

Virtual reality for paediatric needle procedural pain: two randomised clinical trials

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- SmileyScope (www.smileyscope.com)



Background & Importance



Importance



The Royal Australasian
College of Physicians
Paediatrics & Child Health Division

“Venepuncture, intravenous cannulation..... are often **the most feared painful procedures performed on children.**”

RACP. Guideline Statement: *Management of Procedure-related Pain in Children and Adolescents.*
Royal Australasian College of Physicians. Paediatrics and Child Health Division, Sydney, 2005



M^{on}ash
Children's
Hospital

Background

- The single greatest source of **pain** and **anxiety** for paediatric patients and their families is **needle** procedures, such as blood draws, intravenous access, and injections

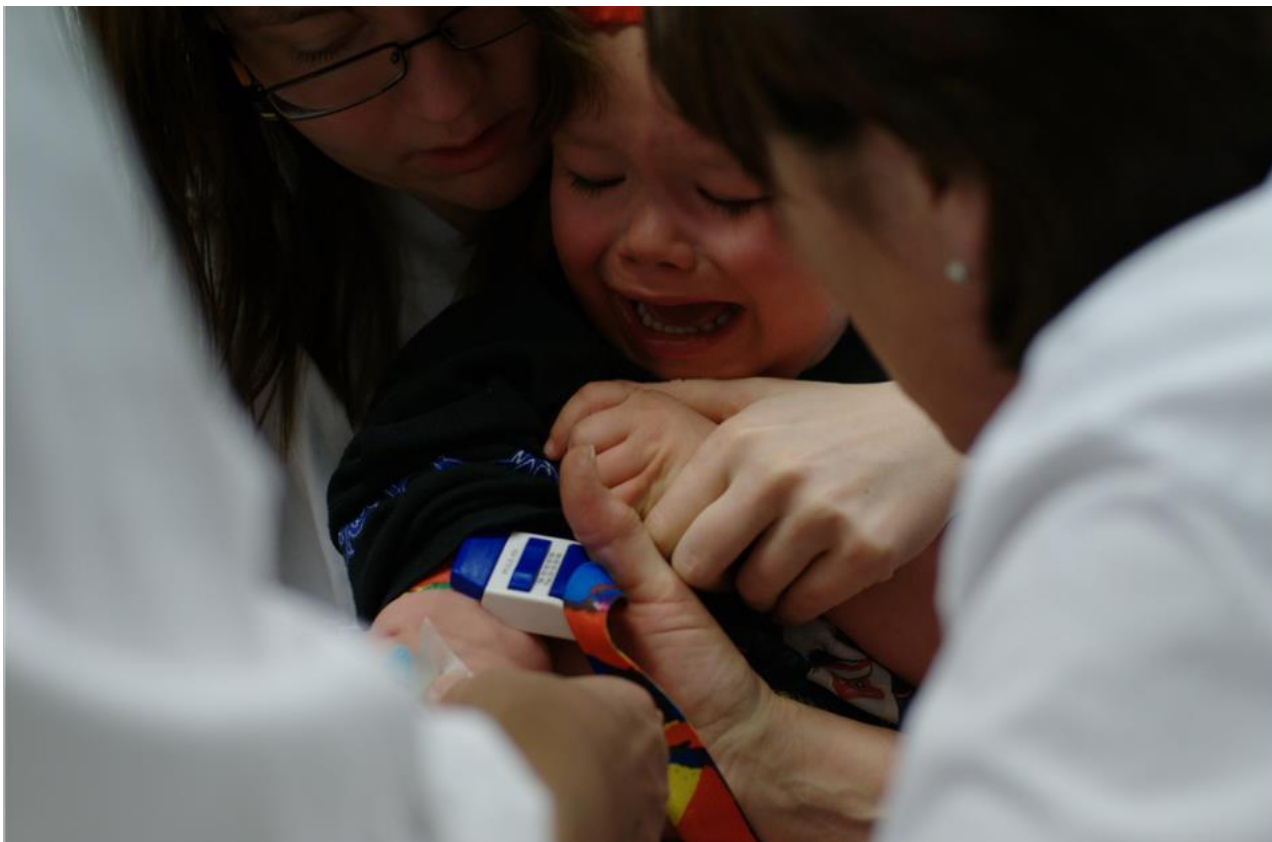
Friedrichsdorf SJ, Postier A, Eull D, *et al.*
Pain Outcomes in a US Children's Hospital:
A Prospective Cross-Sectional Survey.
Hosp Pediatr 2015; **5**: 18–26.



