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CLINICAL TRAIL

The effect of virtual reality versus standard-of-care treatment on pain perception during paediatric vaccination: A randomised controlled trial

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Abstract

Aims and Objectives: To determine the effect of immersive virtual reality (VR) on perceived pain and fear in children during vaccination and parental satisfaction with the procedure.

Background: Virtual reality can reduce the perception of pain by children but only three studies have analysed its use during vaccination to date; these had small sample sizes and imperfect methodological designs.

Design: A randomised controlled clinical trial.

Methods: One hundred and sixty participants from the Tres Forques Health Center were randomly assigned to the intervention group (IG) ($n=82$) in which distraction with immersive VR was used during the vaccination, while standard distraction techniques were used for the control group ($n=80$). The primary outcome was pain (Wong–Baker FACES). Secondary outcomes included (Children's Fear Scale) and parental satisfaction with the vaccination procedure. Chi-squared tests were used for qualitative variables, relationships between quantitative variables were tested with Spearman correlations, and Mann–Whitney *U*- or Student *t*-tests were employed to assess the relationship between quantitative and qualitative variables.

Results: Compared to the controls, the children in the IG reported significantly less pain and fear, while parental satisfaction was significantly higher. Reported pain and fear did not differ according to the sex of the patient. Child age was not linked to fear but was related to pain: the younger the patient, the greater the pain they described.

Conclusions: Immersive VR effectively controlled pain and fear in children during vaccination and increased parent satisfaction with the vaccination process. Patient sex did not influence the level of pain and fear but age did.

Relevance to clinical practice: Improving vaccination experiences can reduce perceived pain and fear in children and increase parent satisfaction, thereby enhancing vaccination schedule adherence and improving group immunity.

Reporting Method: The CONSORT Statement for non-pharmacological randomised clinical trials were followed.

KEYWORDS
ambulatory, care, child, child behaviour, child nursing, clinical, clinical trial, effectiveness, vaccination

1 | INTRODUCTION

The International Association for the Study of Pain (Merksey & Bogduk, 1994) defines pain as: 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage'. Pain is a complex and multidimensional subjective experience that depends on how individuals integrate and perceive the experience. This perception can be influenced by emotional, psychological, pathological, genetic and cognitive factors. Therefore, perceived pain is not always directly related to impulse or nociceptive transmission (Malfliet et al., 2017).

The assessment and treatment of pain in the paediatric population has received very little academic attention in recent decades (García Sánchez et al., 2015). This may be because of misconceptions about the ability of children to perceive pain or because professionals are unaware of possible analgesic alternatives (García Sánchez et al., 2015). Furthermore, evaluating pain and its prevention is directly related to the participants and their guardians' (mother, father, or legal guardian, hereinafter referred to as 'parents') satisfaction with the performance of the healthcare their child receives. Family satisfaction is an important outcome in the assessment of the quality of care provided and is closely related to the use of the health system (Fernández-Pérez & Sánchez, 2019).

Pain can be caused, among other reasons, by diagnostic or therapeutic procedures (Travería Casanova et al., 2010), including the administration of vaccines by needle-puncture injections. Given that this is the most frequently performed painful procedure in the paediatric population, the Vaccine Advisory Committee of the Spanish Association of Paediatrics (García Sánchez et al., 2015), has published evidence-based recommendations for controlling the pain and stress caused by vaccination procedures with the aim of mitigating the undesirable effects of pain.

Among the recommendations with strong evidence are (García Sánchez et al., 2015) as follows: (a) allowing infants to breastfeed during the injection and when not possible, the oral administration of glucose or sucrose solution prior to injection; (b) the synergistic use of topical anaesthetics in the form of an ointment, when applied sufficiently in advance; (c) distraction manoeuvres such as reading a story, listening to music, or using electronic devices for children aged 2 to 19 years and (d) implementing certain technical-procedural aspects, specifically: avoiding the supine position and favouring skin-to-skin contact in infants, or administering vaccines quickly and without aspiration in older children while they are supported by their parents.

What Does this Paper Contribute to the wider Global Community?

- Distraction measures during vaccination can further reduce children's perceptions of pain and fear.
- The decrease of pain and fear will not only improve the experience of paediatric patients but will also increase the satisfaction of both parents and children.
- Better outcomes on pain, fear and satisfaction can enhanced vaccination schedule adherence and leading to improved group immunity and greater protection of our entire population.

2 | BACKGROUND

Of all the previously described recommendations, distraction is included in the group of psychological interventions, and was also included in the latest Cochrane review of the use of these interventions as analgesic methods (Birnie et al., 2018). These authors found evidence for the efficacy of distraction, hypnosis, cognitive behavioural therapy and breathing techniques to decrease the pain caused by needle-puncture procedures in children and adolescents. They cite reading, watching a movie, listening to music, playing video games and virtual reality (VR), as possible forms of distraction. Indeed, several studies have shown that the use of distraction techniques reduces pain in children (Birnie et al., 2018; Bukola & Paula, 2017; Uman et al., 2018).

Of all the possible forms of distraction, the most novel is VR. This technology has become much more prevalent in recent years, especially in health provision settings (Wiederhold & Riva, 2019). In this context, multiple studies have investigated the use of VR as a distraction measure during painful procedures such as venepuncture (Birnie et al., 2018; Eijlers et al., 2019; Gold & Mahrer, 2018), tooth extraction (Niharika et al., 2018), bone marrow aspiration or biopsy (Glennon et al., 2019), or in the treatment of burns (Ford et al., 2018). Research is also being carried out on the application

of VR in treatments designed to help individuals overcome phobias (Wiederhold & Riva, 2019), eating disorders (Wiederhold & Riva, 2019) or for rehabilitation of the extremities in people who have suffered a myocardial infarction (Schuster-Amft et al., 2018).

To the best of our knowledge, to date only three studies (Althumairi et al., 2021; Chad et al., 2018; Chang et al., 2022) have analysed the use of VR during vaccination, with them all describing its effectiveness in reducing fear (Althumairi et al., 2021; Chad et al., 2018; Chang et al., 2022) and pain (Althumairi et al., 2021; Chad et al., 2018). However, it should be noted that these studies also had a series of limitations. First, the publication by Chad et al (2018). was a pilot study without a control group that used a convenience sample ($n = 17$) and had employed non-immersive VR equipment through a smartphone. The study by Chang et al (2022). was a randomised controlled pilot trial with a sample of 30 children (15 for each study group). Finally, the research by Althumairi et al (2021). was a descriptive cross-sectional comparative study of VR ($n = 53$) versus a control group ($n = 50$), where assignment to the study groups was not random but rather, depended on the preferences of the parents.

VR allows users to become immersed in a 'virtual world' thanks to the multimodal sensory experience it creates based on visual, auditory, and tactile stimuli (Gold & Mahrer, 2018). This is achieved by using a special headset which projects a virtual environment in front of the user's eyes (Eijlers et al., 2019). The ability of VR to reduce pain is based on the fact that users' immersion in the VR environment means that they will be less able to devote their attention to the perception of the painful stimulus (Eijlers et al., 2019).

Attention and distraction are two of the most effective cognitive factors in modulating the sensory and affective aspects of pain (Malfliet et al., 2017). A painful signal may be interpreted as more or less intense depending on what the person is thinking at the time (Hoffman, 2004). The way in which individuals process information is limited if all their attention is focused on one task, because this focus diminishes their ability to pay attention to other tasks (Wahn & König, 2017). Consequently, distraction is a useful non-pharmacological tool that can be used to decrease pain and anxiety (Degen et al., 2010).

