

Official Title: Influence of Virtual Reality Distraction on Pain and Satisfaction During Outpatient Pediatric Orthopedic Procedures: A Randomized Controlled Study

NCT Number: NCT05510232

Document Date: July 25, 2018

OBJECTIVES:

To compare the effectiveness of VR gaming simulation to two forms of non-interactive visual distraction on reducing objective and subjective measures of pain and anxiety in pediatric patients undergoing in office cast removal or surgical suture and pin removal.

DESIGN:

The study will be comprised of two treatment arms:

- i) A casting treatment arm
- ii) A pin/suture removal treatment arm

Each treatment arm will have three groups:

- i) A treatment group that will be immersed in the VR game (Bear Blast) via the headset.
- ii) A treatment group that will have headset on and will watch a VR video
- iii) A treatment group that will watch a non-VR video via an iPad

Cast/Suture and Pins will be removed from both the upper and the lower extremities.

Headset setup will be done completely by research team and does not involve the extremities for engagement with the interface. Children in the iPad group will have iPad set up by the research team.

METHODS:***VR Headset Group:***

1. *Demographic appropriate screening for inclusion (including age and available past medical history)*
2. Patient consent (before randomization)
3. VR assembly and administration (description below)
4. Cast sawing
5. physical examination (before and after procedure)
6. pulse oximetry application (HR measured 3 minutes pre-procedure and throughout entire procedure)
7. NRS VAS pain administration (3 minutes pre-procedure and immediately post-procedure) in patients over 8 (Will mark on scale)
8. VAS Faces pain administration (3 minutes pre-procedure and immediately post-procedure) in patients under 8 years (Will point to face)
9. NRS VAS anxiety administration (3 minutes pre-procedure and immediately post-procedure) (Will mark on scale)
10. VAS Faces anxiety scale administration (3 minutes pre-procedure and immediately post-procedure) in patients under 8 years (Will point to face)
11. Patient/parent satisfaction administration (post-procedure)

Headset Video Group:

1. *Demographic appropriate screening for inclusion (including age and available past medical history)*
2. Patient consent (before randomization)
3. Video administration via headset (description below)
4. Cast sawing
5. Physical examination (before and after procedure)
6. Pulse oximetry application (HR measured 3 minutes pre-procedure and throughout entire procedure)
7. NRS VAS pain administration (3 minutes pre-procedure and immediately post-procedure) in patients over 8 years (Will mark on scale)
8. VAS Faces pain administration (3 minutes pre-procedure and immediately post-procedure) in patients under 8 years (Will point to face)
9. NRS VAS anxiety administration (3 minutes pre-procedure and immediately post-procedure) (Will mark on scale)
10. VAS Faces anxiety administration (3 minutes pre-procedure and immediately post-procedure) in patients under 8 years (Will point to face)
11. Patient/parent satisfaction administration (post-procedure)

iPad Group:

1. *Demographic appropriate screening for inclusion (including age and available past medical history)*
2. Patient consent (before randomization)
3. iPad administration (description below)
4. cast sawing
5. physical examination (before and after procedure)
6. pulse oximetry application (HR measured 3 minutes pre-procedure and throughout entire procedure)
7. NRS VAS pain administration (3 minutes pre-procedure and immediately post-procedure) in patients over 8 years (Will mark on scale)
8. VAS Faces pain administration (3 minutes pre-procedure and immediately post-procedure) in patients under 8 years (Will point to face)
9. NRS VAS anxiety administration (3 minutes pre-procedure and immediately post-procedure) (Will mark on scale)
10. VAS Faces anxiety scale administration in patients under 8 years (Will point to face)
11. Patient/parent satisfaction administration (post-procedure)

Virtual Reality Platform with Headset (administration):

VR headset will deliver VR images and sound. Patients will watch a 15-minute VR experience called Bear Blast. Bear Blast is an immersive, 360-degree, game experience that takes place in a fantasy world where the user attempts to shoot balls at a wide range of moving objects by gently maneuvering his or her head toward the targets. Bear Blast is a nonviolent and noncompetitive game that incorporates motivational music and features positively reinforcing sounds, animation, and direct messages to patients. Bear Blast will be used as the standardized game for all patients in the VR group of both study arms. The VR reality Samsung Oculus headset can be controlled entirely via head motion and does not involve the use of patients extremities. iPad will be set up and held for patients in the iPad group.

Video with Headset (administration):

Oculus headset will deliver VR video to patients. Headset will be administered before intervention and removed at the completion of the intervention unless patient requests otherwise. Patients visual field will not change with head motion and will remain static throughout cast removal or pin/suture removal.

A standardized age appropriate video will be used for patients between ages 4-14. The selected videos will be the same for both the cast and suture/pin removal groups.

Video with iPad (administration):

The iPad is a tablet computer first offered by Apple in 2010. The device resembles a much larger version of Apple's iPhone or its iPod Touch, and is about the same size as a magazine. The iPad uses the same operating system as the Apple iPhone, and uses very similar hardware. iPad will be used to deliver non VR video to patients.

A standardized age appropriate video will be used for patients between ages 4-14. The selected videos will be the same for both the cast and suture/pin removal groups.

STATISTICAL ANALYSIS PLAN:

- **Statistical test (T-test, ANOVA, chi-square, regression, etc):** One-way analysis of variance (ANOVA)
- **Alpha level:** 0.017
- **Beta or power level:** 0.899
- **Primary outcome to be measured (and how it will be operationalized):** Heart rate in each study group. A mean of +6.7 beats per minute and standard deviation 1.4 has been previously reported in an outpatient pediatric orthopedic population.
- **Number of groups being compared (use 1 for paired analysis):** 3
- **Effect size or change expected between groups:** 15% difference in the increase in HR from baseline to the maximum rate during the procedure, and therefore assuming a true difference in the experimental and control means is greater than 1 beat per minute.
- **Resulting number per group and total sample size:** 35 per groups, 105 total