Procedural pain is
predictable...

... and preventable





Recommendations



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- Topical anaesthetics (EMLA, AnGel, LMX)
- Nitrous oxide
- Distraction, relaxation, or other coping skills

RACP. Guideline Statement: *Management of Procedure-related Pain in Children and Adolescents*.
Royal Australasian College of Physicians. Paediatrics and Child Health Division, Sydney, 2005

Background

Pain

- Sucrose
- Nitrous oxide
- Topical LA
- Vibration
- Cooling



Patient
experience

Anxiety

- “Hold still”
- iPhone / iPad
- Play therapy
- Cuddles
- Medication
- Books

Virtual reality



- An interactive 3D computer-simulated environment accessed through a head-mounted device.

... and you can't see the needle!

Study question

?



Study question

- Does the use of a **virtual reality device** compared to **usual care** result in less **pain and distress** for **children aged 4 to 11 years** receiving a **venous needle procedure (IV or venepuncture)**?



Why two trials?

?



Two trials?

Pathology



Emergency Department



Two trials?

Pathology



- Anticipation
- Low baseline pain
- Likely to have had previous experiences with venepuncture / IV

Two trials?

- Acute presentation
- More likely to have baseline pain (fracture, abdominal pain)
- May / may not have had previous experiences

Emergency Department



PICO Format

- P Children aged 4 – 11 years
having a venepuncture / IV cannula
- I Virtual reality
- C Usual care
- O Pain and distress (self-reported)

Population

- Children aged 4-11 years
- Undergoing venepuncture or IV cannulation
- Sufficient English to complete study instruments



Exclusion criteria

- Critical medical illnesses
- Deteriorating clinical status
- Medical conditions that precluded study instrument completion
- Inability to consent /assent.



Intervention

- VR visualisation sequence developed by two authors (EC and PL)
- Input from clinicians, child life therapy, medical, pathology and nursing staff.





Control

- “Standard of Care”
 - Whatever the clinician usually does to reduce pain / distress
 - Not prescribed by the study protocol, but documented in the CRF



Randomization

- Written informed consent
- 1:1 Randomization, stratified for site (Pathology / ED)
 - Computer-generated random number generation
- Opaque envelopes
 - Opened once baseline data collected



Primary Outcome

- Change in pain score (due to needle) from baseline
- Faces Pain Scale-Revised (FPS-R)

Hicks CL, von Baeyer CL, Spafford PA, van Korlaar I, Goodenough B.
The Faces Pain Scale-Revised: toward a common metric in pediatric pain measurement.
Pain 2001; **93**: 173–83.

Faces Pain Scale - Revised



Faces Pain Scale - Revised

- Well-established measure for self-reported pain

Tomlinson D, von Baeyer CL, Stinson JN, Sung L
A Systematic Review of Faces Scales for the Self-report of Pain Intensity in Children.
PEDIATRICS 2010; **126**: e1168–98.

- Score from 0 to 10
- Recommended for use in patients aged 4-12 years.

