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Research Article

Advances in the Cognitive Management of Chronic Pain in Children through the Use of Virtual Reality Combined with Binaural Beats: A Pilot Study

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Chronic pain affects the quality of life of those affected. The need to investigate alternative and complementary methods to the pharmacological one to alleviate chronic pain is evident, so virtual reality and binaural tones have become a topic of interest in this field in recent years. This study aims to analyze the contributions of the combination of these two techniques in pediatric patients with chronic pain. For this, data on psychophysiological responses (heart rate and galvanic skin response) and pain perception are collected during and after interaction with this technology using a mixed pre- and posttest experimental methodology. The physiological data and answers in the Pediatric Pain Questionnaire (PPQ) have been collected in a sample of $n = 13$ healthy participants and $n = 9$ pediatric patients with chronic pain. The results show a significant difference between baseline and after applying virtual reality and binaural beats, $m_d = 1.205$ ($t = 3.32$; $p < 0.05$). There are great effects on the perception of chronic pain if virtual reality and binaural beats are combined, even greater than with virtual reality alone, making this combination of technologies a very useful tool to be exploited for the management of chronic pain in pediatric patients with rheumatic diseases.

1. Introduction

Chronic pain (CP) in pediatric patients seriously affects their quality of life [1]. CP appears after a period of prolonged pain greater than 3 months [2] and is characterized by a loss of pleasant activities, which affects the mood of the person and their quality of life [3]. There are several alternative nonpharmacological methods for pain relief collected by [4], such as family support and assistance treatments, cognitive treatments (distraction), behavioral treatments (relaxation), and physical treatments (stimulation). In the case of pediatric patients, the goal is to combine pharmacological and nonpharmacological treatments for better pain management [5] to reduce the pharmacological methods side effects such as drowsiness or others. For this reason [3], we point out the use of virtual reality (VR) within the category of cognitive treatment as an alternative method of special interest. The effectiveness of this method is based on the gate control theory of pain, proposed by the authors of reference [6], since VR is an experience that absorbs large amounts of attentional resources from the patient, leaving pain in the background. They suggested that various factors play a role in how the person will interpret the pain, some of them being previous experiences of pain, the emotions associated, and the level of attention paid to the pain [7]. VR diverts attention from patients' mental processing, thereby decreasing

the amount of pain consciously experienced. Its use is limited to the management of acute pain in the field of health psychology; however, it is a very useful nonpharmacological tool for pain intervention, so its effectiveness should be analyzed more broadly, especially in the case of CP [8]. Definitely, as the authors of reference [9] explain, attention is an essential factor in pain perception, so much so that for nociceptive stimuli to be interpreted as pain it is necessary to pay attention to them. In other words, the intensity of pain and its discomfort could be modulated by modifying the focus of attention and promoting attentional competition with nociceptive stimuli [10]. In relation to VR [8], we concluded their study that CP levels were reduced after the first VR session.

VR is defined by the authors of reference [11] as a new technology consisting of the generation of a set of three-dimensional environments in which the user not only has the feeling of being physically present but can also interact with it in real time. Some of the advantages are that most VR technologies are relatively inexpensive, easy to use, have the potential to be used over a long period of time, and fit in small spaces such as the therapist's office [12]. Some investigations show that this technology exerts an influence during the processing of painful stimuli at the neurophysiological level, reducing brain activity related to pain [13–17] and demonstrating a significant reduction in subjective evaluation of CP that corresponded with changes in objective physiological measures. The authors of reference [18] state that the use of VR in pediatric wards offered a reduction in pain superior to standard distraction tools. In that sense [19], we concluded that VR is among the most effective psychological interventions in reducing both experimental and clinical pain. The authors of reference [20] affirm that VR is not only an immersive distraction technique but can also be used to train and develop new coping responses to pain. These possibilities offered by VR seem to be especially effective if applied to children and young people, mainly due to the interest they usually show in the use of these technologies, especially if they are presented in a playful way.

