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**ORIGINAL ARTICLE** 

# Virtual reality in the outpatient: reducing anxiety and fear in venous puncture

Realidad virtual en el paciente ambulatorio: reduciendo la ansiedad y el miedo en la punción de vías venosas

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# What do we know about the subject matter of this study?

Virtual reality headsets have been successfully used to reduce pain in burn healing, lumbar punctures, and venipunctures worldwide.

# What does this study contribute to what is already known?

Through a clinical trial in a Spanish population, focused on the outpatient, we demonstrated that the use of VR headsets reduces anxiety and fear related to venipuncture. The perception of pain correlates positively with that of anxiety. The venipuncture technique maintains the same success and duration as in the control group.

# **Abstract**

Up to 80% of children admitted to a hospital experience pain, mainly associated with venipuncture. **Objective:** To analyze whether the use of virtual reality (VR) headsets during venipuncture can modify the perception of pain, anxiety, and fear in pediatrics. **Patients and Method:** Open label, randomized clinical trial. The presence of intellectual, visual, or hearing impairment were considered exclusion criteria. Two anxiety and fear scales were administered before and after the procedure, and the Wong-Baker face pain scale at the end. The following were recorded: number of venipuncture attempts, duration of the procedure, and side effects. **Results:** 78 patients were included, 38 males and a mean age of 9.63 years. In the intervention group, the mean pain value was 2.87, with a mean difference (MD) of -0.85 compared with the control one (95% confidence interval (CI) -2.02 to 0.33). There was a significant reduction in the level of anxiety and fear, with MDs of -2.59 (95%CI: -3.92 to -1.26) and -0.85 points (95%CI: -1.45 to -0.24), respectively. **Conclusions**: the use of VR headsets in venipuncture in hospital daytime care decreases the level of anxiety and fear in children and seems to reduce pain, without adverse effects. The venipuncture procedure has the same success rate and does not increase its duration.

Keywords:

Virtual Reality; Anxiety; Acute Pain; Fear;

Peripheral
Catheterization

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# Introduction

If we ask parents what they expect from health care, they will ask for professionalism, speed, and human quality. If we ask the child, her/his answer will differ: "I don't want to be afraid", "I don't want to be alone", "I don't want to be in pain"<sup>2</sup>.

Pain is a subjective, complex symptom in which various factors are involved, including the patient's degree of anxiety. Up to 80% of children admitted to a hospital, either for acute or chronic processes, are in pain, either produced by the disease itself or by the procedures performed during their stay<sup>1,3,4</sup>. A 2018 paper reports that the highest number of painful experiences (48.5%) in children requiring health care is related to venipuncture techniques<sup>5</sup>. In the same year, a systematic review with meta-analysis (MA)<sup>6</sup> on non-pharmacological pain management methods in this procedure showed a significant decrease in pain perception using distraction techniques, hypnosis, and cognitive behavioral techniques. A 2019 meta-analysis, which included 10 controlled clinical trials in children under 3 months of age, compared pharmacological measures (such as topical anesthetics) with non-pharmacological methods. The analysis concluded that pharmacological measures offer little or no benefit and may have side effects like methemoglobinemia<sup>7</sup>.

In our hospital, the use of non-pharmacological methods for pain management is common. Both in the emergency room and in the hospital ward, a child-friendly environment is provided, with decorations, uniforms, adequately trained personnel, and encouraging parental guidance. In addition, small rewards (drawings, stickers), toys, and other distractions (songs, caresses) are offered during the procedure. Pharmacological measures are not used. Despite the use of these measures, pain is still perceived in the child undergoing venipuncture.

The use of virtual reality (VR) headsets may reduce pain and anxiety related to venipuncture in outpatients. It would function as a non-pharmacological distraction method, based on the child's attention being focused on a stimulus other than pain. VR headsets have been used in recent years in healthcare settings during venipuncture<sup>8</sup>, wound and burn healing<sup>9</sup>, in preoperative anxiety, for the treatment of chronic or recurrent pain<sup>10</sup>, for dental procedures, and general routine medical procedures, proving to be effective in reducing anxiety and pain.

The objective of this study was to analyze whether the use of VR headsets during venipuncture can modify the perception of pain, anxiety, and fear in children between 5 and 12 years of age attending the hospital during the day.

