# Effectiveness of non-immersive virtual reality in the management of procedure-related pain in preschool children: A randomized clinical trial

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# Abstract

### Objective

To assess the effectiveness of non-immersive virtual reality as a pain-distraction measure in children between the ages of 3–5 years undergoing painful injection procedures in an outpatient setting.

### Design

We carried out a randomized, unmasked clinical trial in children undergoing venipuncture or intramuscular injection procedures. Patients were randomized to a distraction virtual reality video or standard care. After the procedure, three independent observers (parents, researchers, nursing staff) rated pain on the LLANTO pain scale.

### Results

We recruited 122 subjects, half of which were randomized to virtual reality. The median age was of approximately 5 years and the sample was balanced with regards to sex. Agreement between raters was high for all three types of observers, with Cohen Kappas over 0.79 in all cases. Bivariate analysis showed reductions in the risk of obtaining higher scores in the LLANTO scale. Linear regression models showed a reduction of approximately 3 points in the scale, regardless of the type of observer. These models were adjusted for sex, age, kind of procedure, use of prior analgesia, and recruitment center.

### Conclusions

Non-immersive virtual reality is an effective adjunctive therapy for the reduction of pain in children undergoing painful injection procedures in an outpatient setting. This strategy may be used to improve the quality of care in pediatric outpatient services.

### Trial Registration:

ClinicalTrials.gov Identifier: NCT03985930


# What Is Known

The use of immersive virtual reality (VR) has been described as an effective adjunctive distraction method during painful procedures in children over 5 years.

**What is new:** The utility of non-immersive VR in children below that age is not yet clear. This randomized clinical trial comparing non-immersive VR vs. standard care showed an average reduction of three points in the LLANTO pain scale favoring non-immersive VR. Non-immersive VR is an effective and inexpensive non-pharmacological technique that reduces fear and pain in pediatric patients.

# Introduction

Pain is a negative experience commonly underestimated in children [1]. Research has shown that it is both the most frequent symptom and the least enquired about in children, with a prevalence ranging from 65–84% in pediatric hospital settings [2–4]. Additionally, pediatric symptom management in medical settings frequently necessitates the administration of intravenous or intramuscular injections, which are inherently painful procedures. This acute procedural pain in pediatric patients poses a significant challenge for healthcare facilities, resulting in heightened fear and anxiety and impeding successful treatment. If left unaddressed, this pain may increase the likelihood of chronic diseases, anxiety disorders, and depression in adulthood [5].

To manage pain, anxiety, and fear that may arise during puncture-related procedures, a range of pharmacological and non-pharmacological interventions are employed. Pharmacological methods frequently involves analgesics, which in turn increases the risk of medication-related adverse effects [6]. Medication-related adverse effects are frequent and it is estimated that 30–50% of analgesics used in pediatrics will lead to 9% of the total burden of adverse effects [7]. The rising problem of opioid dependence has highlighted the need for nonpharmacological pain mitigation strategies in adults, some of which have shown considerable effectiveness in other age groups as well. Among the non-pharmacological interventions, distraction has been identified as the most effective strategy to alleviate pain, fear and anxiety in pediatric patients undergoing such procedures and have been found to decrease self-reported and observer-reported pain in children aged 2 to 18 years [8]. Distraction strategies have been a part of the pain mitigation toolbox for centuries and the rise of new technologies has provided more opportunities to engage the patient’s senses more holistically.

VR is a technology that has been used as an adjuvant strategy in pain management since it allows the user to immerse herself in an interactive medium by means of images that cover the entirety of the visual field and sounds that provide a more immersive experience [6, 9]. This technology helps control pain in various ways, preventing the patient from viewing the hospital area, isolating them from noises by means of music, and allowing the user to enter a state of distraction across different sensory modalities [10, 11]. Studies in burn victims, dental procedures and vaccination have shown that this technique can help reduce pain in school-aged children [9, 10, 12]. These kinds of interventions are not explicitly contraindicated in this age group, since recommendations regarding screen use are directed towards cumulative and frequent exposure, not brief interventions [13, 14]. Despite VR likely being safe in this population, no clinical trials to date have reported on its effects. Therefore, this study aimed to determine the effectiveness of non-immersive VR in injection procedure-related pediatric pain reduction by means of a randomized clinical trial. In order to do this and given the paucity of instruments available to specifically measure outpatient procedure-related pain, we also aimed to establish the reliability of a pediatric pain measurement scale.