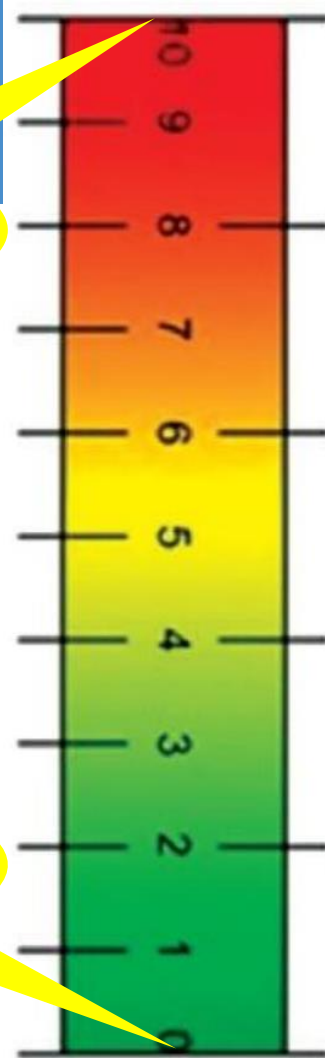
McGrath PJ, Walco GA, Turk DC, *et al.*
Core Outcome Domains and Measures for Pediatric Acute
and Chronic/Recurrent Pain Clinical Trials: PedIMMPACT Recommendations.
J Pain 2008; **9**: 771–83.

Secondary Outcomes

- Child-rated anxiety
 - Visual Analogue Thermometer, 0 to 10
- Caregiver rating of child's distress
 - Visual Analogue Scale, 0 to 10

Extremely
bothered / worried

Not bothered at all



Secondary Outcomes

- Number of needle attempts and success
- Number of people involved in restraint / holding
- Complications



Sample Size

- Minimally clinically significant difference for the Faces Pain Scale – Revised is **2**

Tsze DS, Hirschfeld G, von Baeyer CL, Bulloch B, Dayan PS.
Clinically Significant Differences in Acute Pain Measured on Self-report Pain Scales in Children.
Acad Emerg Med 2015; **22**: 415–22.

- Standard deviation for scores using FPS-R in a trial of paediatric venipuncture is **3.3**

Migdal M, Chudzynska-Pomianowska E, Vause E, Henry E, Lazar J. Rapid, Needle-Free Delivery of Lidocaine for Reducing the Pain of Venipuncture Among Pediatric Subjects.
PEDIATRICS 2005; **115**: e393–8



Sample Size

- Assumptions:
 - Minimally clinically important difference of FPS-R of 1.75
 - Standard deviation: 3.3 in each group
 - $\alpha=0.05$, Power 0.8
 - 1:1 allocation ratio
 - Two-tailed unpaired t-test

- **114** recommended. Allowing for contingencies: **120**

Statistical analysis plan

- Normally distributed data
 - Presentation: Mean difference, 95% CI
 - Analysis: Two-sided T-tests
- Non-parametric data:
 - Presentation: Median, interquartile range
 - Analysis: Mann-Whitney test
- Categorical data
 - Presentation: Number, percentage
 - Analysis: Fisher's exact test

Statistical analysis plan

- SPSS v24.0 and R software
- Intention to treat analysis
- 2-sided $p < 0.05$ indicated statistical significance.