# **Patients and Method**

Randomized, open-label clinical trial in children attending a secondary hospital for venipuncture during the day, either for medication administration, blood sample collections, or peripheral line placement for a sedation procedure was carried out. Patients were recruited from the outpatient pediatrics department, mainly from the gastroenterology, endocrinology, and hematology units.

Inclusion criteria were set as follows: patients aged between 5 and 12 years attending the day hospital who were to undergo venipuncture. The presence of any condition involving intellectual, visual, or hearing disability was considered an exclusion criterion. Parental consent and signature of informed consent were required. Since children aged up to 12 years were involved, informed assent was not requested.

The sample of patients was obtained by consecutive sampling. The sample size was calculated using the GRANMO software (https://apisal.es/investigacion/Recursos/granmo.html) to detect a mean difference of at least two points on the faces pain scale with a common standard deviation of 2.93 according to previous studies, with an alpha error of 5%, a power of 80%, and replacement rate of 10%. The proposed sample size is 78 children.

Simple randomization was performed in two groups using the Epidat 4.2 software (Consellería de Sanidade, Xunta de Galicia, Spain; Pan American Health Organization; *Universidad CES*, Colombia; July 2016). In the control group (CG), venipuncture was performed with the non-pharmacological measures already described. In the intervention group (IG), the usual measures were used, and they were provided with a VR headset (Oculus Quest®, Meta) to display a projection or game during the procedure. Two apps were chosen (Nature Treks VR and Ocean Rift) in which the children did not have to move their hands, according to the age of each patient.

After acceptance to participate in the study, the following validated scales were used: 1) the anxiety thermometer, which measures anxiety for procedures with a score from 0 to 10<sup>11</sup> and it was given to the children before and after the procedure; 2) the children's fear scale, which measures children's fear during painful procedures, was given to the patient and parents<sup>12</sup> before and after the procedure and is scored from 0 to 5; and 3) the Wong-Baker faces pain rating scale (with authorized use) to measure pain, which was given exclusively to the children at the end of the procedure, with a score from 0 to 10 (figure 1). The Spanish translation of the English legend was added to the anxiety thermometer.

During the procedure, the number of venipuncture

attempts, the procedure duration (measured from the time the patient was placed on the stretcher for blood collection to the end of blood collection, the exact moment of compression), and the occurrence of any undesired event were recorded. General demographic data were collected. The procedure was performed by two pediatric specialist nurses, who explained the study, obtained informed consent, placed the VR headset, performed the procedure, gave the scales, and recorded the data in the appropriate chart.

The main outcome variable was the mean difference (MD) of pain between the groups and the secondary variables were MD of anxiety and fear in parents and children after venipuncture, duration of the procedure, and success rate of venipuncture at first attempt. An intention-to-treat analysis was performed.

Categorical variables were described as percentages, and continuous variables as mean and standard deviation (SD) in case of normality (Kolmogorov-Smirnov and/or Shapiro-Wilks) or as medians and interquartile ranges otherwise. Bivariate analysis of categorical variables was performed using the chi-square test, and the difference of means of continuous variables using the Student t-test and the Mann-Whitney U test since normality criteria were not met in the outcome variables. The correlation between the quantitative outcome variables was evaluated using Spearman's coefficient. Statistical analysis was performed using SPSS v23 (IBM) software.

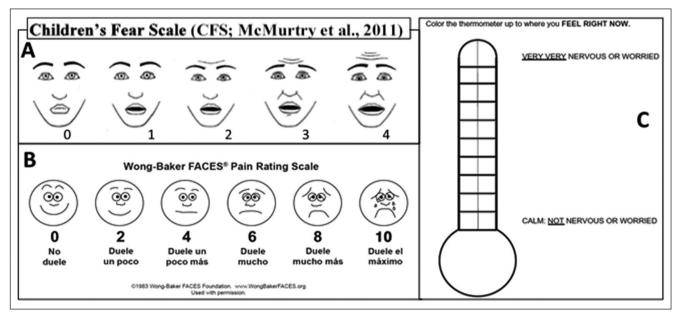
This project was approved by the hospital's Research Ethics Committee (study 082-21, favorable report). The VR headsets were donated by the non-profit organization *Voluntechies* (Voluntechies.org).