## Materials And Methods

## Study design

We carried out an unblinded, randomized clinical trial comparing the use of non-immersive VR with usual care in children undergoing injection procedures in an outpatient setting. The study was carried out in three clinics of the Clínica Colsanitas S.A. organization which care for a diverse pediatric population in the city of Bogotá D.C., Colombia.

# Participants

We invited all patients between the ages of 3–5 years who were undergoing any injection procedure (venipuncture or vaccination) in any of the participating centers. We excluded patients with any symptom of systemic inflammatory response syndrome, neurologic, cognitive, or motor deficits, a history of epilepsy, confirmed or suspected metabolic disease, extreme weight or height alterations, or a history of pulmonary disease which could alter the respiratory pattern.

# Intervention

VR is a non-invasive simulation technology that has become popular in clinical research studies and allows the user to interact with a computer-generated environment in all three dimensions through visual experiences, displayed on a screen or through special devices that integrate a dual-screen system [16]. The interactivity of VR is made possible by head movement tracking and the ability to perform activities in the environment by changing some of its features. [17]. 3D interaction and presence are the key feature that distinguishes an immersive VR experience from other technologies. However, non-immersive VR environments refer to the less interactive application in which the user cannot change the features of the environment or receive feedback through input [16].

Video content was displayed to children using VR goggles designed for use with smartphones (Miniso Simple 3D VR Glasses, Model G04). This device is small, lightweight (300 gr. approx.) and has a system of adjustable straps that allow the free movement of the subject's upper limbs. Children in the VR arm were shown a 3D video of a rollercoaster ride in a candy factory. The video is freely available in YouTube under the Creative Commons Attribution 3.0 [18]. The exposure of the subjects to VR was 3 minutes 4 seconds, the time the video lasts. Despite featuring 3-D video and Head Motion Tracking (HMT) technology, the experience falls short of being fully immersive due to the environment's lack of responsiveness to user interaction. While users can observe the environment from various angles, they are unable to manipulate or alter the configuration, resulting in a non-immersive VR experience. Children in the usual care group received the usual mitigating measures used by nursing staff (comforting language, distraction by parents, etc.).

The non-immersive form of VR used in the study was optimal for the age group being studied and for the clinical scenario. The use of immersive VR would have required a training period in children of this age, becoming burdensome and of less use in an outpatient scenario [16]. Additionally, most immersive VR makes use of handheld controllers, which would have made it more difficult for the nursing staff to carry out the procedure itself making it potentially unsafe.

# Outcome measures

The primary outcome was pain measured on the LLANTO scale by a third party. Parents and nursing staff were instructed to subjectively score each of the items without prior training beyond a cursory explanation of the components. The components scored are crying, attitude, respiratory pattern, posture and facial expressions. The components can be scored as follows: the crying component can be scored as “No crying”, “Crying but consolable/intermittent crying” or “Inconsolable or continuous crying”; attitude as “At ease/sleeping”, “Uneasy/Expectant”, or “Agitated/Hysterical”; breathing as “Regular/paused”, “Tachypneic” or “Irregular” (no breaths per minute limit was used); posture as “Relaxed”, “Indifferent”, and “Retracted”; and facial expression as “Content/asleep”, “Serious” or “Sad”. Each of the components ranges from 0 to 2 and the final score is simply the sum of the elements. Final score ranges are defined as “Absent” (scores of 0), “Mild” (scores 1–3), “Moderate” (scores 4–6), and “Severe” (scores 7–10). This scale was created in Madrid, Spain and was initially validated in children in a surgical recovery ward [19]. LLANTO has shown high concordance with the gold-standard scale for acute pediatric pain in preschool children and infants, CHEOPS [20]. This scale has been validated in Colombian children between the ages of 1 month and 5 years with any kind of in emergency room, inpatient and even intensive care unit settings [21].

The COVID-19 pandemic gave rise to the additional challenge of using a device which could be cleaned thoroughly after each use. A cleaning protocol using a multipurpose cleaning solution was implemented following recommendations from the World Health Organization.