Ethics approval and Trial registration

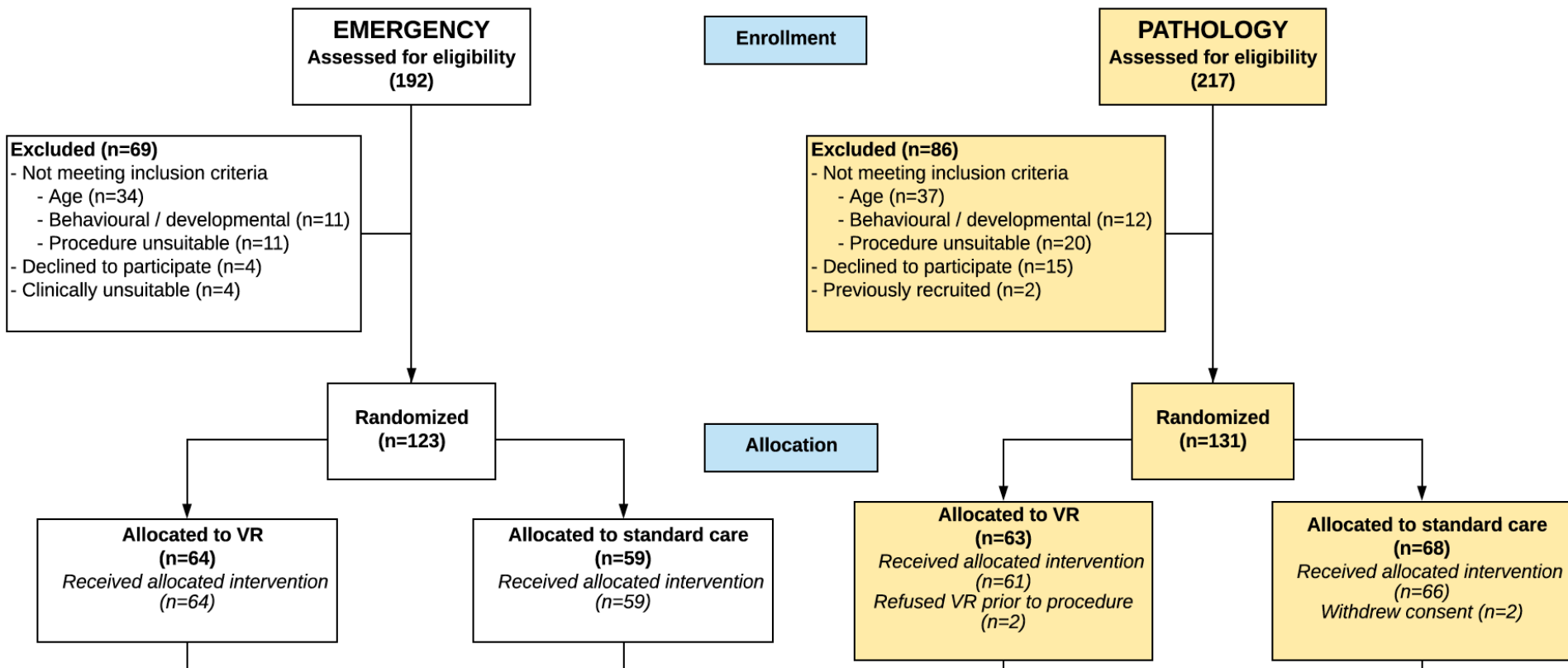
- Approved by Monash Health HREC
- Trial prospectively registered
 - ACTRN 12617000285358