Binaural beats (BB) refer to the synchronization of the human brain through the use of sound frequencies at different ranges [21]. BB stimulation produces changes in the subject's brain, such as cognitive performance and mood [22], anxiety, and pain [23, 24]. Specifically, pain perception is related to changes in beta, alpha, and theta frequencies see Table 1. According to references [26, 27], a decrease in beta waves and an increase in low-frequency alpha and theta waves in the T3T4 and C3C4 regions is associated with a decrease in pain perception. The usefulness of BB in chronic pain has been widely studied in adults; however, the scientific literature on its use in pediatric patients is very scarce. It seems that it is correct to use VR as an alternative and complementary method to the pharmacological one for the management of chronic pain in children and young people, but the prevailing need to maximize its efficacy and minimize the effects of chronic pain on the quality of life of pediatric patients leads us to consider the possibility of combining VR and BB. Audio-visual stimulation training helps achieving long-term improvements in the cognitive process [28], and it is therefore of great interest to analyze the power of BBs on chronic pain and whether the combination of the BB technique with VR enhances this effect, since VR alone has been proved to be effective.

The main objective is to collect data on the effects of virtual reality and virtual reality combined with binaural beats, on the perceived pain of these children based on psychophysiological measures. The study hypothesis is that virtual reality combined with binaural beats will produce a greater decrease in the chronic pain perceived by pediatric patients than virtual reality alone, where the general purpose of this study is to analyze the suitability of this technology as a tool to help pediatric patients manage chronic pain in their daily lives.

2. Materials and Methods

2.1. Study Sample. The participants of this research were children and young people from 7 to 17 years old who suffer from a disease of rheumatological origin that causes CP. All participants and their parents or legal guardians authorized their participation in the study by reading and signing an informed consent. They were selected through three associations that serve children affected by various diseases in Mallorca: ABAIMAR, in MovIBment, and in èditHOS. An anamnesis is carried out and finally, children and young people with a disease of rheumatic origin with chronic pain for more than 3 months are included in the study. The pain interview conducted with the participants allowed for the detection of possible artefacts. One of the parents of each pediatric participant was also counted as a reporting subject to create a Pain Profile of each child, since some participants were not able to properly convey this information due to their young age. Moreover, it was made to be sure that every subject met the requirements of the experimental group. The group of pediatric participants suffering from a rheumatic disease with CP is referred to as the experimental group ($n = 13$, male (8) = 61,54%, and female (5) = 38,46%). In turn, a comparison group was created with healthy participants in the same age range and without PC ($n = 9$, male (2) = 22,22%, and female (7) = 77,78%).

2.2. Data Collection Instrument. The pediatric pain questionnaire from reference [29] was given to each subject in the children version to create a pain profile before the start of the session (pretest) and after each session (post-test). It allowed us to analyze whether there had been changes in the perception of their CP. At the same time, continuous and real-time psychophysiological data were obtained through the empathetic bracelet E4-a wireless smart device that is placed on the wrist. The bracelet has a series of sensors that allow collecting the heart rate (HR) and galvanic skin response (GSR) data [30] stated that the decrease in sweating is an indicator of relaxation [16] showed in their study that the HR was lower during the VR session, indicating a high degree of relaxation. Therefore, the three analyzed variables are presented in Table 2.

Table 1: Simplified classification of brain waves.

Brain wave	Frequency (Hz)	Effects
Beta	14 to 29	Intense mental activity, active concentration, and problem solving
Alpha	8 to 12	Mental relaxation and immune system stimulation
Theta	4 to 7.9	Light sleep and deep meditation
Delta	0.5 to 3.9	Deep sleep

Source: adaptation from [25].

2.3. Methods. The research was approved by the Research Committee (CER) of the University of the Balearic Islands. The methodology used in this study is experimental with a pre and post-test approach, and the data were analyzed both quantitatively and qualitatively through mixed method research. On the one hand, studying the psychophysiological response of the subjects to the use of the technology and, on the other hand, studying their perception through a questionnaire that measures the level of perceived pain in a given moment. This information is recorded in three different stages: before, during, and after the interaction with the tool, both in the experimental group and the comparison group. This technology receives the name of SOTER VR (see Figure 1) and has been created and validated for this project in collaboration with the UGIVIA group from the University of the Balearic Islands [31–33]. The equipment used for the interaction are Oculus glasses and controllers.

Three stages were created with the following characteristics:

(a) virtual reality (VR)

(b) virtual reality and ambient music (VR + M)

(c) virtual reality and ambient music with background binaural beats (VR + M + BB)

The music superimposed on stages B and C is Pachelbel's Canon in D major since it is a neutral soundtrack that does not produce disruption in the process nor does it produce emotional disturbance [34]. Each stage lasts 7 minutes and all participants go through all categories, which are assigned to each participant in a random order. There is a pause between the stages to avoid the "carry-on" effect, and this pause is used to answer the pediatric pain questionnaire in relation to the last completed stage. As mentioned previously, the questionnaire was also answered prior to the beginning of the first session to have a baseline for each participant. The instrument used for collecting the psychophysiological information is the empathetic bracelet E4, which is active throughout the procedure. In addition, it should be noted that the participants were not informed of which stage they were in so they were blind to the process.