# Sample size

A prior study on pain relief using VR during venipuncture measured various components related to the painful experience [22]. For a statistical power of 0.8 and a significance of 0.05, expecting to find effect sizes at least as large as those reported in the prior study, we calculated a sample size of approximately 100 subjects distributed in equally sized groups.

# Randomization

Pairs of children with similar ages undergoing injection procedures were randomized using a colored ball system. The first child would withdraw a colored ball from the opaque bag being assigned to the VR group if the ball was red, or to the control group if the ball was white. The second child would draw the remaining ball. Subjects were not informed of their assignment until right before the procedure.

# Data collection

Parents or caregivers, nursing staff and researchers (LOC, NVV, LPC) filled out a form containing the LLANTO scale for each subject. The results were inputted directly into an online database at each of the participating centers and copies of the formats were stored for data verification purposes.

# Ethical considerations

All national and international ethical guidelines regarding experimental studies in human subjects were followed. All subjects included gave their assent and informed consent was obtained from parents or

caregivers. The protocol for this study was approved by the Ethics in research Committee of the Fundación Universitaria Sanitas (CEIFUS 379 – 19) and can be found at Clinical Trials.gov (NCT03985930).

# Statistical Analysis

We performed descriptive analysis of the subjects' baseline characteristics. Categorical variables are presented as absolute and relative frequencies, and quantitative variables are presented using distribution-appropriate measures of central tendency and dispersion. Normality was determined using the Shapiro-Wilk test. Bivariate analyses compared baseline variable distributions between arms. We searched for clinically significant differences between baseline variables by means of Chi-squared/Fisher exact tests, or t tests/Mann-Whitney U tests as appropriate. Finally, we adjusted linear regression models which included variables of interest as covariates. Assumptions of normality of residuals, heteroskedasticity, and multicollinearity were verified for all models.

# Results

A total of 136 subjects were invited to participate, 8 of which preferred not to due to undisclosed reasons or due to concerns regarding risk of infection during the pandemic (Fig. 1). A total of 128 subjects underwent randomization, three of which were excluded because they removed the goggles before the procedure was finished. Since randomization was paired, data from the corresponding controls was also excluded. The study groups were similar in sex distribution (percentage female 48.3% in VR group), socioeconomic status, type of procedure, use of analgesic medication, and participating center recruitment (Table 1). Only the use of electronic devices at home was different between the groups, with all 7 children whose parents denied contact with electronic devices being randomized to the control group.

Table 1
Patient characteristics at baseline

| Variable | Total (N = 122) | Control (n = 61) | VR (n = 61) | P value |
|---|---|---|---|---|
| **Age in months (median (IQR))** | 60 (48–63) | 60 (48–62) | 60 (48–70) | 0,203+ |
| **Sex** | | | | |
| Female | 58 | 30 | 28 | 0,856 |
| Male | 64 | 31 | 33 | |
| **SES** | | | | |
| Low Income | 25 | 14 | 11 | 0,734 |
| Middle Income | 78 | 37 | 41 | |
| High Income | 19 | 10 | 9 | |
| **Use of electronic devices at home** | | | | |
| No | 7 | 7 | 0 | **0,013*** |
| Yes | 115 | 54 | 61 | |
| **Procedure** | | | | |
| Venipuncture | 50 | 25 | 25 | 1 |
| Vaccination | 72 | 36 | 36 | |
| **Analgesia** | | | | |
| None | 108 | 55 | 53 | 0,776 |
| Acetaminophen | 14 | 6 | 8 | |
| **Participating Center** | | | | |
| Center 1 | 15 | 11 | 4 | 0,138 |
| Center 2 | 71 | 32 | 39 | |
| Center 3 | 36 | 18 | 18 | |

+: T-Test; *: Fisher's exact test, all others Chi-squared test. IQR: Interquartile range. VR: Virtual reality. SES: Socioeconomic status.

The results of the LLANTO scale are shown graphically in Fig. 2, with matching data in Table 2. Interobserver agreement was high, with a Fleiss Kappa of 0.828 and Cohen Kappas above 79% in all cases.