The use of non-pharmacological measures to prevent pain in children during vaccination is an important indication that must be respected and is one which encourages excellence in nursing clinical practice. This requirement is reflected in the *NIC-1400: Pain Management* nursing intervention, and in its related activities as follows: (a) prevent pain when possible during procedures such as venepuncture; (b) select and implement measures (pharmacological, non-pharmacological, and interpersonal) that facilitate pain relief, if appropriate; (c) teach the use of non-pharmacological techniques (feedback, transcutaneous electrical nerve stimulation, hypnosis, relaxation, guided-imagination skills, music therapy, distraction, game therapy, activity therapy, acupressure, application of hot/cold stimuli, and massage), before, after, and if possible during painful activities, before pain occurs or increases, and along with other pain relief measures and (d) ensure the adequate use of pre-treatment and/or non-pharmacological analgesia strategies before carrying out painful procedures (Bulechek et al., 2012).

On the one hand, the right to pain relief is common to all people and is the responsibility of health personnel; it is included in the Hippocratic Oath and in the Declaration of Geneva (Martínez Caballero et al., 2015). On the other hand, systematic vaccination of the paediatric population is one of the greatest public health successes worldwide and has led to the prevention, and even the eradication, of multiple communicable diseases. Compliance with vaccination schedules is a public health priority because it protects the entire population, not only those who are vaccinated (World Health Organization, 2015).

Considering all the above, and given that, to date, no studies published in the academic literature have analysed the use of VR in vaccination, investigation to ascertain whether this new technology can effectively control the pain and fear caused by vaccination in the paediatric population is still required. Thus, in this study we will compare the VR intervention group (IG) to the standard-of-care control group (CG) in paediatric patients receiving a vaccination. This will not imply a choice of comparator conflict because current evidence also indicates that traditional distraction measures are useful for pain control in children during painful procedures such as vaccination, as indicated by the Spanish Association of Paediatrics Vaccine Guidance Committee (García Sánchez et al., 2015).

Adequate pain management is not only a child's right and a responsibility of the nursing profession, decreased pain and fear during vaccinations will also improve parent and child satisfaction, thus increasing adherence to vaccination schedules. Considering that any children who meet any of the criteria indicating that VR may pose a health risk to them, namely: children aged under 3 years (World Health Organization, 2019) or with a history of seizures or dizziness (Won et al., 2017), will be excluded from this study, none of the distraction techniques we will use in the IG or CG will pose a risk to the health of any of the participants. Children will benefit most from the distraction mechanisms that prove most effective in reducing their pain and fear during vaccination.

The main objective of this registered report was our analysis of the effects of immersive VR on pain perception in the paediatric population during vaccine administration. We also investigated the effects of immersive VR on the fear experienced by children during the vaccination procedure, as well as parental satisfaction with the vaccine administration. Finally, we tried to determine if any of the sociodemographic variables of the children were related to their perception of pain and fear during the vaccination procedure or with their parents' satisfaction with the vaccination procedure. Our hypothesis was that the perception of pain and fear in children in the IG would be lower than that in the CG, and that parental satisfaction levels would also be higher for the IG.

3 | METHODS

3.1 | Study design

This study was conducted in Spain as a two-armed, single-centre, single-blinded (data analysts), randomised controlled trial comparing two conditions: IG (immersive VR) and CG (standard-of-care). The randomised controlled trial report adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomised trials of non-pharmacological treatments (Boutron et al., 2017) (File S1). The study protocol was registered at ClinicalTrials.gov with reference number NTC04096833 and has been accepted for publication in the Journal of Clinical Nursing (manuscript: JCN-2020-0668.R2).

3.2 | Study setting and population

This study population comprised children aged between 3 and 14 years (both inclusive) in the Tres Forques Health Centre catchment area and scheduled for vaccination from March 2021 to June 2023.

3.3 | Inclusion and exclusion criteria

The inclusion criteria for participation in the study were the following: (a) children aged 3 to 14 years inclusive, who had come to the Paediatric Nursing Consultation facility at the Tres Forques Health Centre (Spain) for immunisation within the systematic vaccination program; (b) children accompanied by their parent during the procedure; (c) both the child and their parent understood and spoke Spanish or were accompanied by a translator; and (d) parents who had consented to participation in the study by signing the informed consent document while also considering the wishes of the child based on their age and level of maturity.

The exclusion criteria were as follows: (a) children with sensory problems that prevented the use of VR; (b) children with a sensory impairment of pain perception (e.g. spina bifida); (c) children who had taken an analgesic medication on the day of the vaccination (either orally or topically at the injection site); (d) children with a history of seizures or dizziness; (e) children accompanied by a caregiver other than their parent; (f) children who had already participated in this study; and (g) children and parents who, due to their sociocultural or maturity level, were unable to understand any of the questionnaires.

3.4 | Sample size calculation

To carry out the sample calculation, we considered the study by Semerci et al (Semerci et al., 2020). which had similar characteristics to our proposal: it was a randomised clinical trial that had evaluated the efficacy of VR compared to the standard-of-care to reduce pain (measured by Wong–Baker FACES pain scale) associated with venous port access in a paediatric oncology population. The data they used were the mean and standard deviation (*SD*) for VR = 2.34 points (*SD* = 3.27) and standard-of-care = 5.02 points (*SD* = 3.35). We performed the calculation with 99% power and 95% confidence, using the following formula to calculate the sample size to adequately detect a difference in the means:

$$n = \frac{\left(S_1^2 + S_2^2\right) \times \left(Z_{\alpha/2} + Z_{\beta}\right)^2}{\left(\overline{X}_1 - \overline{X}_2\right)^2}$$

$$S_1^2 = 3.27 \quad S_2^2 = 1.13 \quad Z_{\alpha/2} = 1.96$$

$$Z_{\beta} = 1.28 \quad \overline{X}_1 = 2.34 \quad \overline{X}_2 = 1.28$$

The sample calculation was carried out with EPIDAT software (version 4.2), giving a result of $n = 57$ per group with a total of 114 participants. We adjusted this sample size to accommodate potential losses of 30%, therefore the adjusted sample size was $n = 148$. Consequently, no new participants were included in this study to replace any lost patients. In addition, the effect size was calculated using Cohen's *d*, based on the means and *SD* of the results obtained by Semerci et al (2020). The effect size was high, with $d = .809$.

3.5 | Sampling

Children aged between 3 and 14 years who had come for vaccination at the Tres Forques Health Centre between March 2021 and June 2023 were selected consecutively until the required sample size was obtained. Children came to be vaccinated according to their month of birth.

3.6 | Randomisation

An independent researcher unaware of the study characteristics performed the randomisation process. In order to randomly allocate the participants to 1 of the 2 conditions (IG or CG), a computer-generated random number sequence was used (SealedEnvelope™ software). To reduce the predictability of the random sequence and to ensure a 1:1 ratio, 'random permuted blocks' were also used. This sequence was password-protected in a table guarded by the PI and was concealed to the other researchers throughout the study.

3.7 | Blinding design

The study design did not allow treatment allocation to be blinded either to the nurse or the participants. However, the data analysts were blinded to the treatment allocation group (the IG was

numerically coded). To avoid inter-observer variability biases, the measurements were made by the same nurse in every case.

3.8 | Intervention

The study intervention was conducted during the time scheduled for the Healthy Child Programme appointments during which the vaccinations were programmed and they did not require any more time than is usually scheduled (around 30 min). Because the vaccination procedure is carried out by nursing professionals, both the recruitment and the intervention was completed by the paediatric consultation nurse at the health centre where the study was conducted. One nurse performed the procedure in all the study participants in order to reduce variability in the injection technique. The procedure and intervention phases, as well as the estimated times required for each one, are detailed below. With the aim of standardising the intervention, an algorithm was designed to select the participants (File S2), as also shown in the intervention phases diagram (File S3).

3.8.1 | Information for the users of the healthcare centre

To publicise the project among the centre's users and facilitate the nurse's work during the patient recruitment phase, we created an infographic to show basic information about the research, who can participate, and how the study would be carried out. This infographic was posted in the health centre's paediatric service waiting room 3 months before the research started.

