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Impact of Virtual Reality-Delivered Biofeedback and Yoga on Pediatric Headaches: A Pilot Study

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Objectives: This study assessed the feasibility and acceptability of two types of innovative approaches, namely biofeedback-assisted relaxation in virtual reality ([VR]-delivered biofeedback) and yoga in the management of pediatric headaches. The secondary aim was to evaluate the preliminary efficacy of both interventions. ***Method:*** Children were randomized to three conditions: waiting list, yoga, and VR-delivered biofeedback. Feasibility was assessed by applicability to the pain problem, and acceptability by attendance (missed sessions, dropout rate) and the use of learned strategies in everyday life. Preliminary efficacy was evaluated with questionnaires: frequency of headaches, functional disabilities, pain anxiety, and pain catastrophizing. Mean scale scores postintervention and two months afterward were compared with the baseline with repeated-measures analyses of variance and contrast analyses. ***Results:*** A total of 46 children were enrolled; 39 completed the questionnaires at the baseline and participated in interventions. Regarding feasibility, the safety of the interventions seems demonstrated by the absence or infrequency of headaches during sessions. Regarding acceptability, compliance with the sessions was excellent for VR-delivered biofeedback condition and satisfactory for yoga. Most of the children reported using the strategies learned in daily life, even after the interventions. Regarding efficacy, participants reported significantly fewer headaches and functional disabilities postintervention and 2 months later. Minimal or no effects were observed on pain anxiety and pain catastrophizing. ***Conclusion:*** This pilot study indicates that VR-delivered biofeedback and yoga exercises may be feasible and acceptable interventions for the treatment of pediatric headaches.

Implications for Impact Statement

This study evaluates the feasibility and preliminary efficacy of two innovative interventions for pediatric headaches: virtual reality-delivered biofeedback and yoga exercises. The findings indicate that these interventions are feasible and applicable (good attendance, limited or no discomfort, and positive evaluation) and show preliminary efficacy (improvements in frequency of headaches and functional disabilities).

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Migraines and tension headaches are among the most common chronic illnesses in children and adolescents (prevalence of 5%–10% in Europe; Roos, 2019). Several studies have highlighted the significant impact headaches have on quality of life, including significant functional disability, missed school days, reduction in social activities, distress, and risks of developing comorbid mental disorders (e.g., Nieswand et al., 2020). Although the pharmacological approach has shown its efficacy (e.g., Rastogi et al., 2018), guidelines based on empirical evidence often conclude that isolated medical interventions do not generate adequate results. The biopsychosocial model supports the claim that pain is influenced by several factors which determine, at least in part, its management and its consequences (Turk, 1996). The factors that contribute to the sensory experience of pain include pain catastrophizing, which corresponds to negative pain-related cognitions (worries, amplification, and helplessness about the pain experience). Another factor is pain anxiety, which includes cognitive (increased difficulty concentrating when experiencing pain), emotional (fear of consequences associated with experiencing pain and fear of amplification of the pain), physiological (bodily reactions to the experience of pain such as increased heart rate) and behavioral reactions (active efforts to avoid the onset and exacerbation of pain; Pagé et al., 2010).

Particular attention has therefore been paid to nonpharmacological interventions, and especially cognitive-behavioral therapies focused on learning coping strategies including biofeedback, relaxation techniques, and the restructuring of dysfunctional beliefs related to pain (e.g., Rastogi et al., 2018). A literature review showed these treatments produce sizeable reductions in headache frequency and should no longer be considered solely as an alternative to pharmacological treatments; rather, they should be included in first-line treatments for headache disorders (Grazzi et al., 2021). More specifically, relaxation techniques, sometimes in association with biofeedback, were one of the first interventions to be investigated in the management of childhood headaches (e.g., Larsson et al., 1987). These mind–body approaches have been demonstrated to be effective in improving body awareness, relaxing tensed muscles, reducing stressful situations likely to trigger headaches and better managing headaches when they occur (e.g., Ng et al., 2018). In recent years, the use of complementary and alternative medicine (CAM) has become common in the management of headaches (Anheyer et al., 2020; Long et al., 2022). In this study, biofeedback-assisted relaxation in virtual reality ([VR]-delivered biofeedback) and yoga, both CAM interventions to practice relaxation, were investigated as management tools for pediatric headaches.