Table 2
Results of overall scores on the LLANTO scale per group

| Observer | Total | Control | VR | P value |
|---|---|---|---|---|
| | (N = 122) | (n = 61) | (n = 61) | |
| | Median (IQR) | | | |
| Researcher | 5 (4.75) | 7 (3) | 3 (3) | **< 0.001** |
| Parent or caregiver | 5 (4) | 7 (3) | 3 (4) | **< 0.001** |
| Nursing staff | 5 (4.75) | 7 (3) | 3 (4) | **< 0.001** |
| VR: Virtual reality; IQR: Interquartile range | | | | |

Table 3 shows the results of the linear regression models. On average, children randomized to the VR group during the procedure had LLANTO scores approximately 3 units below those of children in the usual care group. In the linear models for all observers, venipuncture was associated with an increase in pain ratings of slightly over one unit as compared with vaccination procedures. For two of the observer groups, parents/caregivers and researchers, the subject's sex had a significant effect on pain ratings, with females scoring slightly one unit below males. The results for bivariate analyses of each subcomponent of the LLANTO scale can be found in the Supplementary material. No adverse events occurred.

Table 3
Linear regression models per observer

| **Researcher scores** | **Coefficient (95% CI)** |
|---|---|
| VR | **-3.34 (-4.19; -2.48)** |
| Venipuncture | **1.43 (0.46; 2.41)** |
| Male | **0.89 (0.04; 1.73)** |
| Use of electronic devices | -0.57 (-2.42; 1.28) |
| Age | 0 (-0.04; 0.03) |
| No analgesia | -0.04 (-1.45; 1.37) |
| Center: 2 | 0.36 (-1.16; 1.88) |
| Center: 1 | -0.4 (-2; 1.19) |
| **Parent/caregiver scores** | |
| VR | **-3.04 (-3.93; -2.14)** |
| Venipuncture | **1.39 (0.37; 2.41)** |
| Male | **1.03 (0.14; 1.91)** |
| Use of electronic devices | 0.33 (-1.61; 2.27) |
| Age | 0.01 (-0.03; 0.04) |
| No analgesia | 0.29 (-1.18; 1.77) |
| Center: 2 | -0.59 (-2.18; 1.01) |
| Center: 1 | -0.89 (-2.56; 0.78) |
| **Nursing staff scores** | |
| VR | **-3.05 (-3.96; -2.14)** |
| Venipuncture | **1.29 (0.25; 2.33)** |
| Male | 0.68 (-0.23; 1.58) |
| Use of electronic devices | 0.25 (-1.73; 2.22) |
| Age | 0.01 (-0.03; 0.05) |
| No analgesia | 0.38 (-1.12; 1.88) |
| Center: 2 | -0.01 (-1.64; 1.61) |
| Center: 1 | -0.35 (-2.05; 1.35) |
| VR: Virtual reality; CI: Confidence interval | |

# Discussion

The pediatric population is particularly vulnerable to medical procedures as a whole. In a systematic review, Eijlers et al. suggest that procedures of any kind performed in children can lead to adverse effects ranging from escape attempts to post-traumatic stress [23]. These effects can be minimized by distraction strategies including screens, music and smells, among others [24–26]. Crevatin et al. carried out a randomized clinical trial comparing the use of a videogame in a handheld device with usual care, finding that only 1 in 6 children in the active arm reported any pain. However, this distraction strategy was no more effective than being distracted by the nursing staff [24]. The present study examined the effectiveness of VR as a pain distraction strategy for painful outpatient procedures in children. The results showed that non-immersive VR is an effective pain distraction tool in children between the ages of 3–5 years subjected to venipuncture and vaccination procedures, reducing pain by at least three points on the LLANTO scale. VR offers the integration of several of these sensory modalities into a single immersive experience, which could explain the clinically significant effect observed in this study.

Pain perception is known to require significant attentional resources. However, due to limited attentional capacity, if attention can be diverted, patients may have a slower response to incoming pain signals [10, 11]. VR offers a solution to this by integrating several sensory modalities into an immersive experience that effectively diverts attention away from pain. In fact, functional magnetic resonance imaging studies of healthy individuals subjected to painful stimuli and subsequently treated with VR have demonstrated that the activity of the individual pain matrix decreased by over 50% [27–29]. This decrease in neural activity was found to be consistent with the decrease in their subjectively reported pain scores [27, 28].