3.8.2 | Participant recruitment

The nurse took advantage of scheduled vaccination appointments to recruit potential participants who met the inclusion criteria, in each case informing the parents about the research and answering any questions they may have had. This took an average of 2 min and took place in the nursing consultation room.

3.8.3 | Reading and signing the informed consent and anonymising it

Once the parents agreed to participate in the study, they had to read and sign the informed consent document; they were then assigned a numerical code to anonymise their data for future analysis. These numerical codes were linked chronologically to a random sequence (previously generated using SealedEnvelope™) assigned to each participant for their allocation to the IG or CG. We estimated that 5 min and 30 s, respectively, were required to read and sign the informed consent document and for participant encoding. This took place in the paediatric nursing consultation room.

3.8.4 | Measurement and recording of the pre-injection variables collected by the nurse

The child's heart rate was measured in the paediatric nursing consultation room before preparing the vaccine (estimated time required: 1 min).

3.8.5 | Intervention

When the nurse discovered which group the participant would belong to (the IG or CG), they performed the corresponding intervention. As the distraction measure, the IG viewed an immersive VR experience appropriate to all ages through a VR headset while remaining seated, alone, and without any physical contact from their parent (without picking them up, talking to, or touching the child). The VR program includes vision and sound of 4 scenarios in a 360° environment, which appear cyclically with a duration of 2 min per scenario. The virtual environments are: desert with cows and snakes, polar environment with penguins, polar bear and stars, field with cows and forest with moles. Figure 1 shows snippets of the software and VR headset (Oculus Go, Oculus VR). The VR immersion started 5 min before the injection (while the nurse prepared and recorded the vaccine details) and continued during the vaccination procedure. Once the headset was put on, if the child decided they did not want to wear it, it was removed and the participant was considered a case lost to the study. This stage lasted an average of 5 min.

Standard-of-care distraction was applied in the CG, which included the child being held in their parent's arms or the maintenance of physical contact (e.g. by touching their hands or talking to them), playing with books or musical toys, and/or playing or watching videos on their parent's mobile phone. The estimated time required for the vaccination in both the IG and CG was 1 min and this took place in the paediatric nursing consultation room in both cases.

3.8.6 | Measurement and recording of the post-injection variables by the nurse

The child's heart rate and vaccination data (combination of several injections in the same session) were recorded by the nurse in the paediatric nursing consultation room after having vaccinated the child. This took about 1 min.

3.8.7 | Recording the pain and fear variables experienced by the child immediately after the injection

The nurse explained to the child (by reading the authors' instructions for use) how to fill in the scales used to measure these variables. The child completed the two scales in the paediatric nursing consultation room. This task took about 2 min.

FIGURE 1 Virtual reality headset and nippets of the software. [Colour figure can be viewed at wileyonlinelibrary.com]

3.8.8 | Recording the patents' post-injection variables

A self-administered survey was completed by the child's parent. According to the vaccination protocol, all children who have been vaccinated should wait in the waiting room for 30 min to make sure they have had no adverse reactions to the vaccine. This time was used for their child's parent to complete the self-administered surveys that collected their sociodemographic and satisfaction variables. Completion of this questionnaire in the paediatric area waiting room took an estimated 5 min and fell within the protocolised waiting time anyway. In addition to the above, the nurse also recorded any observed adverse effects related to participation in the study in a space provided for this purpose in the data collection questionnaire. All the data were recorded in the data collection notebook.

3.9 | Auditing

There was continuous communication with the data collection nurse from the start until the end of this study. In order to guarantee the accuracy of the data collection process, during the first month of data collection, two nurses from the research team were in the Paediatric Nursing Consultation facility to cross-check the assessment accuracy of the data collection nurse. Besides, the principal investigator (PI) visited the centre carrying out the study once a month and was available to resolve any question or incident. In addition, a study evaluation report was also written a year after the start of the study to communicate the results of this work to the hospital Ethics Committee.

3.10 | Outcome assessment

Some of the variables were provided by the child and their parent (self-administered scale data for pain, fear, and satisfaction and sociodemographic variables). However, variables related to the vaccination procedure and child's heart rate were collected by the nurse performing the intervention. In no case was access to the participant's clinical history required to collect any data related to the research.

3.10.1 | Main variable

The child's perception of pain during the injection

This variable was measured using the Wong–Baker FACES pain scale (Wong et al., 1999), a validated scale ($r = .90$, Cronbach Alpha = .93) comprising faces with expressions that represent different degrees of pain. The child had to choose the face that, to them, best represented the pain they had felt. The scale is interpreted as a final value, with each face assigned a score, where 0 = 'no hurt'; 2 = 'hurts a little bit'; 4 = 'hurts a little more'; 6 = 'hurts even more'; 8 = 'hurts a whole lot'; and 10 = 'hurts worst'. This assessment was carried out immediately after the injection. This scale has been used in children aged ≥3 to rate pain, and it is not limited to children (Garra et al., 2013).

3.10.2 | Secondary variables

The child's fear level during the injection

This was measured using the Children's Fear Scale (McMurtry et al., 2011), a tool not yet validated in Spanish, which comprises faces with expressions that represent fear. The scale is interpreted as a final value, with each face assigned a score, where 0 = 'not scared at all'; 1 = 'a little bit more scared'; 2 = 'a bit more scared again'; 3 = 'a bit more scared'; 4 = 'the most scared possible'. This assessment was carried out immediately after the injection. Fear can be assessed in children from 3 years of age and older (Wadji et al., 2023).

Parental satisfaction with the vaccination procedure

This was measured using satisfaction procedure questionnaire of Gold and Maher (2018) which was completed by the parent. This questionnaire was used for the first time in a randomised clinical trial that aimed to evaluate the feasibility and efficacy of VR compared with standard of care for reducing pain, anxiety, and improving satisfaction of patients and their caregivers associated with blood draw in children. This questionnaire comprised 11 questions. The first question (Q1) was open and asked about how the parent and child had prepared for the vaccination. Question 2 (Q2) asked if the vaccination experience had gone as expected and, in addition to using a Likert scale (where 1 = 'not at all', 5–6 = 'somewhat', and 10 = 'definitely'), also included an open question for the participant to explain the reason they had assigned their score. Questions 3, 4, 7, and 8 (Q3, Q4, Q7, and Q8) used a 1–10 Likert scale (in which 1 = 'not at all well', 5 = 'moderately well' or 'moderately', and 10 = 'extremely well' or 'extremely'), where the higher the score, the greater the respondent's satisfaction with the procedure. Question 5 (Q5) analysed whether the parent believed more could have been done to reduce their child's pain and also used a 1–10 Likert scale (where 1 = 'nothing more', 5 = 'something more', and 10 = 'a lot more'). The sixth question (Q6) required a dichotomous yes/no answer. Questions 9 and 10 (Q9 and Q10) referred to the VR intervention and were only answered by parents of children assigned to the IG. The last question (Q11) was an open question about feelings and thoughts regarding the vaccination. The analysis metric was a final value which was measured after the injection procedure.

Sociodemographic variables of the child

Age and sex of the child.

Sociodemographic variables of the parent

The guardian's relationship to the child and their sex, age, marital status and educational level.

Sociodemographic variables of the child's family

The family's country of origin, years living in Spain, number of children, order of the child among its siblings, type of residence, and family socioeconomic level.

Pre- and post-vaccination heart rate

The child's heart rate values were measured using a pulse oximeter (MD300C2, ChoiceMMed) before and after the injection.

Combination of several injections during the same session

This analysis metric was recorded after completing the injection procedure.

Injections received in the year prior

Any injections the child had received in the year prior as a result of venepuncture, canalisation, etc. was recoded as a 'yes/no' answer after the injection.

Previous use of VR during an injection

This analysis metric was recorded as a 'yes/no' answer after the injection procedure.

The randomisation groups

The group to which the child had been assigned (IG or CG) was determined using SealedEnvelope™ software. The randomisation results are emailed to the data collection nurse.

