The benefits of playing interactive games on virtual reality headsets during procedures in food allergy clinical trials

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Background

- Frequent procedures required in food allergy clinical trials often induce fear and anxiety for food-allergic participants and their caregivers.
- Fear of phlebotomy can lead to attrition in food allergy trials, which necessitates the development of interventions to mitigate fear and anxiety in food allergy trials.
- Virtual Reality (VR) has demonstrating promising results for decreasing pain and anxiety in phlebotomy in adult pediatric populations. However, the present study is the first to examine its efficacy in food allergy patients.
- VR is a 3-dimensional, computer-generated, immersive environment that can be explored and interacted with by the user.
- VR integrates both auditory and visual sensory information and can block anxiety-producing stimuli from being perceived, acting as a distraction for a user undergoing a clinical procedure.

Present Study

- This pilot study set out to determine whether Virtual Reality (VR) Headsets could be used as a tool to decrease fear and anxiety in subjects while participating in a clinical trial.

Methods

Participants

- Participants (ages 6-17) undergoing study related phlebotomy at an allergy research center were enrolled and randomized (N = 47) to a VR intervention group (n=24) or control group (n = 23).
- In the VR group, subjects played interactive games on a customized Samsung Gear VR headset during phlebotomy.
- For patients in the control group, the standard of care was provided.

Measures

- Pediatric participants completed the Children's Fear Scale (CFS), Childhood Anxiety Meter (CAM), and a pain measure before randomization and after the phlebotomy procedure.
- Using the Modified PCS-P, parents rated their anxiety surrounding the phlebotomy procedure that their child was undergoing before randomization and after the procedure.
- After the procedure, VR group participants and their parents completed a satisfaction survey and were asked whether they would recommend this intervention to others.
- After completing the procedure, phlebotomists and nurse practitioners completed a similar satisfaction survey.

Analyses

- Analyses were per-protocol, eliminating participants who withdrew after randomization or were noncompliant.
- Wilcoxon signed-rank tests were conducted using R (version 3.6) to examine between group differences in anxiety reported before and during phlebotomy, as well as the between groups difference in Induction Compliance.

Results

- Forty-seven participants (21 female) were randomized to a VR group (n=24) or a control group (n=23).
- Baseline characteristics were comparable between the VR and control groups (Table 1).
- VR participants experienced a 41.7% mean decrease in anxiety (12.5% decrease for control) and a 26.4% decrease in fear (10.3% increase for control) from baseline to post-procedure (Figure 1 and Figure 2, respectively).

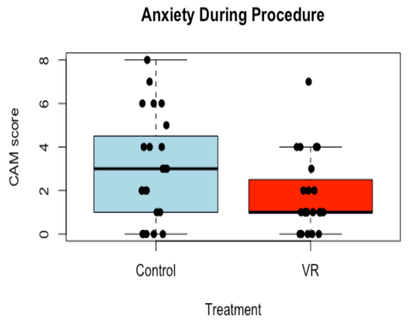

Figure 1: Childhood Anxiety Meter (CAM) scores. Scores in the VR group were lower than in the control group during the blood draw (p= 0.051). Scores were based on a scale of 0-10.

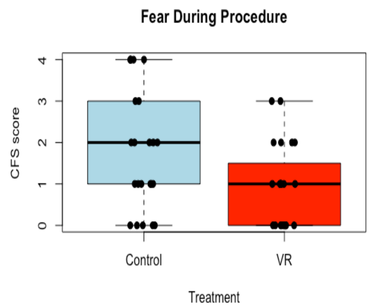

Figure 2: Children's Fear Scale (CSF) scores. Scores in the VR group were lower than in the control group during the blood draw (p=.017). Scores were based on a scale of 0-4.

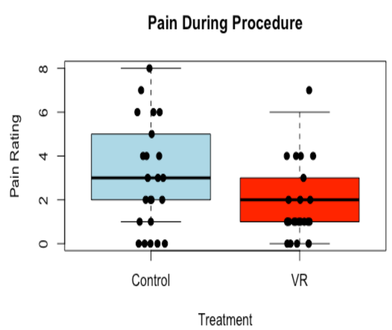

Figure 4: Pain Rating Scores. Scores in the VR group were significantly lower than in the control group during the blood draw (p=.0398). Scores were based on a scale of 0-10.

