RESEARCH PROTOCOL

USEFULNESS OF VIRTUAL REALITY IN THE MANAGEMENT OF PAIN ASSOCIATED WITH VENIPUNCTURE IN PEDIATRICS: A MULTI-CENTER RANDOMIZED CLINICAL TRIAL (RealPED)

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INTRODUCTION

Pain in Paediatrics

Throughout history, different definitions of pain have been formulated. The International Association for the Study of Pain (IASP) in 1979 defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(1). In 1994, the end of the definition – "described in terms of such harm" – was excluded, because it was considered to exclude the paediatric population, the elderly or people with difficulties in expressing themselves. All definitions agree that pain is a personal and multifactorial experience with physiological, behavioural, emotional, developmental and sociocultural components, which result to a different perception of pain(2).

The perception of childhood pain has been a source of controversy for years. Although it is currently accepted that infants and children may present pain, there is still a high rate of undertreatment of paediatric pain at the hospital level(3). The first step in treating pain is to make an adequate assessment of it(4). For this, we have three types of strategy: self-report or self-evaluation, observation of behaviour and physiological assessment.

Management of pain associated with procedures

Certain procedures, such as venepuncture for a routine blood test, can cause pain, anxiety or fear in children. We have pharmacological and non-pharmacological analgesia techniques to treat pain and anxiety associated with procedures. Their implementation in hospitals and health centers has an impact on a better quality of care and greater satisfaction of children and their families.

Some of the most widely used pharmacological methods are topical anaesthetics like EMLA. In addition, we have useful drugs in the treatment of anxiety associated with procedures, such as nitrous oxide or intranasal midazolam. (5). Non-pharmacological methods can complement pharmacological methods. They are generally effective and economical. They can be classified into (6):

- Support methods: promote psychosocial assistance to the child. Example: parental presence during procedures.
- Cognitive methods: try to influence the thoughts and imagination of children. Example: active or immersive distraction (playing, holding a conversation) and passive or non-immersive distraction (music therapy, watching TV).
- Behavioural methods: they are based on the child's own actions. Example: deep breathing.
- Physical methods: involve the sense of touch. Example: caresses, hugs.

Virtual reality as a method of non-pharmacological analgesia

Play, in a broad sense, is the main occupation of healthy children, so that through play their development is promoted and constitutes a means of communication and expression(7). To date, studies have been conducted on various types of gambling. In a literature review in which the literature published between 2005 and 2015(8) was reviewed, it is stated that different games or toys have been shown to be effective in reducing pain and anxiety generated during venepuncture. Among them we find music tables, portable video games, virtual reality glasses and the kaleidoscope.

Virtual reality, like the other types of game, is another method of active distraction. However, it has its own characteristics that differentiate it from play therapy in general. Virtual reality is defined as "a computer-generated, interactive, three-dimensional environment into which the person is introduced"(9). There are numerous studies conducted in paediatric age with virtual reality to reduce pain associated with procedures. Most of them have been performed in hospitalized patients or patients of the Emergency Department, who need intravenous insertion or blood test. In a randomized clinical trial conducted in our country with children aged 6 to 14 years(10), pain and anxiety associated with venepuncture and intravenous insertion were evaluated in a group that used virtual reality and in a control group with usual care (distraction with objects, questions of daily life).

In this study, they obtained lower means of pain and anxiety in the virtual reality group, although without statistically significant differences, probably due to the small sample size (17 participants).

Management of pain associated with procedures in Xàtiva-Ontinyent Health Department

In Xàtiva-Ontinyent Health Department, a population of 194,799 inhabitants is served. Of these, 26,165 are under the age of 15. Scheduled blood tests are performed at health centers of the department and at the two hospitals.

Non-pharmacological analgesia methods such as the presence of parents, distraction of the patient talking about daily life and pharmacological analgesia methods such as the application of EMLA are usually used.

1- JUSTIFICATION

In Spain there is a high prevalence at the national level of paediatric pain, often related to procedures such as venepuncture. Currently, due to the rise of new technologies, there are numerous studies carried out with virtual reality as a method of analgesia, but they are very diverse in terms of the type of patient and procedure.

With this project, we intend to verify the effectiveness of virtual reality in reducing pain and anxiety associated with scheduled blood collection in the paediatric population.

2- HYPOTHESIS

The use of virtual reality glasses decreases the pain associated with venepuncture in children.

3- OBJECTIVES

Main objective: to determine the effectiveness of the use of virtual reality in reducing pain and anxiety associated with scheduled blood tests.

Secondary objectives:

- To evaluate the satisfaction of parents or caregivers.
- To evaluate the satisfaction of the professional in charge of venepuncture.