3. Results

The data obtained in each of the variables were analyzed using the statistical package IBM SPSS Statistics 25.0. The descriptors of the pre- and post-pain questionnaires compare the means of the comparison group versus the experimental group-Table 3. In both groups, the initial pain was greater in the presession and decreased, reaching its lowest peak in the questionnaire after the (VR) session ($m = 1.846$ in the control group and $m = 2.611$ in the experimental group) and the (VR + M + BB) ($m\,(c) = 0.923$ and $m(e) = 1$). In the case of HR in the comparison group, there was no variation, while in the case of the experimental group it was lower before starting the session ($m = 108.6$) and increased until reaching the (VR + M + BB) session, where it reached its maximum ($m = 138.5$). The comparison group had a significantly lower means in GSR than that of the experimental group, in each of the three sessions, with differences of almost two points. By means of a transformation, the PAIN variable is turned from 4 to 3 dimensions. For this, instead of taking each of the questionnaires as an independent variable (1 survey is taken before starting and then 1 survey is taken after each session, which makes a total of 4), the subtraction of each of the posts with the pre is performed, thus it is possible to study the difference produced in the perception of pain in each session separately as a function of the change that occurs with respect to the baseline. The descriptive analysis of the new variable PAIN CONTRAST shows a maximum variation in the difference between the pain perceived before and after the session with BB ($m = -1.688$). Another transformation is carried out, this time including the psychophysiological variables, with the aim of estimating the variation of each variable in a session with respect to its previous session, regardless of the order of application. In this case, the variable PAIN is transformed into the variable PAIN INCREMENT with 3 dimensions. This variable shows a greater difference with the previous session in the VR session of the experimental group ($m = -2.00$) and the (VR + M) session of the control group ($m = -2.25$). The same transformation applies to the heart rate and sweating variables. The results show a maximum of the variation of HR in the VR session of the experimental group ($m = 32{,}970$), and a maximum decrease in the (VR + M) session of the control group ($m = -9{,}561$). In the case of GSR, the maximum increase occurs in the (VR + M) session of the experimental group ($m = 2{,}023$) and the maximum decrease occurs in the (VR + M + BB) session of both groups.

Levene's test of homogeneity of variance in the four pediatric pain questionnaires shows a $p > 0.05$, an indicator that there is homogeneity. In the case of HR, homogeneity was analyzed using the Mauchly sphericity test ($p = 0.015$), while in the case of GSR there was no sphericity (see Table 4). Levene's test for pain contrast indicates that there is homogeneity in each of the three dimensions of the variable. There is no homogeneity of variance in the variable pain increment since $p < 0.05$ in all cases. On the other hand, in

Table 2: Variables considered in the study and measuring instruments.

Variable	Name	Implementation	Measure instrument	Type	Authors	Analysis
Pain perception	PAIN	Pretest Post-test phase 1 Post-test phase 2 Post-test phase 3	Pediatric pain questionnaire	Subjective/psychological	Riquelme et al. [29]	Qualitative
Heart rate	HR	Whole session	Empathic bracelet E4	Objective/Physiological	Wiederhold et al. [16]	Quantitative
Galvanic skin response	GSR	Whole session	Empathic bracelet E4	Objective/Physiological	Spyridonis et al. [30]	Quantitative

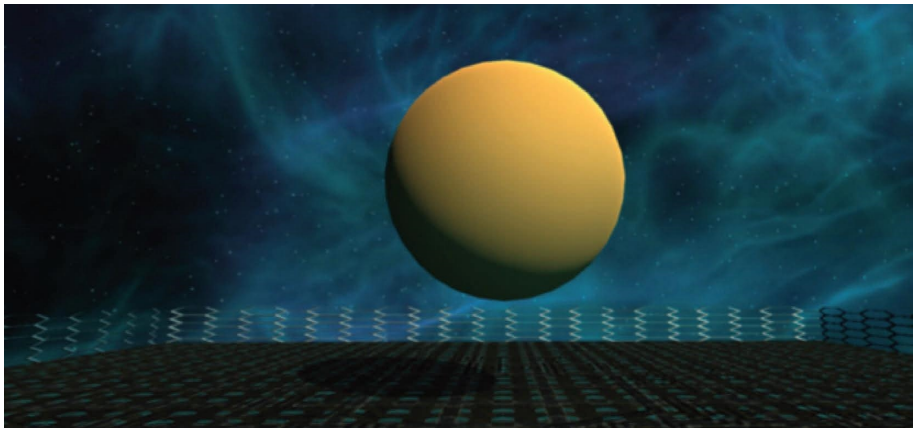

Figure 1: Experience with the SOTER VR application.