3.10.3 | Data analysis

The data were analysed using IBM SPSS statistics v.26. The significance of the data were established based on a confidence level of 95% ($p < .05$). The descriptive analysis of the quantitative variables was carried out by calculating the means, *SD*s, and ranges (minimum and maximum values) for the data. We analysed the absolute and relative frequencies and proportions for the qualitative variables. The normal distribution of the variables was verified using Kolmogorov–Smirnov tests. All the data were analysed based on the assumptions of each statistic.

Chi-squared tests were used to test our hypotheses for the qualitative variables. Spearman correlations were used to test the relationship between quantitative variables (with Spearman's Rhos = 0–.25, .26–.5, .51–.75, and .76–1 being interpreted as 'little or no association', 'weak association', 'moderate association', or 'strong association', respectively). Finally, to test the relationship between quantitative and qualitative variables according to the normality of the data and dependence between the variables, Mann–Whitney *U*-, Student *t*, or binary logistic regression tests were used. A subgroup analysis was conducted according to the age of the patients (subgroup 1 being aged 3 to ≤8.5 years and subgroup 2 those aged >8.5 to 14 years).

Our analysis was conducted on an intention-to-treat basis, respecting the initial intention of the group assignment. We applied a sensitivity analysis for any losses with unknown results in which the worst response was assigned to all the patients lost to the IG, while the best response was applied to all those lost to the CG, in order

to evaluate how much the result of the trial had changed based on these assignments. Related to the variables under study, only the baseline data for heart rate was collected.

3.11 | Ethical considerations

This study was conducted according to the principles established in the Declaration of Helsinki, in the Convention on Human Rights and Biomedicine (Oviedo Convention), and the UNESCO Universal Declaration on the human genome and human rights. This work was approved by the Ethics Committee for Biomedical research at the Cardenal Herrera CEU University, on 17 July 2019 (Report: CEI19/092) and by the Ethics Committee for Research with Medicines at the Valencia General University Hospital.

All the participants and their parents were informed of the duration and characteristics of the study and its voluntary nature. After explaining the project in detail, any questions the participants or their parents may have had were answered in full before providing them with an informed consent document which they had to sign if they wanted to participate. Given that this study was conducted in a population of minors, and in accordance with Law 41/2002 on patient autonomy, consent was granted by representation by the father/mother/legal guardian of the minor (Ley, 2002). However, in accordance with the provisions of article 9 of Organic Law 1/1996 of 15 January, on the Legal Protection of Minors (Ley Orgánica, de Protección Jurídica del Menor, 1996) and the second final provision of Law 26/2015 of 28 July, for the modification of the protection system for children and adolescents (Ley, 2015), the opinion of the child was heard and due account was taken of their opinions (depending on their age and maturity levels) and their verbal consent was requested.

After signing the consent, the parents were given a copy of the document which stated the contact details of the PI so participants or their parent could communicate with the PI at any time. Participants were also informed that all the data collected during the research would be treated confidentially in accordance with current regulations on the protection of personal data, Organic Law 3/2018, of 5 December, on the protection of personal data and guarantee of digital rights (LOPD + GDD) (Ley Orgánica, 2018), and EU regulation 2016/679 of the European Parliament and Council, of 27 April 2016 (Regulation (EU), 2016), regarding the protection of natural persons with regard to the processing of personal data and the free circulation of this data. To maintain patient confidentiality, the data collection notebooks were identified by a numerical code. Both the informed consent documents and data collection notebooks were kept by the nurse performing the intervention until they were collected by the study PI. These documents were stored under key in a safe place at all times. Furthermore, access to databases related to this study were password protected and were only be accessible to the person in charge of the data processing.

4 | RESULTS

A total of 278 children were screened during participant recruitment; 106 were excluded because they did not meet the inclusion criteria or did not wish to participate in the study. Thus, 172 participants were randomised into the IG or CG. There were three losses to follow-up in the CG and 6 in the IG; of these, five were losses because of incomplete data at the primary endpoint. Nine children in the IG group discontinued the intervention because they did not want to wear the VR headset or because the headset had failed. Despite not having worn the headset, these nine cases were still included in the IG and were analysed on an intention-to-treat basis. Hence, 162 participants were finally analysed. A flow diagram of how the patients moved through the study is shown in Figure 2. Recruitment took place from 10 March 2021 to 7 June 2023, when the desired sample size was achieved.

4.1 | Participant demographics

The clinical and sociodemographic characteristics of the participants are listed in Table 1. At baseline, there were no significant differences in the participant demographics between the original assigned groups: IG and the standard-of-care CG ($p > .05$). Only the data for parent age and child heart rates followed a normal distribution. Neither child nor parent preparedness for vaccination differed between the IG and CG ($\chi^2 = 8.57$; V Cramer = 29.9%; $p = .80$ and $\chi^2 = 6.21$; V Cramer = 22.8%; $p = .72$, respectively), as shown in File S4, Table 1. No adverse effects attributed to immersive VR (such as dizziness, headache, or nausea) were described for the IG group.

4.2 | Primary outcomes

The findings for the comparisons of pain perception during the injection between the groups are included in Table 2. The level of perceived pain in the IG was significantly lower than in the CG, with a difference of 28.03 points between the medians (mid-range = 67.31 vs. 95.34; $p < .001$) with a median effect size of $r_{bis} = -.31$ (Table 2). Similarly, there was a significant relationship between the pain categories and distraction technique used (Table 2 and Figure 3). The significant differences in the frequency distribution of pain categories occurred in the extremes of the reported pain, with better results for the children in the IG. In other words, more children reported not feeling pain in the IG compared to the CG (31.3% vs. 9.8%; $p < .001$) and the number of children who said they had felt the worst possible pain was lower in the IG compared to the CG (8.8% vs. 20.7%; $p = .03$).

4.3 | Secondary outcomes

As shown in Table 2, the perceived fear described by the children in the IG was significantly lower than in the CG (mid-range = 73.89