4- PATIENTS AND METHODS

5.1- STUDY DESIGN

Multicenter randomized clinical trial carried out in 5 Health Centers and in the 2 Hospitals of the Xàtiva-Ontinyent Health Department, in which scheduled blood extractions are performed. The test will be carried out following the CONSORT guidelines(11). Patients are distributed in a 1:1

ratio to the intervention group (use of virtual reality during blood test) and to the control group (usual care). In the intervention group, OCULOS QUEST 2 Virtual Reality glasses will be used in which a video will be displayed from the beginning of the technique (preparation of material) to the end (compression). In the control group, venepuncture will be performed through usual care (distraction by nursing talking to the patient or through the use of topical anaesthetic in chronic patients undergoing multiple extractions).

5.2- SELECTION OF THE SAMPLE

The patients potentially eligible for the study will be those who come to perform a routine blood test to the centers participating in the study to perform a blood collection during the study recruitment period.

The Questionpro calculator (https://www.questionpro.com/es/calculadora-de-muestra.html) was used to calculate the sample size. With a confidence level of 95%, a margin of error of +/- 5, and an available population of 70 children, the required sample is 60 patients.

- Inclusion criteria:

Children aged between 7 and 12 years, who agree, both they and their parents or tutors, to participate in the study by signing the informed consent.

- Exclusion criteria:

- Children under 7 years old for not having completed the development of visual function(12).
- Children over 12 years old, since by expanding the age range, it would be a very heterogeneous sample.
- Not having signed the informed consent.
- Children with psychomotor and neurocognitive delay, due to the difficult assessment of anxiety.
- Children with visual or hearing disabilities, because they cannot adapt virtual reality glasses to their conditions.

- Randomization:

The sequence that will be carried out to carry out the study is:

1- Inform and recruit the participant.
2- Sign informed consent.
3- Open the envelope with the randomization.
4- Perform the technique (blood test with usual care or with virtual reality).

- Pseudonymisation:

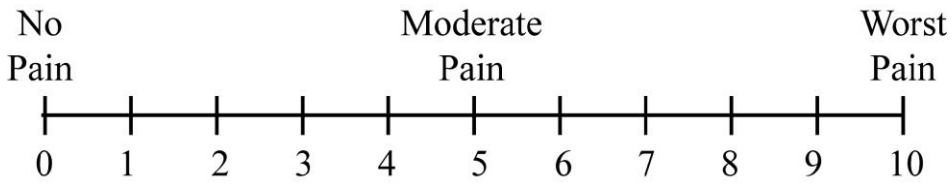
After including patients in the study, they will be assigned a code that will be formed by the initials of the two surnames followed by the last 3 digits of the number of the health card number.

5.3- OUTCOME MEASURES

- Primary outcome measures:

- Pain associated with venepuncture (Visual Analogue Scale) (Figure 1) (13)

Figure 1. Visual Analogue Scale.



- Anxiety associated with venepuncture: Groningen distress scale (Table 1) (14)

Table 1. Groningen distress scale

GRADE	STATUS OF CHILD	MUSCLE TENSION	CRY
1	Calm and no cry	No	No
2	Tension without crying	Clenches fists, pale knuckles, grinds teeth, closes eyes, muscle contraction, body stiffness	No
3	Tension with some cry	Like 2	Intermittent
4	Tension and continuous cry	Like 2	Continuous
5	Aggression / screams / physical resistance	Agitation, violent movements of the body and extremities, a lot of resistance to the procedure	Continuous, screams

- Secondary outcome measures:

- Number of attempts for analytics (1 to 5).
- Time required for analysis (minutes).
- Difficulty level of the technique (easy, normal or difficult)
- Parents satisfaction (1 = unsatisfied, 10 = very satisfied)
- Nurse anxiety (1 = totally calm 10 = very anxious)
- Pacient age at the moment of venipuncture (years)
- Pacient sex
- Venipuncture in the last 6 months (yes or not)

- Parental presence at the moment of venipuncture (yes or not)

5.4- ETHICAL ASPECTS

Prior to participation in the study, the parents or guardians of the patients will sign the informed consent.

5.5- STATISTICAL ANALYSIS

All the information obtained in the study will be tabulated in a database designed for this purpose in the SPSS program (Statistical Package for the Social Sciences) version 22, maintaining the anonymity of the patients. Descriptive analysis of the variables will be performed. The qualitative variables will be expressed with frequency distribution. Chi square will be applied to compare the qualitative variables and Mann Whitney U for ordinals. A significance level of $p < 0.05$ is established.

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