The use of VR to manage acute pain has mainly been studied for its potential as a distraction by directing the attention captured by the painful stimulus toward another source of stimulation (e.g., Arane et al., 2017). A meta-analysis by Eijlers et al. (2019) underscored the efficacy of VR in reducing pediatric pain during medical procedures in oncology, in burns care, in intravenous placement, and in the emergency room. Several studies suggest VR's potential for reducing chronic pain (e.g., Pourmand et al., 2018). Significant results in adults indicate that further research in children would be interesting (Shahrbanian et al., 2012), although none exists to date. Beyond its distractor potential, a few studies have tested the usefulness of VR in learning self-regulation techniques, such as deep breathing relaxation (Ahmadpour et al., 2020; Bossenbroek et al., 2020; Cook et al., 2021). In this study, the relevance of this tool is based on its capacity to offer an environment to practice relaxation with a biofeedback device and to master relaxation skills in increasingly difficult contexts.

Yoga, characterized by a combination of physical poses and breathing exercises, is considered an alternative medicine that is widely practiced. It improves muscle strength and flexibility while increasing circulation, oxygen uptake, and hormone function. The parasympathetic nervous system can become more dominant and stabilize the autonomic nervous system to improve resistance to stress (Evans et al., 2008). Several studies carried out in an adult population highlight the efficacy of yoga for physical and mental health, such as a reduction in symptoms of anxiety/stress and depression (e.g., Saeed et al., 2019), coronary heart disease (e.g., Li et al., 2021), and pain (e.g., Bakshi et al., 2021). Yoga has been investigated to handle pain-related somatic symptoms among children with internalizing disorders; improvements in pain-related coping were found (Allen et al., 2018). Although yoga has been seen as a promising approach (Anheyer et al., 2020), it has not been investigated much as a treatment for pediatric headaches. A recent review of alternative approaches recommended that the efficacy of yoga should be investigated (Rastogi et al., 2021). Moreover, a pilot study has provided preliminary data on the feasibility, acceptability, and safety of yoga for youths with chronic headaches (Hainsworth et al., 2014).

This pilot study investigated the feasibility (applicability to chronic headache disease), acceptability (participation, compliance), and clinical outcomes (headache frequency, functional disability, and pain representation as perceived by the child and the parents) of two innovative approaches, namely VR-delivered biofeedback and yoga, in the management of pediatric migraines and tension headaches. Considering that these two CAMs are increasingly popular and used in different clinical settings, we thought it would be interesting to explore, first, their feasibility and acceptability in the context of pediatric headaches and, second, their relative efficacy for pain relief. This is a necessary first step prior to conducting a large-scale randomized clinical trial (RCT) or other kind of clinical trial (e.g., preference trial), to establish whether the treatment is feasible, outcome measures are appropriate, and the treatment is applicable and safe in this chronic pediatric headache population. The efficacy of the two active interventions was not compared given the absence of previous data to ground hypotheses, and to keep the statistical analyses orthogonal.

Methodology

Participants

Participants were recruited by pediatric neurologists from hospitals in the Liège region (Belgium) who informed potential participants about the project. The study sample constituted 37 children aged 7–16 years, $M = 10.95$, $SD = 2.52$ (14 boys, $M = 11.00$ years, $SD = 2.72$; 23 girls, $M = 10.91$ years, $SD = 2.45$), and their parents aged 30–53 years, $M = 41.00$, $SD = 5.03$ (32 mothers and five fathers). Inclusion criteria were being aged 7–16 years, speaking French fluently, having a history of headaches for at least 6 months, and having been diagnosed with migraines and/or chronic tension headaches according to International Headache Society criteria by a pediatric neurologist. Participants were asked not to undertake any psychological or dietary treatment during the intervention, nor to make any changes to their medication. This study was carried out between October 2018 and June 2021. The study design and procedure were approved by the Institutional Ethics Committee (B707201731964). All participants took part voluntarily and signed an informed consent form in which they were guaranteed anonymity. They were also informed that they could stop participating at any time without justifying this decision. Written informed consent was obtained from the parents and assent was obtained from the children. The participants anonymously (assigned code) completed the self-report measures at home. The questionnaires were administered to the children using standardized written instructions (oral reading of the statements of each questionnaire). Parents responded to their questionnaires alone and in separate rooms.