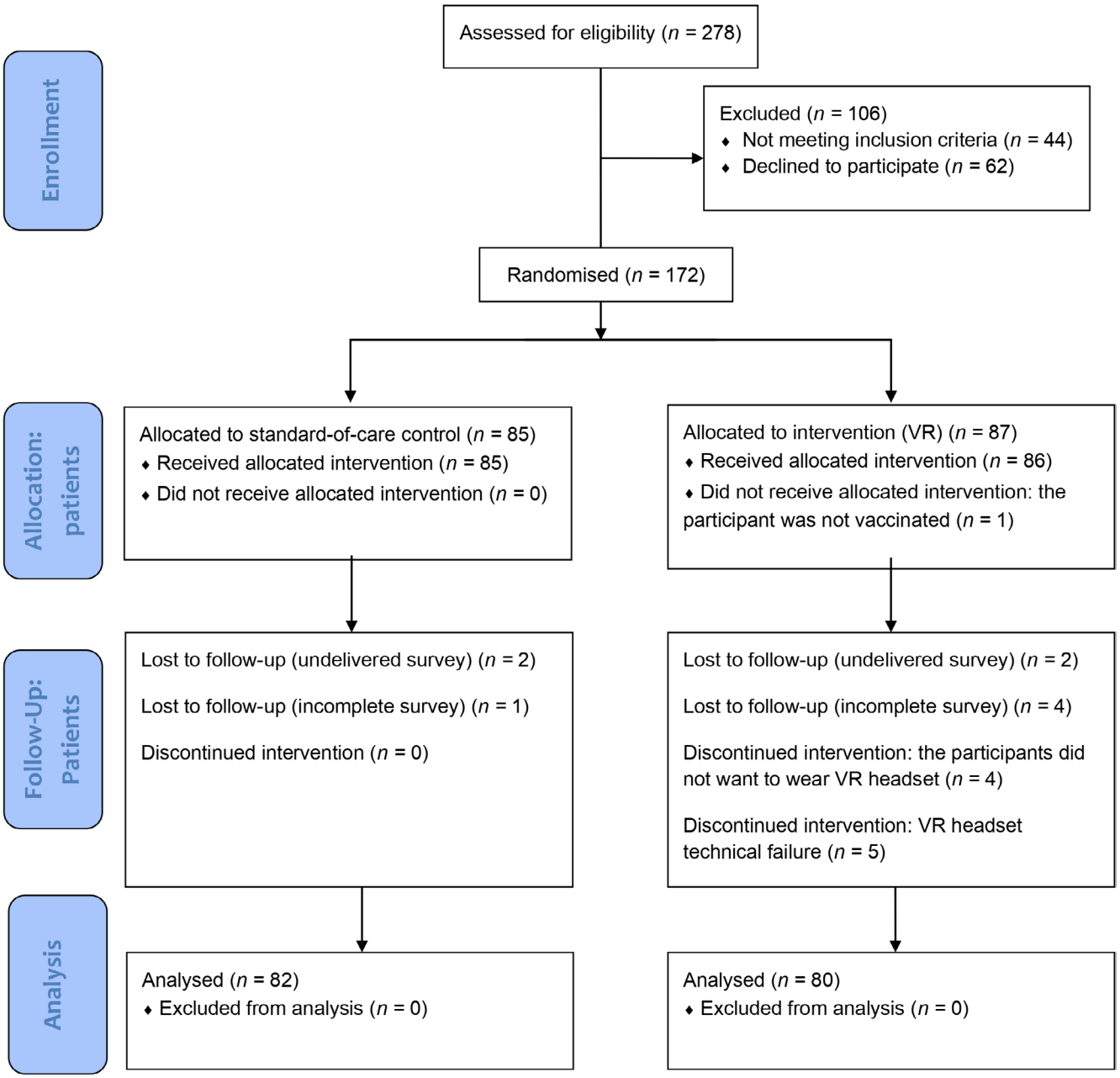

FIGURE 2 Patient flow diagram. [Colour figure can be viewed at wileyonlinelibrary.com]

vs. 88.93; $p = .03$). The parents' satisfaction with the vaccination procedure (Table 3) was higher for all the IG items compared to the CG, significantly so for general satisfaction with the vaccination procedure (Q8; $p = .03$) and their opinion on whether something more could have been done to reduce their child's pain (Q5; $p = .01$). Furthermore, more parents of children in the CG (37.8%) said their child had experienced distress (anxiety or worry) compared to the IG (Q6; 23.1%; $p = .04$). In addition, compared to the CG, more parents of children in the IG thought that the vaccination procedure had not gone as they had expected (Q2; $p = .037$). More parents of children in the IG gave more positive explanations for the scores they had assigned compared to those in the CG (see File S4, Table 2).

Finally, more of the parents of the participants in the IG said that the VR experience had helped their children during the vaccination (Q9: mean satisfaction (SD) = 8.32 ± (2.5) out of a possible 10 points; median = 10; range = 1–10) and that VR had helped their child as much as they had imagined it would (Q10: mean (SD) = 7.96 ± (2.5) out of 10 points; median = 9; range = 1–10). Of note, of the three parents who gave the lowest scores, the VR headset had not been used in two, either because the child did not want to wear it or because it had not worked. The comments written by parents in relation to these questions (File S4, Tables 4 and 5) described the positive aspects of VR, except in one case.

There were no differences in the levels of pain and fear according to the sex of the children ($p > .05$). However, there was a

TABLE 1 Demographic characteristics of children in the intervention and control groups.

	Total ($n=162$)	Virtual reality (IG) ($n=80$)	Standard-of-care (CG) ($n=82$)	Statistical test	Effect size (r_{bis} for Mann–Whitney U; V Cramer for χ^2; d for Student t-test)	p-value
Child age (years), mean ± (SD) ([range])	7.89 ± (3.72) ([3–14])	7.61 ± (3.75) ([3–14])	8.12 ± (3.7) ([3–14])	2973.5 (−1.03)[a]	−.08	.31
Sex, *n* (%)						
Male	86 (53.1)	45 (56.2)	41 (50)	.64[b]	6.3%	.43
Female	76 (46.9)	35 (43.8)	41 (50)			
Had used a VR headset before the study, *n* (%)						
No	140 (86.4)	70 (87.4)	70 (85.4)	.22[b]	3.8%	.64
Yes	16 (9.9)	9 (11.3)	7 (8.5)			
N/A	6 (3.7)	1 (1.3)	5 (6.1)			
Number of injections, mean ± (SD) ([range])	1.32 ± (0.59) ([1–3])	1.35 ± (0.64) ([1–3])	1.29 ± (0.53) ([1–3])	3217 (−0.28)[a]	−.02	.78
Injections in the year prior, n (%)						
No	111 (68.5)	55 (68.8)	56 (68.3)	.003[b]	0.4%	.96
Yes	46 (28.4)	23 (28.7)	23 (28)			
N/A	5 (3.1)	2 (2.5)	3 (3.7)			
Number of children in the family, mean ± (SD) ([range])	2.02 ± (1.02) ([1–6])	2.13 ± (1.08) ([1–6])	2.05 ± (0.97) ([1–5])	2850 (−.30)[a]	−.02	.77
Place of residence n (%)						
Family home	156 (96.3)	79 (98.7)	77 (93.9)	[c]	[c]	[c]
Foster home	0 (0)	0 (0)	0 (0)			
N/A	6 (3.7)	1 (1.3)	5 (6.1)			
Child's companion, n (%)						
Father	26 (16)	14 (17.5)	12 (14.6)	1.20[b]	8.8%	.55
Mother	129 (79.6)	63 (78.7)	66 (80.5)			
Legal guardian	1 (0.6)	0	1 (1.2)			
N/A	6 (3.7)	3 (3.8)	3 (3.7)			
Companion age, mean ± (SD) ([range])	39.71 ± (7.23) ([23–58])	39.29 ± (7.56) ([24–58])	40.13 ± (6.92) ([23–53])	−0.72[d]	−.84	.47
Companion marital status, *n* (%)						
Single	23 (14.2)	12 (15)	11 (13.4)	1.67[b]	10.3%	.89
Domestic partner	19 (11.7)	11 (13.7)	8 (9.8)			
Married	96 (59.3)	47 (58.7)	49 (59.7)			
Separated	6 (3.7)	2 (2.5)	4 (4.9)			
Divorced	9 (5.6)	5 (6.3)	4 (4.9)			
Widowed	3 (1.9)	1 (1.3)	2 (2.4)			
Other	0 (0)	0 (0)	0 (0)			
N/A	6 (3.7)	2 (2.5)	4 (4.9)			
Companion education level, *n* (%)						
Basic	41 (25.3)	23 (28.7)	18 (22)	1.92[b]	11.2%	.38
Intermediate	66 (40.7)	29 (36.2)	37 (45.1)			
Higher	46 (28.4)	25 (31.3)	21 (25.6)			
N/A	9 (5.6)	3 (3.8)	6 (7.3)			

TABLE 1 (Continued)

	Total ($n=162$)	Virtual reality (IG) ($n=80$)	Standard-of-care (CG) ($n=82$)	Statistical test	Effect size (r_{bis} for Mann–Whitney U; V Cramer for χ^2; d for Student t-test)	p-value
Family country of origin, *n* (%)						
Europe	101 (62.3)	50 (62.5)	51 (62.2)	2.47[b]	12.6%	.78
Africa	5 (3.1)	3 (3.7)	2 (2.4)			
The Americas	34 (21)	17 (21.2)	17 (20.7)			
Asia	1 (0.6)	0	1 (1.2)			
Dual nationality (European + another country)	7 (4.3)	5 (6.3)	2 (2.4)			
N/A	14 (8.6)	5 (6.3)	9 (11)			

Abbreviations: CG, control group; IG, intervention group; N/A, not available; *SD*, standard deviation; VR, virtual reality.
[a]Mann–Whitney U test (*Z*);
[b]Chi-squared test;
[c]This calculation could not be performed because the variable is a constant;
[d]Student *t*-test.

difference for the perceptions of parents regarding whether their child's pain had been managed well: poorer results were described when the vaccinated child had been female rather than male (Q4: median = 73.34 vs. 87.85; $p = .04$), although the effect size was small ($r_{bis} = -.16$) (Table 4). Complete data for parent satisfaction can be found in File S5, Table 1.