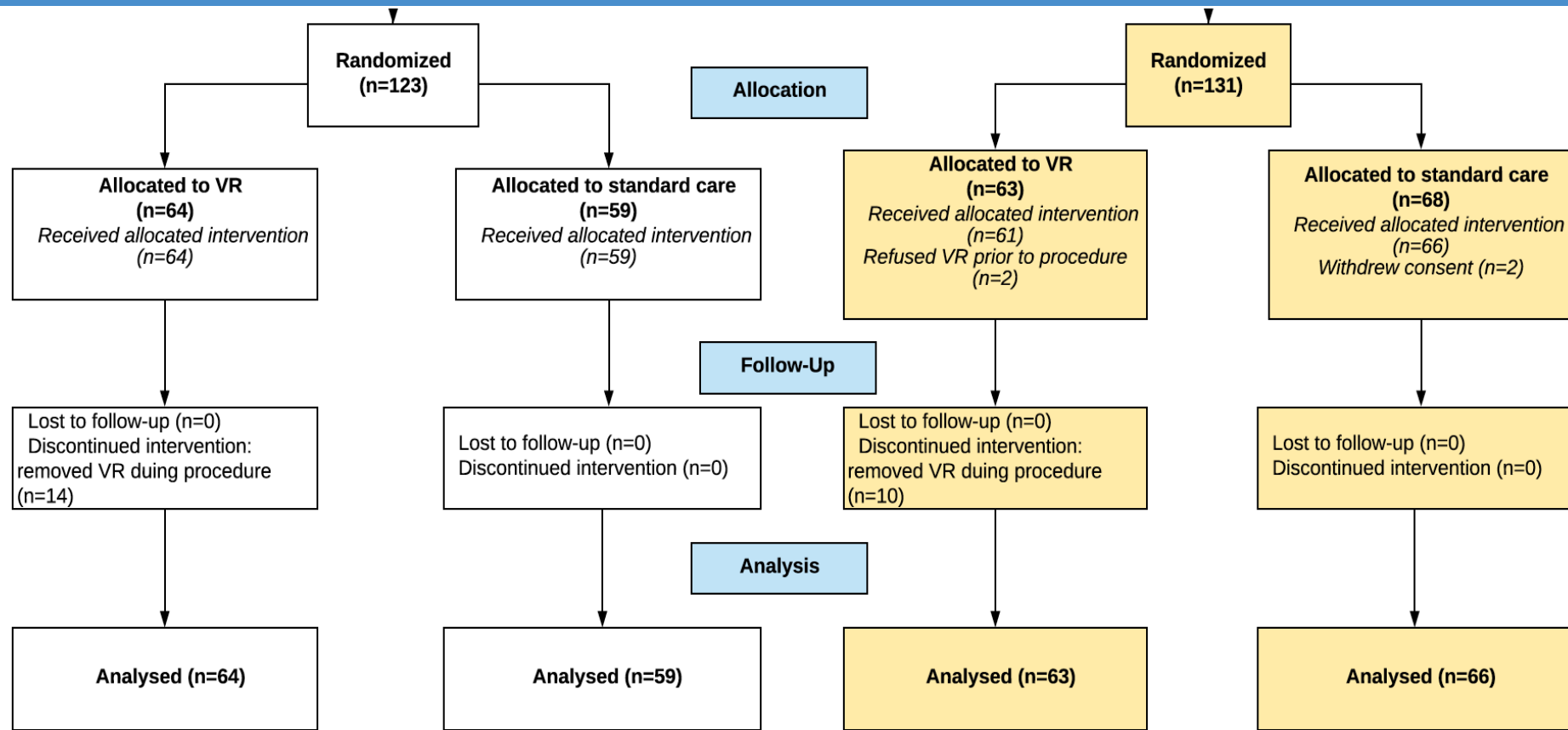
Results



Results



Results



Baseline

Emergency Department

Pathology

	Standard care n=59	Virtual reality n=64
Age , median (IQR), years	8.2 (5.8-10.6)	7.9 (6.4-9.9)
Female sex, No. (%),	27 (45.8%)	29 (45.3%)
Use of topical anaesthetic , No. (%)	50 (84.7%)	57 (89.0%)
Faces Pain Scale – Revised, median (IQR)	4 (1-6)	4 (2-6)
Visual Analog Thermometer Anxiety Score, median (IQR)	5 (2-8)	6 (4-8)