Characteristic	VR (n=24)	Control (n=23)
Age in years	13 [6, 17]	10 [7, 15]
Female	8 (33.3%)	13 (56.5%)
Non-Hispanic	22 (91.6%)	23 (100%)
Race		
Caucasian	12 (50%)	8 (34.8%)
Black	1 (4.2%)	0
Asian	10 (41.6%)	9 (39.1%)
Native Hawaiian or Pacific Islander	0	1 (4.3%)
Prefer not to report	1 (4.2%)	5 (21.7%)
Similar Experiences		
Similar procedure before	23 (95.8)	19 (95.0)
Virtual Reality-Specific		
Used VR before	17 (70.8)	
Recommend VR to other children	22 (91.7%)	
Recommend VR to other parents	22 (91.7%)	
VR during procedure was helpful	16[6, 17]	

Table 1. Summary of demographic and baseline characteristics. Continuous variables reported as median (range), categorical are count (percentage).

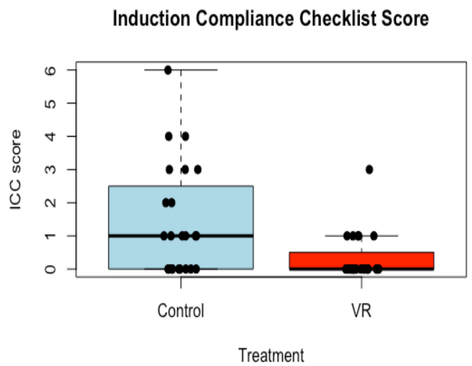

Figure 3: Induction Compliance Checklist (ICC) Score. ICC score in the VR group was significantly lower than in the control group (p=.005). Scores were based on a scale of 0 – 10 items.

- The mean CAM change for the VR group was -1.25, SD=2.49 (p=0.022) while the mean control group change was -0.43, SD=2.21 (p=0.36).
- Fear ratings decreased by 0.33, SD=1.27 in the VR group (p=0.21) and increased by 0.17, SD=0.83 (p=0.33) in the control group.
- Induction Compliance Checklist (ICC) scores differed significantly between the VR and control groups (p = .005), with participants in the control group scoring higher, meaning they showed greater symptoms of noncompliance (Figure 3).
- The mean pain rating for the VR group was 2.33 SD=1.79, while the mean in the control group was 3.61 SD=2.29. The mean difference between groups was significant (p=0.0398).

Discussion

Findings & Implications

- The ability to utilize interactive distraction tools in pediatric populations may streamline phlebotomy procedures by reducing symptoms of noncompliance, resulting in widespread positive implications for clinicians, participants, and caregivers.
- The between-groups difference in cumulative induction compliance score demonstrates that using virtual reality during phlebotomy can improve the safety of these procedures, for both patients and clinicians, through reducing potentially dangerous reactions such as kicking and flailing.
- Additionally, as determined by the between-groups ICC measure, participants who received the Virtual Reality intervention were less likely to engage crying and screaming behaviors during phlebotomy, demonstrating that Virtual Reality may reduce anxiety in both participants and other patients in their proximity through reducing unpleasant and anxiety-provoking noises.

Limitations & future directions

- As the present study compared VR to a control group that received the standard of care without other technology, future VR research should trend towards comparing VR to technology that is already prevalent and accessible for participants in clinical settings, such as television.
- Comparing VR to a control of personal electronic devices of the participants' choice may be the next step in evaluating VR.
- Studying VR under these conditions will be integral in providing evidence for clinicians to determine whether this technology is worth purchasing.
- In the present study, post-randomization withdraw for control group participants occurred on multiple occasions. An active control group may mitigate post-randomization withdraw.
- The present sample consists of predominately Caucasian and Asian participants. Future studies could benefit from recruiting a more racially diverse sample.

Conclusions

- These preliminary results suggest that playing interactive games on a VR headset could be an effective tool for reducing a participants' fear and anxiety during phlebotomy for clinical trials.
- Increasing patient and caregiver satisfaction can increase patient retention in studies.
- Increasing clinician satisfaction can improve workflow and patient interactions.
- The present study was a pilot study, with a small participant cohort. A larger cohort and greater statistical power may produce more robust findings.

Acknowledgements

We are grateful to our participants at the Sean N. Parker Center for Allergy and Asthma Research.

Funding

This work was supported by the Sean N. Parker Center for Allergy and Asthma Research at Stanford University.

*** Please contact salonzi@tulane.edu for any questions or concerns.**