The age of the children was weakly associated with their levels of perceived pain (Spearman's Rho: −.17; $p = .03$): the younger they were, the greater their reported pain. Of note, the differences in the frequency distribution of the pain categories occurred at the extremes of the reported pain levels, with worse results for the youngest children (Table 5). Regarding parental satisfaction, the younger the child's age, the more the parents considered could have been done to manage the pain, with medians of 85.07 for the group aged 3–8.5 years and 70.93 for those aged 8.5–15 years (Q5; $p = .04$). Complete data for satisfaction can be found in File S5, Tables 2 and 3. Finally, no relationship was observed between the age of the vaccinated child and their described fear levels (Spearman's Rho: −.08; $p = .29$).

5 | DISCUSSION

The main results of this work showed that immersive VR had a positive effect on the perceived pain and fear of children who were vaccinated. Furthermore, parental satisfaction with the vaccination procedure was better when the distraction was performed with immersive VR rather than with the standard-of-care. In this sense, our initial hypotheses were confirmed. To the best of our knowledge, this is the first RCT to analyse the effect of VR as a distraction method during paediatric vaccinations, with only 3 studies to date (Althumairi et al., 2021; Chad et al., 2018; Chang et al., 2022) having analysed the use of VR during vaccination, although they all presented a series of limitations as described below.

Chad et al (Chad et al., 2018). carried out a pilot study with a small sample group ($n = 17$) and no comparison group. In turn, Chang et al (Chang et al., 2022). carried out a pilot study, also with a small cohort ($n = 30$). Finally, the research by Althumairi et al (Althumairi et al., 2021). was descriptive and had a sample size of 103 participants, but the group assignments (VR or CG) were done according to parental preference. Of note, all these methodological problems were avoided in this present work. Our research had a large sample size ($n = 162$) compared to prior studies, one of the highest of all the studies published to date on VR. Given all the above, the reliability of our results was high. Thus, analysis of the main variable results showed that VR was useful for pain management in children during vaccinations. These findings are consistent with previous RCTs that described less pain ($p < .05$) when VR was used versus standard-of-care distractions during other painful needle procedures (Lluesma-Vidal et al., 2022) such as venipuncture (Chen et al., 2020) or puncture for venous port access placement (Gerçeker et al., 2021; Semerci et al., 2020).

Importantly, this current research compared standard care (CG) and immersive VR (IG). In the CG, children had physical contact with their parents and were also distracted by other means (playing with their parents, a toy or musical book, looking at a mobile device, etc.) because distraction is a cognitive behavioural approach that helps disengage children from what may otherwise be perceived as unpleasant stimuli, instead focussing their attention on more pleasant stimuli (Goettems et al., 2019). The results of this present RCT indicate that immersive VR was better able to create an effective distraction than the aforementioned measures and therefore, better reduced the perception of pain in paediatric patients. In this vein, in the work by Miró et al (Miró et al., 2007)., the effects of VR were superior to other forms of distraction, reminding us that attention is a key factor in nociceptive stimuli being interpreted as painful. The use of VR focusses this attention on the virtual experience, strongly

TABLE 2 Comparison of the reported pain and fear felt during the vaccination between intervention and control groups.

	Virtual reality (IG) ($n=80$)	Standard-of-care (CG) ($n=82$)	Statistical test	Effect size (r_{bis} for Mann–Whitney U, V Cramer for χ^2; d for Student t-test)	p-value
Pain level, mid-range	67.31	95.34	2,145 (−3.94)[a]	−.31	<.001*
Pain, *n* (%)	80 (100)	82 (100)	16.94[b]	32.3%	.005*
No hurt	25 (31.25)	8 (9.76)	11.53[b]	26.7%	<.001*
Hurts a little bit	31 (38.75)	29 (35.36)	.20[b]	3.5%	.66
Hurts a little more	13 (16.25)	18 (21.95)	.85[b]	7.2%	.36
Hurts even more	3 (3.75)	5 (6.1)	.48[b]	5.4%	.49
Hurts a whole lot	1 (1.25)	5 (6.1)	2.67[b]	12.8%	.10
Hurts worst	7 (8.75)	17 (20.73)	4.61[b]	16.9%	.03*
Pre-injection basal heart rate, mean ± (SD) ([range])	95.19 ± (15.81) ([55–136])	95.74 ± (17.57) ([56–137])	−.21[c]	−.56	.83
Post-injection heart rate, mean ± (SD) ([range])	97.94 ± (18.92) ([58–143])	101.08 ± (19.73) ([63–150])	−1.03[c]	−3.14	.31
Fear level, mid-range	73.89	88.93	2,671 (−2.17)[a]	−.17	.03*
Fear, *n* (%)	80 (100)	82 (100)	5.86[b]	19%	.12
Not scared at all	42 (52.5)	31 (37.8)	3.53[b]	14.8%	.06
A little bit more scared	20 (25)	19 (23.2)	.07[b]	2.1%	.79
A bit more scared again	11 (13.75)	22 (26.8)	4.27[b]	16.2%	.04*
A bit more scared again	0 (0)	0 (0)	-	-	-
The most scared possible	7 (8.75)	10 (12.2)	.51[b]	5.6%	.47

Abbreviations: CG, control group; IG, intervention group; *SD*, standard deviation; VR, virtual reality.

*$p < .05$ was considered statistically significant.

[a]Mann–Whitney U test (*Z*);

[b]Chi-squared test;

[c]Student *t*-test.