Baseline

Emergency Department

Pathology

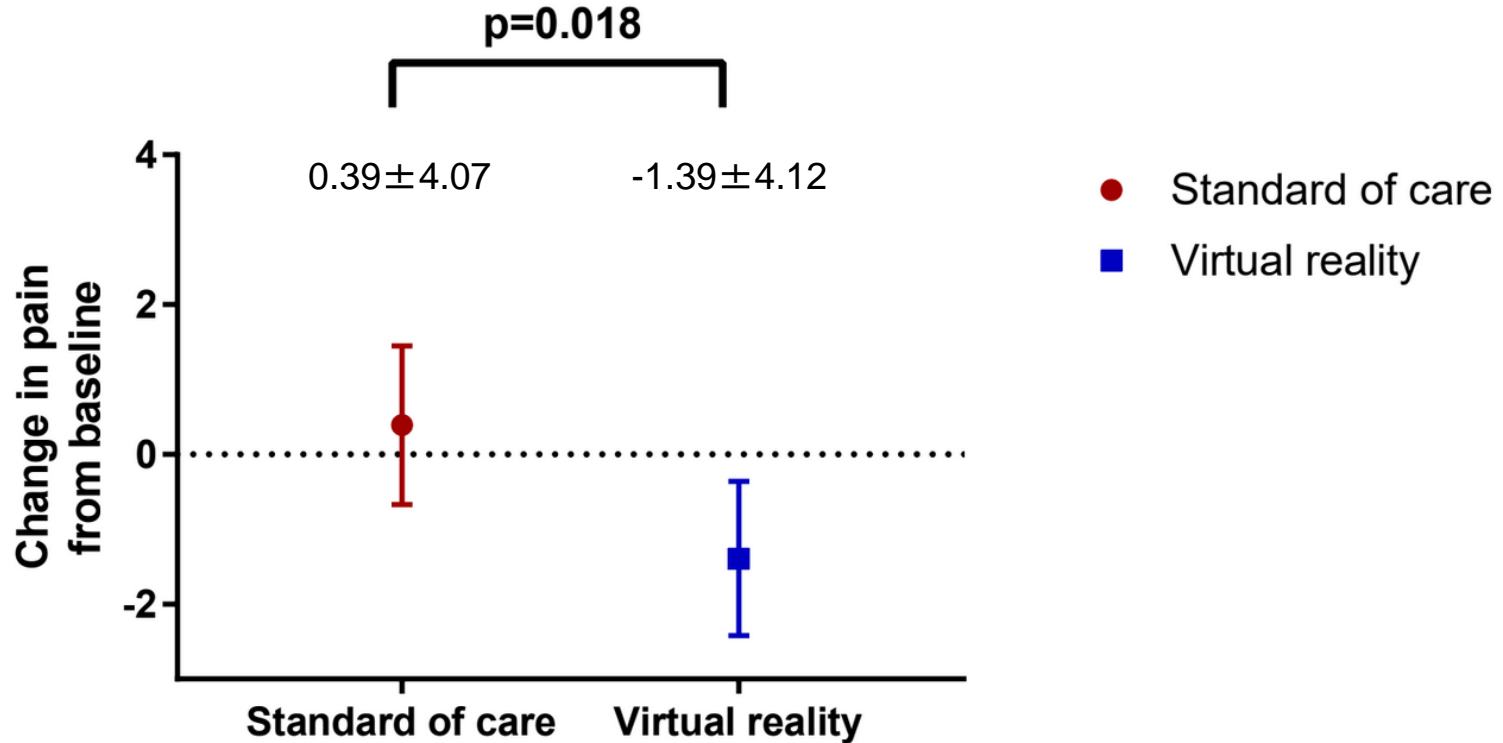
	Standard care n=59	Virtual reality n=64
Previous exposure to procedure, No. (%)	31 (52.5%)	37 (57.8%)
Distraction used in “standard care”		
None	16 (27.1%)	N/A
Electronic media	32 (54.2%)	
Child-life therapy	6 (10.2%)	
Other	5 (8.5%)	