Table 3: Descriptive analysis of the three study variables: PAIN, HR, and GSR, and two transformed variables: PAIN INCREMENT and PAIN CONTRAST.

Variable	Subvariable	Group	*N*	Mean	SD
Pain	PRE	C	13	1.846	3.023
		E	9	2.611	2.667
	VR	C	13	1.115	1.960
		E	9	1.556	2.228
	VR + M	C	13	1.038	1.941
		E	9	1.278	1.481
	VR + M + BB	C	13	0.923	1.742
		E	9	1.000	1.299
HR	PRE	C	11	127.7	29.72
		E	3	108.6	12.04
	VR	C	11	130.4	10.67
		E	3	117.8	11.26
	VR + M	C	11	130.1	12.89
		E	3	132.5	18.19
	VR + M + BB	C	11	128.8	25.41
		E	3	138.5	24.53
GSR	VR	C	13	2.220	2.741
		E	6	4.047	5.302
	VR + M	C	13	2.169	2.546
		E	6	3.157	4.509
	VR + M + BB	C	13	1.825	2.534
		E	6	3.530	5.621
Pain contrast	VR	C	13	−0.731	1.333
		E	8	−1.063	1.208
	VR + M	C	13	−0.808	1.601
		E	8	−1.375	1.529
	BB	C	13	−0.923	1.789
		E	8	−1.688	1.668
Pain increment	VR	C	13	−0.500	3.536
		E	8	−2.000	
	VR + M	C	13	−2.250	1.768
		E	8	0.500	
	VR + M + BB	C	13	−1.500	0.707
		E	8	−1.000	

Table 3: Continued.

Variable	Subvariable	Group	N	Mean	SD
HR increment	VR	C	12	10.625	26.41
		E	4	32.970	68.72
	VR + M	C	12	−9.561	40.51
		E	4	5.060	11.92
	VR + M + BB	C	12	−4.156	28.04
		E	4	10.688	22.61
GSR increment	VR	C	12	1.424	2.921
		E	6	1.585	1.734
	VR + M	C	12	0.501	1.602
		E	6	2.023	4.921
	VR + M + BB	C	12	−0.227	0.743
		E	6	−0.060	1.684

Data collected with artifacts have been removed from the analysis. E refers to the experimental group. C refers to the comparison group.

Table 4: Homogeneity of variances and sphericity tests.

Variable	F	df1	df2	p
PAIN_PRE	0.162	1	20	0.691
Pain (VR)	0.016	1	20	0.899
Pain (VR + M)	0.037	1	20	0.850
Pain (VR + M + BB)	0.431	1	20	0.519
HR*				
GSR**				
Pain contrast (VR)	0.212	1	19	0.650
Pain contrast (VR + M)	0.089	1	19	0.769
Pain contrast (VR + M + BB)	0.119	1	19	0.734
Pain increment (VR)	0.000	1	1	<0.001
Pain increment (VR + M)	0.000	1	1	<0.001
Pain increment (VR + M + BB)	0.000	1	1	<0.001
HR increment (VR)	3.510	1	14	0.082
HR increment (VR + M)	0.860	1	14	0.369
HR increment (VR + M + BB)	1.058	1	14	0.321
GSR increment (VR)	0.060	1	16	0.809
GSR increment (VR + M)	1.263	1	16	0.278
GSR increment (VR + M + BB)	1.195	1	16	0.290

*Mauchly's W (HR) = .265 ($p = 0.015$), Greenhouse–Geisser (HR) = .608, Huynh–Feldt (HR) = .712. **Mauchly's W(GSR) = .834 ($p = 0.234$), Greenhouse–Geisser (GSR) = .857, and Huynh–Feldt (GSR) = .944.

the transformed HR variable there is homogeneity in all cases, as well as in the variable GSR increment.