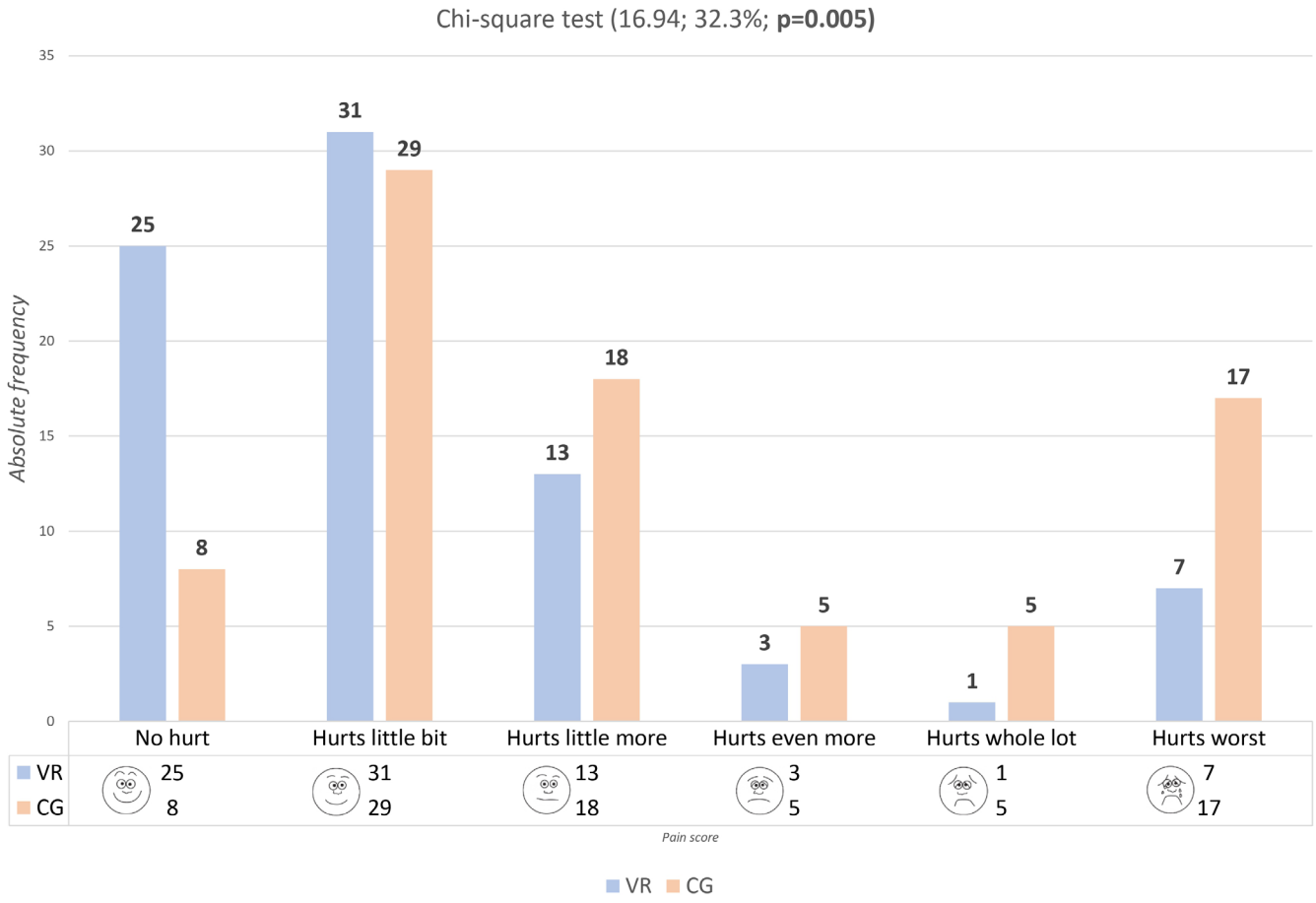

FIGURE 3 Comparison of pain scores between intervention group (VR) and control group. Copyright 1983, Wong–Baker FACES Foundation, www.WongBakerFACES.org. Used with permission. Originally published in Whaley & Wong's Nursing Care of Infants and Children. © Elsevier Inc.15. [Colour figure can be viewed at wileyonlinelibrary.com]

isolating the patient from their environment. This can block multiple senses and reduce pain and anxiety, as previously indicated by Inan and Inan (Inan & Inal, 2019).

However, fear of needles is also common in the paediatric population (Sørensen et al., 2020; Taddio et al., 2022), and so it is important to devise strategies available that help children cope with this fear (Sørensen et al., 2020). Some procedures used to reduce fear during vaccination are sitting (rather than lying supine) (Taddio et al., 2015), informing the child in advance about the procedure (Taddio et al., 2015) and the use of VR (Lluesma-Vidal et al., 2022). In line with these recommendations, in the present study, 39 parents indicated that they had given their child information about the vaccination beforehand and 8 children had expressly requested such information. Very few RCTs have studied the effect of VR on fear in children, in each case comparing VR with a CG (Chen et al., 2020; Gerçeker et al., 2021; Windich-Biermeier et al., 2007). Most of these studies (Chen et al., 2020; Gerçeker et al., 2021) produced results similar to ours, with less fear described in the IG than in the CG. Notwithstanding, Windich-Biermeier et al (Windich-Biermeier et al., 2007). showed the opposite, with no differences in the level of fear shown between both groups. This could have been because the procedure was repeated, given that the study population were children and adolescents with cancer who had undergone 6 or more prior punctures while also using a topical anaesthetic.

As previously mentioned, vaccination is the most common painful procedure performed in the paediatric population (García Sánchez et al., 2015; Hussein, 2015). Taddio et al (Taddio et al., 2022). also noted that inadequate pain and fear management during vaccinations has undesirable effects, causing unnecessary suffering and negative experiences for children and parents, promoting the fear of needles and negative attitudes towards vaccination, and even non-compliance with vaccination schedules (Sørensen et al., 2020; Taddio et al., 2022) in the long term. Thus, it will be important to continue reducing these negative experiences by employing measures to reduce fear and pain in paediatric patients. In addition, nurses also have an ethical obligation to try to relieve children's pain (Hussein, 2015). Among the distraction measures available, active distraction (including VR) is more effective than passive distraction (Hussein, 2015).

It is worth highlighting that VR has been well received by healthcare professionals who described high levels of satisfaction with this new technology when used as a distraction measure during painful procedures (Gold & Mahrer, 2018); 98% said they believed it had helped the procedure and that they would use it again (Gold &

TABLE 3 Parent satisfaction with the vaccination procedure between the intervention and control groups.

	Total[a]	Virtual reality (IG) ($n=80$)	Standard-of-care (CG) ($n=82$)	Statistical test	Effect size (r_{bis} for Mann–Whitney U; V Cramer for χ^2; d for student t-test)	p-value
Q2. Was the procedure as you had expected? mid-range	10	69.63	83.55	2,385.5 (−2.09)[b]	−.17	.04*
Q3. How well do you think the procedure went? mid-range	9	81.9	79.16	3,088.5 (−.4)[b]	−.03	.69
Q4. How well do you think your child's pain was managed? mid-range	9	82.39	79.66	3,129 (−.39)[b]	−.03	.70
Q5. Do you think more could have been done to reduce your child's pain? mid-range	1	71.3	88.38	2,48.5 (−2.57)[b]	−.20	.01*
Q6. Did your child experience any distress (anxiety or worry) before or during the procedure? *n* (%)						
No		60 (76.9)	51 (62.2)	4.08[c]	16%	.04*
Yes		18 (23.1)	31 (37.8)			
Q7. If your child experienced any distress (anxiety or worry), how well do you think it was managed? mid-range	8	60.73	54.7	1,445.5 (−.99)[b]	−.09	.32
Q8. How satisfied were you with the procedure as a whole? mid-range	10	87.39	73.61	2,649 (−2.13)[b]	−.17	.03*

*$p<.05$ was considered statistically significant.

[a]Median;

[b]Mann–Whitney U test (Z);

[c]Chi-squared test.

Mahrer, 2018). Indeed, several lines of research have analysed satisfaction with the use of VR as a distraction measure during painful procedures performed in the paediatric population. From among these, most of the studies that compared the level of satisfaction by groups (patients, parents, or professionals) (Dumoulin et al., 2019) described greater satisfaction in the IG than in the other comparison groups.

As already mentioned, this present study also analysed the satisfaction of parents with the vaccination procedure, comparing the results based on the distraction measure used (immersive VR vs. standard-of-care). Satisfaction with the procedure as a whole was high in both study groups but was greater when the child had used the immersive VR headset ($p=.03$). This may be because the children in the IG experienced less pain and fear and consequently, less suffering. This could have contributed to their parents evaluating the experience positively because, as previously indicated, pain relief is closely associated with satisfaction (Bukola & Paula, 2017). Similar results were described by Dumoulin et al (Dumoulin et al., 2019). who reported greater parental satisfaction in an IG than in the CG. However, in the study by Thybo et al (Thybo et al., 2022)., parent satisfaction was higher in the CG (allowing the child to play a two-dimensional game on a mobile device while accompanied by a nurse or anaesthetist) than in the IG (VR), perhaps because as the reported pain was low in all the children studied, with no differences according to the distraction method used ($p=.19$), parents were more satisfied if their child had been accompanied someone than connected virtually.

It is also worth noting that we found no differences in the reported pain levels according to sex, which concurs with the findings of previous work (Althumairi et al., 2021). Our results further suggested that fear levels were similar in both sexes, as also described by Althumairi et al (Althumairi et al., 2021). but contrasting with other authors (Taddio et al., 2012) who reported more fear in girls than boys (although these results were analysed in general situations in which distraction had not been used). Regardless, these conflicting results still support the usefulness of VR for the management of fear in paediatric populations. In the present work, the only variable for which significant differences were described according to sex was the perception of parents regarding how well their child's pain had been managed, with poorer results for female children compared to

TABLE 4 Relationship between the sex of children and their perceived levels of pain and fear.