Primary Outcome

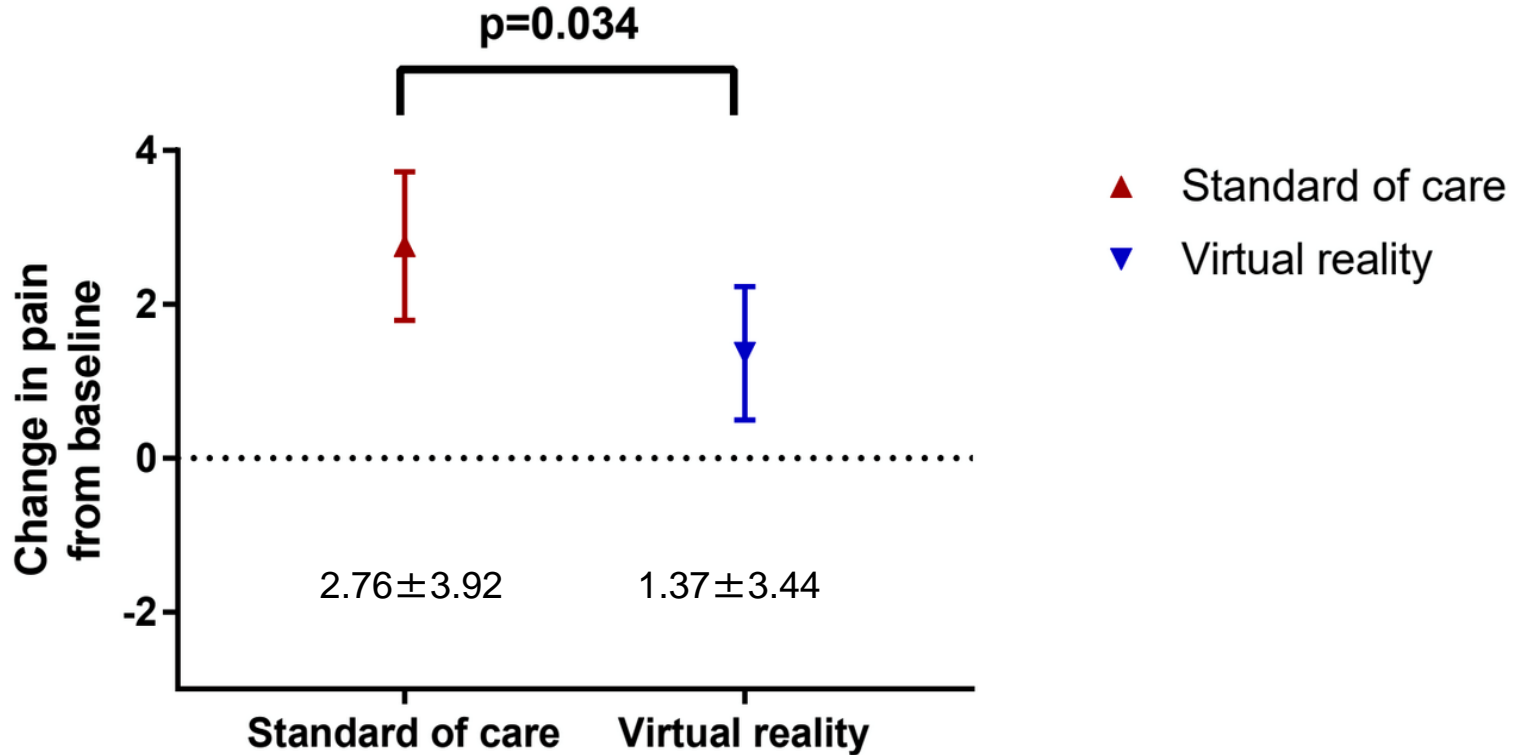
Change from baseline in Faces Pain Scale - Revised



Emergency Department



Pathology



Secondary Outcomes

Change in anxiety score from baseline (child-rated)

Caregiver-rated distress

Number of people involved in restraint / holding

Success rates

Complications



Secondary Outcomes

Emergency Department

Pathology

	Standard care n=59	Virtual reality n=64
Venipuncture / Cannulation	12/47	11/53
Change in Visual Analog Thermometer	-0.46±3.47	-2.2±4.01
Anxiety Score from Baseline, Mean±SD	P=0.011	
Caregiver rating of child distress using	4 [1-8]	1 [0-5]
Visual Analog Scale, Median (IQR)	P=0.02	
Success after 1 st attempt	45 (76.3%)	47 (73.4%)
Success after 2 attempts	55 (93.2%)	61 (95.3%)