Interestingly, the multivariate models for both parents/caretakers and researchers showed higher pain scores for male subjects, a finding that has been reported in other studies. A clinical trial which sought to replicate a prior result compared pain scores given by adults to the same video of a child experiencing pain [30]. The scores differed significantly depending on whether the child was described as a “boy” vs. a “girl”, with higher scores given to the former. Additionally, the authors carried out a survey on gender bias, finding that the pain difference disappeared after controlling it. Since our study included no assessment on gender bias, exploring the contribution that it may have had is not possible.

In contrast to the findings of this study, a randomized clinical trial carried out in India did not find an effect of VR on the Venham self-reported anxiety sale, while finding significant changes on physiological parameters related to pain [31]. However, that study only included subjects with a documented aversion to the procedure, in whom a pre-existing emotional response may have accounted for a reduction in effect size. Similarly, a randomized clinical trial carried out in hospitalized patients found no differences in pre or postprocedural self-reported pain [32]. Differences in setting have also been described, as shown by Chan et al., who carried out two parallel clinical trials in the emergency department and another in an outpatient pathology unit. A significant effect of VR over usual care on pain reduction was found only in the emergency setting [33].

Several differences in both the design and setting between the studies may account for the different findings. The age of the participants, for example, ranged between 7–13 years. Children of that age would be expected to have a greater cumulative exposure to screens and even VR, potentially reducing the effect. The setting may have also a played a significant role since in one study the patients were hospitalized and where likely suffering from a diverse group of painful pathologies, and in the other isolation from the often hectic environment of an emergency department may have enhanced the effect over usual care [32, 33]. The statistical analysis may have given rise to an additional difference since the change in pain scores in the study by Caruso et al. was analyzed by means of a logistic regression splitting the outcome into reduction vs no change or increase, which may have reduced the statistical power [32].

At least two components of the pain scale used in the study add to the limitations. The breathing component includes a score for “Tachypnea” which is itself a formal definition with well-defined age ranges. Parents were not trained to determine the presence of tachypnea and were merely instructed to score whether or not the child seemed to be breathing more rapidly. The facial expression component is highly dependent on the behavioral cue that each scale provides, and this has previously been shown to be inconsistent, leading to insensitivity in the detection of differences in increases in pain intensity in children [34]. However, this would have likely biased our results towards the null hypothesis.

As is often the case in clinical trials, the selected sample may or may not be representative of the population. To counter this, we attempted to collect a broad sample of patients undergoing venipuncture or vaccination procedures in different surroundings. Additionally, the exclusion criteria ruled out children whose clinical condition could have altered the results of the scale (breathing and attitude). This included children with nutritional alterations like overweight and obesity which are increasingly more common in the general population, thus limiting the study’s external validity.

Another limitation of this study is that we did not enquire whether the parents or children would be willing to use the device in future procedures. Prior studies show high acceptability of VR among parents/caregivers, subjects and medical staff, despite negative results with regards to pain reduction [32]. Due to this we suspect that the parents of included subjects would display high acceptability.

Given that electronic device use at home was so widespread, it was not possible to examine the effect that this would have over the intervention’s effectiveness. This variable was included under the rationale that subjects with a greater exposure to screens may display a reduced distraction effect from VR. This constitutes a significant limitation of our study and is a research question that could be examined in future studies. In particular, a quantitative analysis on cumulative screen exposure duration would be of interest.

Finally, in this study we assessed pain levels solely from the perspectives of parents and healthcare personnel. Although self-reported pain levels are invaluable as they directly reflect the experiences of children with pain, anxiety, and fear. However, we could not report such scores due to limitations inherent to the childrens’ developmental age, which makes it difficult for them to articulate the different elements

that make up the painful experience [11]. It is important to note that observer-reported scores may not always accurately determine the quality of an intervention since they depend on the conditions under which the intervention takes place. In future research, efforts should be directed towards developing appropriate ways of involving infants and schoolchildren in self-reporting pain.

# Conclusion

The use of non-immersive VR used as a distraction strategy during painful procedures such as venipuncture and vaccination proved to be an effective non-pharmacological method for pain reduction in children. In this clinical trial, non-immersive VR was able to reduce pain in children aged 3 to 5 years by at least 3 points on the LLANTO scale, which was shown to have excellent interobserver agreement (parent, nursing staff, investigator). The low-cost commercial availability of non-immersive VR makes it a viable tool for use in this clinical setting. The implementation of non-immersive VR in outpatient settings is suggested in order to create humanized services and a better experience for children.