The intrasubject analysis of the repeated measures ANOVA for the pain factor showed an effect $F = 9.314$ (with significance $p = 0.002$). In the case of the pain and group factors (group means comparison v experimental), there was no interaction ($p > 0.05$). In the case of the variables HR and GSR, there was no interaction in any of the three factors ($p > 0.05$), see Table 5. The intrasubject ANOVA of the transformed pain contrast variable shows an effect $F = 2.768$ ($p = 0.05$), a value very close to the limit $a = 0.05$. On the other hand, it does not show any interaction between the variable and the group (control or experimental). The intersubject's ANOVA also shows no effect on the group.

The post-hoc analysis of the pain questionnaire showed that there were significant differences between the pre- and the three post-test variables. On the other hand, in the three post variables, there were no differences between them. The post-hoc analysis of the groups of variables of HR and GSR did not show differences either ($p = 0.529$ and $p = 0.395$), as seen in Table 6. The post-hoc analysis for pain contrast shows that the greatest difference is found between the VR session and the BB session ($p = 0.072$). In the group analysis, there were no differences ($p = 0.415$). Intragroup ANOVA did not show any effect on the variable pain increment or any interaction depending on the group, as well as on the variable HR increment. On the other hand, although the ANOVA between groups of the variable GSR INCREMENT shows no effect on the group or the order, the intragroup analysis shows an interaction. The effect of the increase factor in GSR is $F = 13.976$ ($p < 0.001$) and that of the interaction of the variable with the order of application shows an effect $F = 15.601$ ($p < 0.001$). The effect of the interaction between the variable and the group is lesser ($p = 0.061$).

4. Discussion

The results of the pain questionnaire differ from those obtained by physiological tests. The information obtained from the empathetic bracelet does not show signs of greater relaxation in the participant; however, the participants reported feeling less pain than at the beginning of the test. On the other hand, in the pain questionnaire, there did not seem to be differences between groups; although at the beginning of the test the participants in the experimental group manifested a higher pain score, once the test started the scores were equalized. Neither are there any significant differences in the variables HR and SGR. Figure 2 appears to exhibit differences between groups in the variable GSR, but the post-hoc analysis shows that it is not statistically significant ($p = 0.395$). In all participants who manifested pain in the pretest, in the posttest, it was equal or lower. Only in one case did participant #9 go from a mean of 1.5 to 2 points due to the fact that the VR caused him a headache. The rest of the participants agreed that it was useful and did not report any discomfort.

By means of the new variable "pain contrast," it can be observed that pain decreases to a greater extent in the experimental group, although it always decreases regardless of the session and the group. Furthermore, this decrease in pain perception is not related to the order in which the sessions were applied (there were 6 possibilities). The greatest

Table 5: ANOVA statistics of the variables.

Variable	*Intrasubject's ANOVA*					*Intersubject's ANOVA*				
	Sum of squares	df	Mean square	*F*	*p*	Sum of squares	df	Mean square	*F*	*p*
Pain	19.992	1.492	13.403	9.314	0.002					
Pain*group	1.401	1.492	0.939	0.653	0.485	3.077	1	3.077	0.191	0.667
Pain residual	42.928	29.832	1.439			322.161	20	16.108		
HR	1410	1.825	772.7	1.207	0.315					
HR*group	1244	1.825	681.5	1.065	0.356	227.3	1	227.3	0.421	0.529
HR residual	12018	21.897	640.2			6484.1	12	540.3		
GSR	2.351	1.715	1.371	1.973	0.162					
GSR*group	1.688	1.715	0.984	1.416	0.257	27.94	1	27.94	0.760	0.395
GSR residual	20.256	29.154	0.695			624.86	17	36.76		
Pain contrast	1.655	1.627	1.018	2.768	0.088					
Pain contrast*group	0.465	1.627	0.286	0.777	0.444	4.568	1	4.568	0.693	0.415
Pain contrast residual	11.361	30.905	0.368			125.202	19	6.590		
Pain increment	0.250	2	0.125	0.016	0.984					
Pain increment*group	6.028	2	3.014	0.383	0.723	0.681	1	0.681	1.815	0.407
Pain increment residual	15.750	2	7.875			0.375	1	0.375		
HR increment	4654.792	2	2327.396	1.626	0.216					
HR increment*group	5.097	2	2.549	0.002	0.998	2134.1	1	2134.1	2.585	0.132
HR increment*order	1999.760	2	999.880	0.699	0.506	562.1	1	562.1	0.681	0.424
HR increment residual	37204.900	26	1430.958			10732.5	13	825.6		
GSR increment	93.46	2	46.730	13.976	<0.001					
GSR increment*group	20.50	2	10.250	3.066	0.061	5.769	1	5.769	1.201	0.290
GSR increment*order	104.33	2	52.165	15.601	<0.001	1.797	1	1.797	0.374	0.550
GSR increment residual	100.31	30	3.344			72.024	15	4.802		

Greenhouse–Geiser spherical correction was applied to all variables.