#### Results

Between February 2022 and October 2023, 83 patients were offered to participate in the study, 5 of them refused to sign the informed consent. 78 patients were included, 38 (48.7%) were male, median age of 9.63 years, and interquartile range (IQR) of 4.14. The reasons for venous puncture were to collect a sample for analysis in 74.4% of the cases and to administer intravenous treatment in the rest, including procedural sedation. Table 1 shows their baseline characteristics, which show a greater difference than expected in sex between the IG and CG (most being male), with the rest of the variables being homogeneous. The children had a mean pre-procedure anxiety score of 4.15 points and a fear score of 1.38, with parents' fear of the child's face being greater than that reported by the child.

After the procedure, a global pain assessment score of 3.29 points with a standard deviation (SD) of 2.63 was obtained. In the IG, a score of 2.87 (SD 2.52) was obtained with an MD of -0.85 points on the rating scale for the IG (95%CI: -2.02 to 0.33), although this value was not statistically significant. In contrast, the reduction in the level of anxiety and fear, perceived by both parents and children, showed statistically significant differences (table 2), with an MD of -2.59 in perceived anxiety (95%CI: -3.92 to -1.26) for the IG and a decrease in fear reported by the children of 0.85 points (95%CI: -1.45 to -0.24). The MD of parents' perceived fear was higher, reporting -1.28 points (95%CI: -1.90 to -0.66).

In the Spearman's Rho correlation analysis performed between the results of the anxiety and fear scales



**Figure 1.** Scales. **A)** Fear scale for children, scored from 0-4. **B)** Wong-Baker face scale, scored from 0-10. **C)** Thermometer for anxiety, scored from 0 to 10 depending on the squares that the child paints.

with pain, a correlation coefficient of 0.622 (p < 0.001) and 0.457 (p < 0.001) was observed between perceived fear after puncture and pain and between anxiety after puncture and pain, respectively. These values were significant both in the total sample and in the CG and IG (table 3).

Regarding the puncture technique, the sample collection or venous line placement was successful on the first attempt in 71 cases and the mean duration of venous puncture was 97.63 seconds, with no differences between the two groups in either case (table 2).

A study was carried out by subgroups according to sex, reason for venipuncture (venous line placement or sample collection), and age, dividing the sample into three groups (5 to 7 years, 8 to 9 years, and over 10 years) showing no statistically significant differences in pain reduction.

No side effects were reported in any case. Only one child, from the IG, removed the VR headset during the procedure.

### Discussion

Our study shows that, in school-age children attending the day hospital, the use of VR headsets reduces pain after venipuncture, although not significantly. Anxiety associated with venipuncture is reduced by more than two points on a scale of 10, and fear by almost one point on a scale of 4. The reduction in pain shows a moderate correlation with the reduction in the levels of fear and anxiety, therefore, according to our results, the lower the perception of fear and anxiety, the less pain there will be. The use of the VR headset does not affect the duration of the technique, nor does it increase the difficulty of the procedure, as can be

seen in the first attempt success rate of almost 90% in the IG, similar to that of the CG.

The group of patients studied, outpatients in the day hospital, may be similar to the patients who come to primary care for analysis since they are not hospitalized patients, nor do they have acute or chronic complex pathologies that make them carriers of vascular catheters, so, although the study is not specifically carried out in children in primary care, we believe that the results could be extrapolated.

In the work published in 2023 by Wong<sup>13</sup>, they plan and carry out stratification by age in two groups, from 4 to 7 years and from 8 to 12 years and observe that the reduction in pain is significant only in the group from 4 to 7 years and immediately after the puncture, without being significant in older children, nor when measured 30 minutes after venous puncture. To investigate whether there might have been a similar effect in our sample by age and sex, we performed the subgroup analysis described above, but in our study, we could not find a similar effect either by sex, despite the differences described in the randomization, or by age or reason for venipuncture.

Our results are in line with those obtained in other similar studies. A randomized clinical trial (RCT)<sup>13</sup>, published in 2023, with the use of VR not only as a distraction but also adding an explanation of the procedure. It measures pain and anxiety at the end of the procedure and shows a reduction in the pain scale (MD -0.78; 95%CI: -1.21 to -0.35) and anxiety (MD -0.41; 95%CI: -0.76 to -0.05) with values similar to those obtained in other studies. This study did not include a group that did not receive an explanation of the procedure through the VR headset, so its effect cannot be analyzed. It also observed a greater effect in the younger age group, which was not found in our study.

