FACULTY OF MEDICINE & DENTISTRY
DEPARTMENT OF PEDIATRICS

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

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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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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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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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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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?

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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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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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										

Ali S, *et al. BMJ Open* 2022; 12:e057892. doi: 10.1136/bmjopen-2021-057892

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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:	