# Abbreviations

IQR: Interquartile range

SES: Socioeconomic status

VR: Virtual Reality

# Declarations

### COMPETING INTEREST AND FUNDING INFORMATION

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript. The authors have no relevant financial or non-financial interests to disclose.

### CONFLICTS OF INTEREST

The authors have no conflicts of interests to declare.

### AUTHORS CONTRIBUTIONS:

Drs. JCC and MAPA had primary responsibility for protocol development, patient screening, enrollment, outcome assessment, preliminary data analysis and writing the manuscript. Drs. LOC, NVV and LPC participated in the patient screening, enrollment, outcome assessment for the study and contributed to the writing of the manuscript. Dr. JMB supervised data collection and contributed to the writing of the manuscript. Dr IP supervised the design and execution of the study, performed the final data analyses and contributed to the writing of the manuscript.

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# Figures

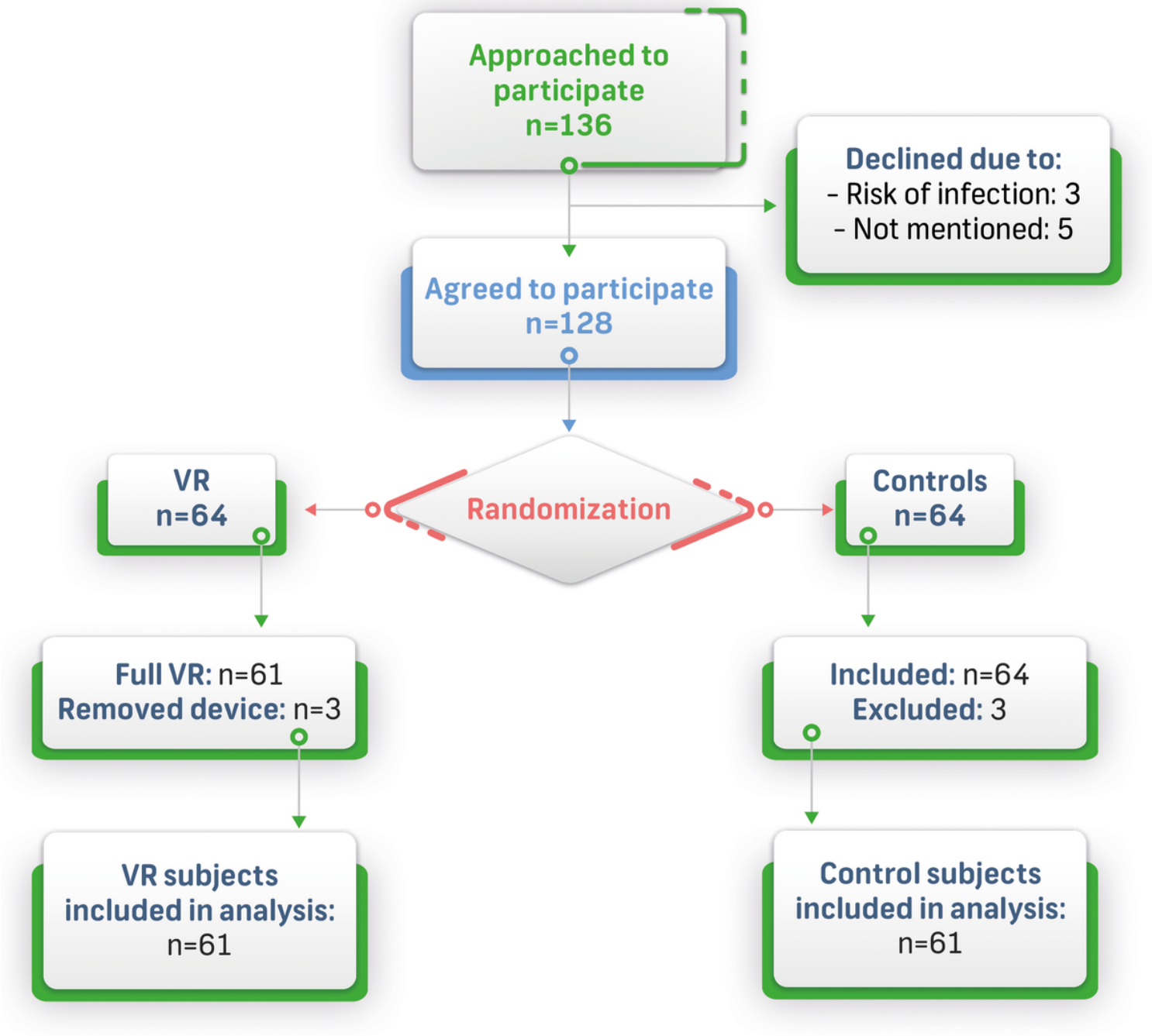


**Figure 1**

Consort flow diagram.

VR: Virtual Reality. Tree subjects in the VR arm removed the device and were excluded along with corresponding controls.

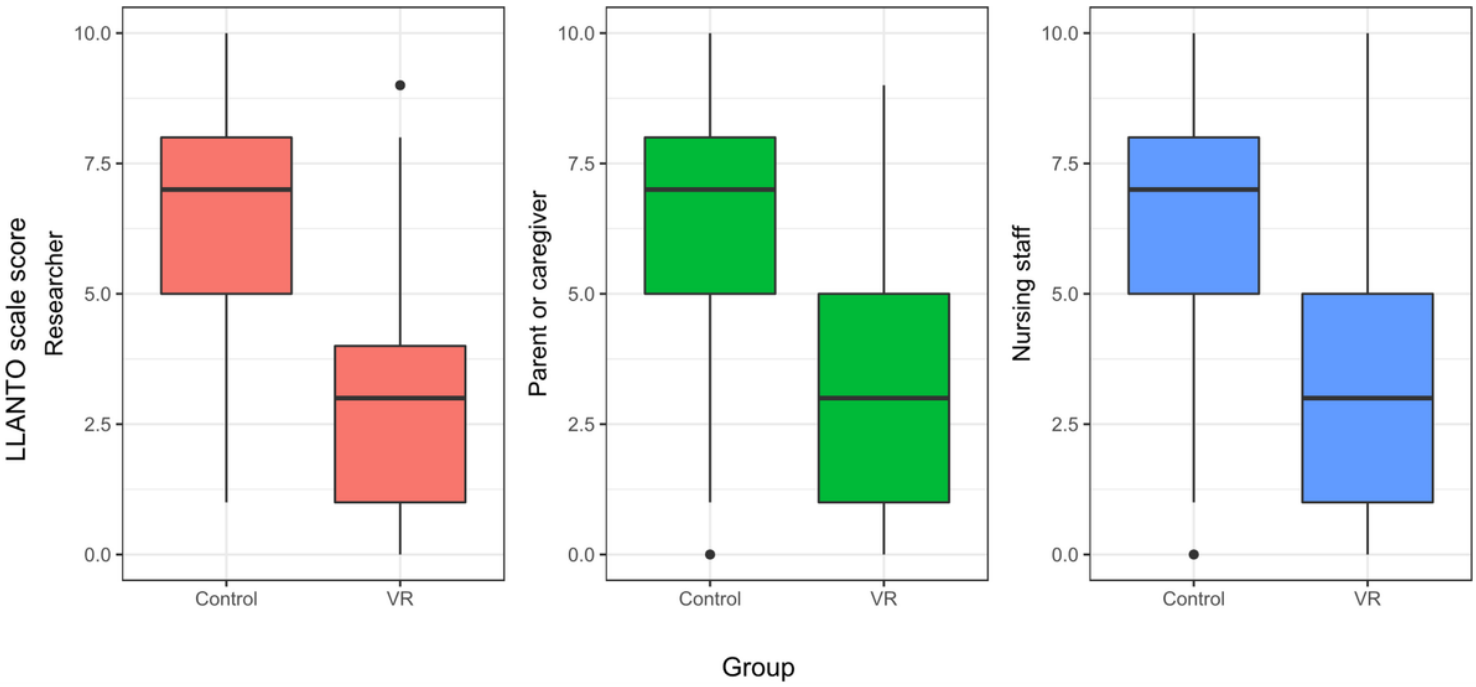


**Figure 2**

Distribution of total scores on the LLANTO scale by intervention group and observer

VR: Virtual Reality

# Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementalMaterial.pdf