	Male ($n=86$)	Female ($n=76$)	Statistical test	Effect size (r_{bis} for Mann–Whitney U; V Cramer for χ^2)	p-value
Pain level, mid-range	80.87	82.21	3,214 (−.19)[a]	−.01	.85
Pain, n (%)	86 (100)	76 (100)	4.82[b]	17.3%	.44
No hurt	21 (24.4)	12 (15.8)	1.85[b]	10.7%	.17
Hurts a little bit	28 (32.6)	32 (42.1)	1.58[b]	9.9%	.2
Hurts a little more	15 (17.4)	16 (21.1)	.34[b]	4.6%	.56
Hurts even more	3 (3.5)	5 (6.6)	.82[b]	7.1%	.37
Hurts a whole lot	4 (4.7)	2 (2.6)	.46[b]	5.3%	.5
Hurts worst	15 (17.4)	9 (11.8)	1.0[b]	7.9%	.32
Fear level, mid-range	79.21	84.1	3,071 (−.7)[a]	−.05	.48
Fear, n (%)	86 (50)	76 (100)	3.53[b]	14.8%	.32
Not scared at all	43 (50)	30 (39.46)	1.81[b]	10.6%	.18
A little bit more scared	16 (18.6)	23 (30.26)	3[b]	13.6%	.08
A bit more scared again	17 (19.8)	16 (21.05)	.04[b]	1.6%	.84
A bit more scared again	0 (0)	0 (0)	-	-	-
The most scared possible	10 (11.6)	7 (9.21)	.25[b]	3.9%	.61

*$p<.05$ was considered statistically significant.
[a]Mann–Whitney U test (Z);
[b]Chi-squared test.

their male counterparts. This was consistent with the suggestion by Carvajal-Campos et al (Carvajal Campos et al., 2017). that girls are more susceptible to overprotection by their parents.

We also found a weak association between fear and child age, suggesting that both these factors were linked, similar to the findings by Gold and Maher (Gold & Mahrer, 2018) ($r=-.21$, $p<.05$). It is therefore not surprising that other research (Althumairi et al., 2021; Chang et al., 2022) did not describe this same association.

In addition to the effectiveness of VR for managing pain and fear during vaccination, as shown by our results and those published elsewhere (Chang et al., 2022; Gerçeker et al., 2021; Miró et al., 2007; Schlechter et al., 2021), another reason for its use is because it has no adverse effects. The only complications described for VR in previous studies were anxiety (Thybo et al., 2022), nausea (Gold & Mahrer, 2018; Walther-Larsen et al., 2019), and dizziness (Walther-Larsen et al., 2019), although there was no significant difference between the VR and CG groups in this respect (Thybo et al., 2022; Walther-Larsen et al., 2019), thereby suggesting that these complications were not associated with VR. Some authors (Schlechter et al., 2021) also reported a lack of cooperation, specifically indicating that 8 children had removed the headset during the intervention. Similarly, in this present work, we encountered 4 children who did not want to wear the VR headset.

5.1 | Limitations

One of the main limitations of this study was related to how fear was assessed. Because the baseline fear levels were not measured, any changes in fear before and after the intervention remain unknown. Therefore this represent a potential risk of bias to statistical test. Furthermore, although the children were asked about the fear they had felt 'during the vaccination', they may have answered with the entire process in mind. Another limitation of the study was the lack of blinding of the intervention to the participating children, parents, and vaccinating nurse (the same one that had explained how to complete the pain and fear scales).

5.2 | Recommendations for future research

Given that it has been shown that immersive VR is useful for managing pain and fear during vaccinations, it may be interesting to conduct future studies that analyse the reduction in the time required for each vaccination (and therefore representing potential economic savings) when using immersive VR compared to standard distraction techniques. Furthermore, in such studies it would be useful to measure fear both before and after vaccination in order to analyse whether it changes, as well as recording other physiological parameters related to pain and fear. Another aspect for improvement in future work is the blinding of the nurse and so we recommend that the nurse performing the vaccination be different from the one collecting the study data.

6 | CONCLUSIONS

Immersive VR is an effective distraction measure to control pain and fear in the paediatric population while being vaccinated.

TABLE 5 Relationship between the age of children (as ranges) and their perceived levels of pain and fear.

	Children 3–8.5 years ($n = 105$)	Children 8.5–14.9 years ($n = 57$)	Statistical test	Effect size (r_{bis} for Mann–Whitney U; V Cramer for χ^2)	p-value
Pain (quantitative), mid-range	84.35	76.25	2,696.5 (−1.09)[a]	−.09	.28
Pain, *n* (%)	105 (100)	57 (100)	25.07[b]	39.3%	<.001*
No hurt	27 (25.71)	6 (10.5)	5.25[b]	18%	.02*
Hurts a little bit	28 (26.66)	32 (56.1)	13.76[b]	29.1%	<.001*
Hurts a little more	17 (16.19)	14 (24.6)	1.67[b]	10.2%	.20
Hurts even more	5 (4.76)	3 (5.3)	.02[b]	1.1%	.89
Hurts a whole lot	6 (5.71)	0 (0)	3.38[b]	14.4%	.07
Hurts worst	22 (20.95)	2 (3.5)	8.91[b]	23.4%	.003*
Fear (quantitative), mid-range	82.34	79.95	2,904 (−0.33)[a]	−.03	.741
Fear, *n* (%)	105 (100)	57 (100)	1.28[b]	8.9%	.73
Not scared at all	47 (44.8)	26 (45.6)	.01[b]	.8%	.92
A little bit more scared	25 (23.8)	14 (24.6)	.01[b]	.8%	.92
A bit more scared again	20 (19)	13 (22.8)	.32[b]	4.5%	.57
A bit more scared again	0 (0)	0 (0)	-	-	-
The most scared possible	13 (12.4)	4 (7)	1.13[b]	8.4%	.29

*$p < .05$ was considered statistically significant.

[a]Mann–Whitney *U*-test (*Z*).

[b]Chi-squared test.

Furthermore, parents reported greater satisfaction with the vaccination process when immersive VR was employed. It appears that the sex of the children does not influence their levels of pain and fear but their age does, given that the younger they were, the more pain they reported. The positive effects of immersive VR can help encourage increased compliance with vaccination schedules and help to avoid suffering in children and their parents. Therefore, nurses should consider including this distraction technique in the standard care provided to children during immunisations.

7 | RELEVANCE TO CLINICAL PRACTICE

Improving vaccination experiences is one of the responsibilities of the nursing profession, with the identification of distraction measures that can further reduce children's perceptions of pain and fear being one way to achieve this. This will not only improve the experience of paediatric patients but will also increase the satisfaction of both parents and children, thereby enhancing vaccination schedule adherence and leading to improved group immunity and greater protection of our entire population.

AUTHOR CONTRIBUTIONS

García-Garcés, Sánchez-López, Ruiz-Zaldibar, Lluesma-Vidal, Tomás-Saura, Martínez-Fleta and Gutiérrez-Alonso contributed to the conception and design of the research and will conduct this randomised clinical trial; García-Garcés and Sánchez-López also wrote the first draft of this manuscript and Ruiz-Zaldibar, Lluesma-Vidal critically revised the manuscript. All the authors approved the manuscripts and agree to be fully accountable for ensuring the integrity and accuracy of the work.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in Mendeley Data at https://data.mendeley.com/datasets/79jxcbgs46/1, reference number 10.17632/79jxcbgs46.1.

STATISTICS

The statistics were checked prior to submission by an expert statistician (Francisco José Santonja Gómez; francisco.santonja@uv.es).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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