	Total	Control group	Intervention Group	
Age*	9.25 (4.2)	9.83 (4.12)	9.30 (4.59)	
Sex^				
Male	38 (48.7)	14 (35.9)	24 (61.5)	p < 0.05
Famale	40 (51.3)	25 (64.1)	15 (38.5)	·
Indication for venipuncture^				
Blood test extraction	58 (74.4)	26 (66.7)	32 (82.1)	
Venous cannulation	20 (25.6)	13 (33.3)	7 (17.9)	
Pre-procedure anxiety	4.15 (2.70)	4.62 (2.77)	3.69 (2.60)	
Pre-procedure fear#				
Children	1.38 (1.07)	1.44 (1.17)	1.33 (0.98)	
Parents	1.73 (1.30)	1.87 (1.12)	1.59 (1.16)	

Table 2. Values obtained in the differents scales in the contro	I and intervention groups
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_	Post-puncture		Mean differences	Mann-Whitney Test
	Control group	Intervention group	post-puncture^	post-puncture
Pain*	3.72 (2.70)	2.87 (2.52)	0.85 (-0.33 a 2.02)	p 0.129
Anxiety*	5.12 (3.19)	2.54 (2.67)	2.59 (1.26 a 3.92)	p 0.000
Children fear*	1.84 (1.44)	1 (1.24)	0.85 (0.24 a 1.45)	p 0.000
Parents fear*	2.13 (1.54)	0.85 (1.16)	1.28 (0.66 a 1.90)	р 0.000
Success on the first puncture#	92.5	89.7		р 0.697
Time (seconds)	93.5	101.66		p 0.775

Table 3. Correlations between pain and anxiety/fear after procedure

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	Pain
Postpuncture anxiety	0.457
Control group	0.559
Intervention group	0.331
Postpuncture fear	0.620
Control Group	0.658
Intervention Group	0.552
Statistical significance (Rho Sperman)	р 0.000

Another paper published in 2019<sup>14</sup> evaluated the use of VR and projected content (roller coaster vs. traveling through the ocean) comparing it with a control group, finding no differences between the groups with different visualized content, but with respect to the control group, in which there is a 20% increase in fear and 34.1% increase in anxiety levels. An Australian study carried out an RCT in two departments: the emergency department and the outpatient one, in both of which a significant reduction in pain was demonstrated with the use of VR<sup>15</sup>. In this case, the patient's baseline pain is considered, which in our case was not measured as they were day hospital patients with no acute pathology at the time of the intervention.

In our study, two specialist nurses performed the venipuncture on all the participants, which may have avoided bias due to the experience of the professionals and allowed for homogeneity in the explanations given to families and children at the time of data collection. A similar organization has been described in other studies<sup>8,14</sup>. The subjective impression of the nurses in charge is that, despite the additional time needed to prepare the VR headset (adjustment of the helmet and defining the play area), this time is offset by the good acceptance by the patients and their parents. It could

be said that the level of difficulty in using the VR device is low.

As a limitation, it can be pointed out that it is not possible to blind patients or the staff to the study, so there may be an unquantified placebo effect. Patients were recruited in a single setting (day hospital), so there is no guarantee that the results can be extrapolated to other settings, such as primary care. We did not collect other data that could have acted as confounders, such as a history of previous venipuncture or regular use of a VR headset at home, but a recent study that did collect these data did not demonstrate their influence<sup>13</sup>.

#### Conclusion

The use of VR headsets during venipuncture procedures in the day hospital reduces the level of anxiety and fear among children and their parents, and produces a non-significant reduction in pain, with no adverse effects. The venipuncture procedure has the same success rate as in children in whom it was not used and does not increase the duration of the procedure. For this reason, it is proposed as a distraction technique that could be available in places where venipunctures are performed (primary care, hospital outpatient clinics, hospital admission, or emergency departments) as another tool to reduce children's fear and anxiety before visits to health centers.

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#### Note

Authorization is available for the use of the Wong-Baker scale. The anxiety and fear scales are free to use.

# **Ethical Responsibilities**

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

**Data confidentiality:** The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

#### **Conflicts of Interest**

Authors declare no conflict of interest regarding the present study.

# Financial Disclosure

Authors state that no economic support has been associated with the present study.

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