendix 2 for Case Report Form
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9

Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11

Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14-15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	12-13
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Table 1
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in	13

		results databases, or other data sharing arrangements), including any publication restrictions	
3Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15-16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Table 1
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A