Secondary Outcomes

Emergency Department

Pathology

Number of people required to restrain child for procedure	Standard care	Virtual reality	Standard care	Virtual Reality
	n=59	n=64	n=66	n=63
0	13 (22%)	14 (21.9%)	10 (15.1%)	19 (30.2%)
1	17 (28.8%)	39 (60.9%)	12 (18.2%)	32 (50.8%)
2	25 (42.4%)	9 (14.1%)	42 (63.4%)	11 (17.5%)
3 or more	4 (6.8%)	2 (3.1%)	2 (3%)	1 (1.6%)

Adverse effects

Emergency Department

Pathology

	Standard care n=59	Virtual reality n=64	Standard care n=66	Virtual Reality n=63
Dizziness	1	0		
Headache	1	0	1	
Nausea	1	0	1	2
Vomiting	1	0	1	1

Summary

- Virtual reality led to
 - Reduction in pain (child-rated)
 - Reduction in anxiety (child-rated)
 - Reduction in distress (care-giver rated)
 - Reduction in number of people needed for restraint / holding
 - Minor adverse effects

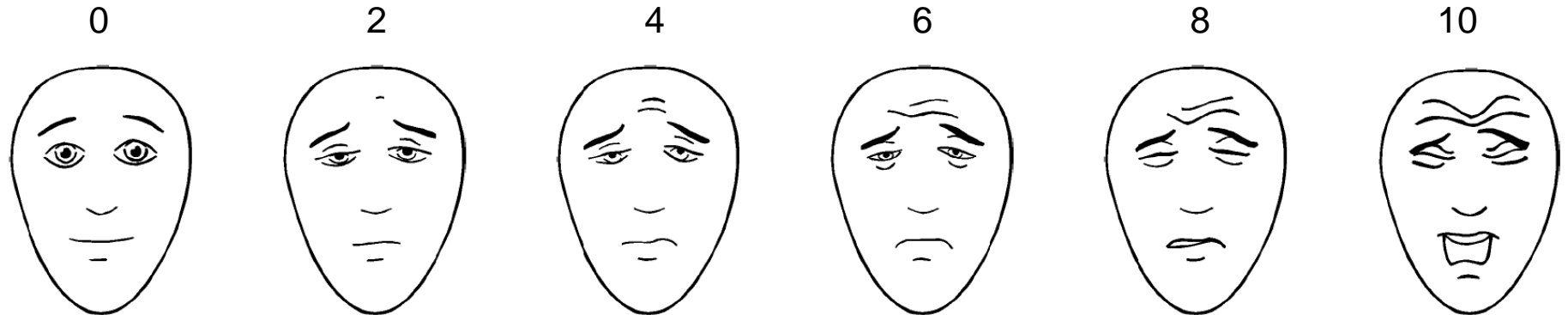


Discussion



When is a “difference” important?

- Pain reduction:
 - Emergency -1.78 units (95%CI -3.24 to -0.32)
 - Pathology -1.39 units (95%CI -2.68 to -0.11).



When is a “difference” important?

- Most pain scales validated for painful conditions rather than painful procedures
- No validation of Minimally Clinically Significant Difference in pain reduction for brief painful procedures.



Limitations

- Unblinded study
- Self-report (no observational pain scale used)
- Tertiary centres only



“The child has become
uncooperative”



Co-operation and children



Conclusion

- The VR intervention used was **safe** and **effective** in children aged 4-11 years, **decreasing needle pain, anxiety, distress and the need for restraint** in two hospital-based settings.



Future Directions

- Other applications
 - Ward
 - GP
 - Vaccination
 - Finger-pricks
 - Repeated procedures
- Does content matter?



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- Patients and families
- ED staff at Monash Medical Centre, Clayton



Questions?

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