Table 6: Post-hoc analysis of the variables.

Variable	Comparison variable	Mean difference	SE	*t*	Cohen's d	*p* bonf
PAIN_PRE	PAIN_(VR)	0.864	0.264	3.277	0.699	0.022
	PAIN_(VR + M)	1.023	0.325	3.149	0.671	0.29
	PAIN_(VR + M + BB)	1.205	0.363	3.320	0.708	0.020
PAIN_(VR)	PAIN_(VR + M)	0.159	0.190	0.837	0.178	1.000
	PAIN_(VR + M + BB)	0.341	0.159	2.143	0.457	0.264
PAIN_(VR + M)	PAIN_(VR + M + BB)	0.182	0.125	1.449	0.309	0.972
HR comparison group	HR experimental group	4.910	7.570	0.649		0.529
GSR comparison group	GSR experimental group	−1.506	1.728	−0.872		0.395
CONTRAST (VR)	CONTRAST (VR + M)	0.195	0.174	1.121		0.808
	CONTRAST (VR + M + BB)	0.409	0.174	2.352		0.072
CONTRAST (VR + M)	CONTRAST (VR + M + BB)	0.214	0.174	1.231		0.677
CONTRAST control group	CONTRAST experimental group	0.554	0.666	0.833		0.415

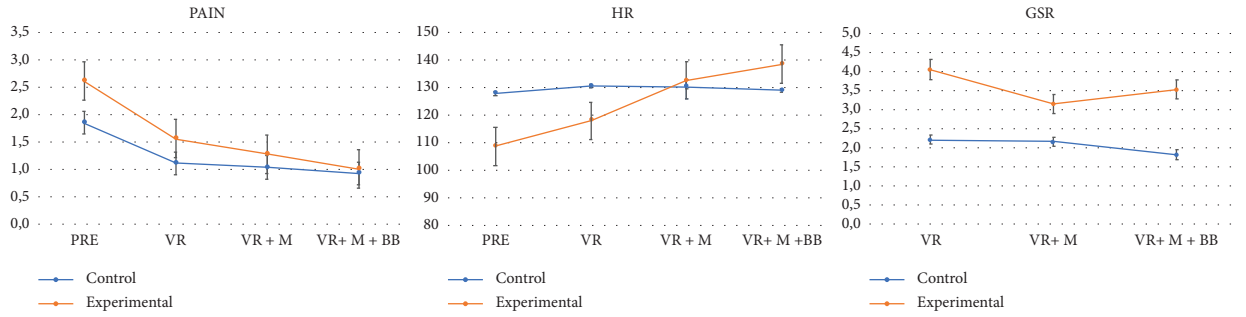

Figure 2: Graphic representation of the descriptive analysis of the three study variables. The horizontal axis shows each of the sessions and the vertical axis shows the mean value in the units belonging to each variable. It is observed that as elements are added to the RV (the M and BBs), pain perception, and GSR decrease, contrary to the HR.

difference between sessions occurs between VR and (VR + M + BB), with p very close to the limit value a. The descriptors of the variable "PAIN INCREMENT" show that, in all cases and regardless of the order and group, the perceived pain is lesser than in the previous session, except in the case of the experimental group in session (VR + M). Surprisingly, the comparison group of the same session is the one that shows the greatest decrease in pain perception compared to the previous sessions. Within the group of "INCREMENT" variables, pain is the only one that does not show homogeneity by Levene. In addition, as can be seen in the previous tables, the INCREMENT variable in general and mostly does not have any statistical value, although it does in the following cases. The HR is highly variable and does not seem to follow an apparent sense, even so, the minimum of both groups were found in the (VR + M) session and the maximum in the VR session. The ANOVA analysis shows an intrasubject effect of the variable "GSR INCREMENT" as well as an effect of the interaction between the factors and the order of application of the sessions. Sweating shows very little apparent variation, but it turns out to be statistically significant. In all cases, it increases with respect to the previous session except in the (VR + M + BB) session in both groups, and the post hoc analysis shows that the differences between the (VR + M + BB) session and the other two are significant, as well as the differences between the control group and the experimental group.

