

**Study title :** *Virtual Reality for Pain and Anxiety Control in Pediatric Vaccination:  
randomized controlled trial*

**PhD Program in Nursing – UL/ESEL**

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**Advisors:** Prof<sup>ª</sup> Luísa Barros and Prof<sup>ª</sup> Isabel Malheiro

## ***The Participant Information Sheet (PIS)***

The study is part of the researcher's PhD in Nursing. She is a Specialist Nurse in Child and Pediatric Health at the Local Health Unit of Castelo Branco/ Personalized Health Care Unit of Castelo Branco, Portugal.

The study aims to investigate the procedures nurses use to ensure the child's well-being during vaccination, and in particular, the effectiveness of the application of Virtual Reality in controlling pain and anxiety during vaccination of five-year-old children in a Health Centre setting.

Participants are five-year-old children eligible for vaccination, registered at the Covilhã and Teixoso Health Units, from the Cova da Beira Health Center Groupment, and their parents/ legal guardians. Participation is entirely free and voluntary, and whatever the parents' or child's decision, it will not influence the received at the health centre.

The Participant Information Sheet is intended to clarify for parents/legal guardians how their child's vaccination will occur if you accept that your child and you participate in this study. Please read it carefully, and feel free to ask any questions: to signal your agreement, please sign it. The researcher will also sign and give parents/legal guardians a copy.

Participant children will be randomly distributed into two groups randomly, without the intervention of the researchers or nurses carrying out the procedure. In one group, the children are invited to use Virtual Reality glasses to watch a brief animated film during the entire vaccination procedure. In the other group, the children are vaccinated according to the usual procedure in the Health Unit. The groups will function on different days. In both groups, the nurses will take care to ensure the child is comfortable and supported during vaccination.

On the day of the vaccination, children and their parents/legal guardians will be welcomed by the nurse, who will explain the whole procedure and let them know which group the children belong to. Parents/legal guardians will answer a sociodemographic questionnaire and children the Children's Fear Scale (CFS) to assess anxiety before immunization; children will answer the Children's Fear Scale (CFS) and the Faces Pain Scale-Revised (FPS-R) to assess anxiety and pain after the administration of the two vaccines. The nurse will assist children in responding to the instruments.

In the group selected to use VR, the nurse will show how the equipment works, and explain how the procedure will occur and present the assessment instruments. In the group selected to use the usual procedure, the nurse will explain the procedure and present the assessment instruments.

A vídeo of the child's behavior during the procedure will be recorded to apply Face, Legs, Activity, Cry, Consolability (FLACC) afterwards. The video will be stored safely, accessible only to the researchers and may not be used for any purpose other than the current study. All the data collected will be collected and pseudo-anonymized for posterior analysis. After all the information is stored in anonymized data sets the images will be destroyed.

*Please contact the researcher if you need any further clarifications.*

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***Thanks***

Signature of the child's parent/legal guardian \_\_\_\_\_

Researcher's signature \_\_\_\_\_