Ultimately, a decrease in the perception of pain is observed in all cases, except #9. Comparing the pre and posttest sessions, significant changes are observed, indicating a clear positive effect of the application. It has been proven that, in all combinations, the results are positive, causing a decrease in pain perception. It should be noted that the BB session is the one that has had the best results compared to the initial situation. It is also determined that the order of the sessions does not affect the results. The experimental group underwent more changes than the comparison group which may be because they start from a higher point on the scale, so that, in turn, there is also a greater decrease in pain. On the other hand, in the healthy group, the variation is not so great because the margin is smaller. Regarding the changes produced in the physiological variables, disparate results are obtained in the GSR between the groups, observing, as is the case with the questionnaires, a greater decrease in the BB session. Along these lines, as the authors of reference [30] comment, the decrease in sweating is an indicator of relaxation, so that, depending on the results obtained by the different techniques, BBs are effective in reducing pain. In the case of HR, the results do not coincide with those obtained through the questionnaires and the cited literature, observing a greater decrease in the HR in the M session in both groups, contrary to what was expected. The initial hypothesis indicated BB as the session that would achieve the greatest relaxation. These expected results are only fulfilled in the pain questionnaire and the GSR but are not supported by the HR. These conflicting results may be due to certain limitations of the research discussed .

In answer to the general purpose of this study: to examine the suitability of this technology as a tool to help pediatric patients manage chronic pain, there are not enough data to be able to give a clear answer to it. Although, as indicated by the contributions of the authors of references [14, 18, 19, 35–40], VR can be used as a distraction tool for pain reduction. The results obtained indicate that, despite its limitations, VR may represent a non-pharmacological intervention with great potential. On the other hand, and contrary to the postulates of references [16, 17], the results obtained in the psychophysiological measures do not correspond to the subjective evaluations. Regarding the hypothesis that VR combined with BB would produce a greater change in perceived pain than VR alone, the results indicate that the BB session is the one that produced a greater decrease in the perception of pain, as well as a decrease in sweating, in a way that coincides with that shown by the authors of references [23, 41]. The combination of VR with BB seems to be an emerging research line to improve pain management, and this study represents the first advance in this line, although, as an initial exploratory study, this work has limitations. First, the sample size. Due to the specificity of the sample, it is difficult to access a statistically significant number of participants, which is why it is necessary to replicate the study with a higher N so that the results can be generalized. Second, the best way to study VR applications is through a cohort study with a larger sample. Third, the previous experience of the participants with VR programs was not considered in the statistical analyzes. Also, the excitement of being the first experience with such equipment can be reflected in the psychophysiological measures, biasing the results, which is why it is necessary a larger sample or to consider this fact in the analysis. In addition, this circumstance can cause the participant not to achieve relaxation. Fourthly, participants may have given the expected answer in the subjective questionnaire. Finally, the difficulty of developing interventions for chronic pain is that it occurs throughout the day. However, we assessed the effect of the intervention during a short period, which limits the external validity of the study design.

5. Conclusions

The usefulness of VR as a distraction tool stands out, despite the limitations identified in this study. Another determining factor is the variations produced by BB in the mood [22, 23, 32, 41], among others. The research has shown that, indeed, BB produces certain changes in the mood of users, mainly aimed at causing states of greater relaxation. Based on the results obtained, it is intended to continue with this line of research to expand the subjects under study and the context of the application (day hospital, pediatric patients admitted to the ward, and patients from the Pediatric Palliative Unit of Son Espases Hospital). On the other hand, and in the long term, the aim is to obtain design criteria for tools based on VR and BB that are effective for the management of chronic pain in pediatric patients, not only on an ad hoc basis but also sustained over time. In addition, we have initiated the application of explainable AI algorithms to the SOTER VR intending to improve functionalities that allow the characteristics of the sessions to be adjusted to the

specific needs of each user and are expecting to have future results in upcoming evaluations.

Data Availability

The numerical data used to support the findings of this study have been deposited in the Zenodo repository (10.5281/zenodo.6817359).

Conflicts of Interest

The authors declare that they have no conflicts of interest regarding the publication of this paper.

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