Design

Children were randomly assigned to one of three conditions—yoga ($n = 11$), VR-delivered biofeedback ($n = 14$), or control (waiting list [WL], $n = 12$)—with a random numbers table before recruitment. The random allocation sequence, recruitment of participants, and assignment of participants to conditions were done by one experimenter. A different experimenter administered the questionnaires. Neither the participants nor the experimenters were blinded to the group assignment given the active nature of the interventions. The participants anonymously completed a set of self-report measures in paper-and-pencil format at home. Participants in the experimental conditions (yoga and VR-delivered biofeedback) received the intervention immediately, while those in the WL condition received the intervention of their choice after a delay of two months. Participants in the WL condition completed the questionnaires twice (pre- and postintervention), without benefiting from intervention. Participants in the experimental conditions completed the questionnaires three times: before the intervention (pre), after the intervention (post), and 2 months later (2-month follow-up).

For both the yoga and VR-delivered biofeedback interventions (detailed description in the online supplemental materials), psychoeducation on migraine and tension headaches was given at the beginning of each session. The yoga intervention was executed in a group (four to six maximum), once a week for 8 weeks (45-min sessions) by a psychologist trained in the Yoga Bali Program, adapted for children with headaches and based on the Bali method (Bali, 2015). The children were accompanied by one of their parents, who participated in the intervention to facilitate the transfer of skills at home. The intervention included yoga poses, breathing, and visualization practices. At the end of the session, the children were taught exercises and invited to practice regularly at home. The VR-delivered biofeedback intervention was delivered individually once a week for 8 weeks (45-min sessions) by a psychologist trained in VR. The tool combined VR equipment and biofeedback. At the first session, relaxation skills were introduced and practiced (abdominal breathing and muscle relaxation recalled at the start of each session). Next, the children were instructed to reach a state of relaxation in three virtual environments (an apartment, a classroom, and a convenience store developed by the Cyberpsychology Lab of University of Quebec in Outaouais), allowing them to practice biofeedback in increasingly challenging situations. Heart rate frequency was used to illustrate relaxation via a gradual change in the color and joyful energy of a virtual butterfly called Billy displayed in the VR environment. The objective was to train participants to do abdominal breathing while being engaged in day-to-day tasks (e.g., walking, giving a speech, and shopping). At the end of the session, it was suggested that children practice breathing exercises at home.

For both treatment conditions, all professionals used an intervention manual written by Céline Stassart, describing precisely, step by step, the theoretical and practical content of each session.

Measures

To evaluate primary outcome (feasibility and acceptability), enrollment, completed surveys, and the children's and parents' attendance at sessions (percentage of individual sessions attended) were assessed. The frequency of headaches during yoga and VR-delivered biofeedback sessions was also assessed. In the VR-delivered biofeedback condition, each child reported their feeling of presence in the virtual environment using the Gatineau Presence Questionnaire (Laforest et al., 2016). This is a four-item instrument with an 11-point Visual Analog Scale (0–10), which evaluates the sensation of having left the real environment and being present in the virtual environment. Total score ranges from 0 to 100, with higher scores indicating *greater feeling of presence*. The scale's psychometric properties were reported by Laforest et al. (2016). In this condition, children also reported the severity of side effects due to their immersion in VR (e.g., nausea, eye fatigue, dizziness, etc.) with the Simulator Sickness Questionnaire for Children (St-Jacques, 2007), an 11-item instrument with 3-point Likert scales (0–2) that was administered before and after each VR immersion. Total score ranges from 0 to 22, with higher scores indicating *more simulator sickness*. Children also completed surveys after the intervention and 2 months later regarding their use (outside the sessions) of breathing techniques learned as a strategy to manage headaches, with 4-point Likert scales (*never*, *sometimes*, *often*, *all the time*).

The preliminary efficacy of the interventions was evaluated with several scales. The Measurement of Frequency of Headache assesses the frequency of headaches in the last month with a 9-point Likert scale (0–8), with higher scores indicating *higher levels of limitation*. The Child Activity Limitations Interview-21—Child and Parent (CALI-C and CALI-P; Palermo et al., 2008) was used to assess children's pain-related activity limitations during the last 4 weeks. It is a 21-item instrument with 5-point Likert scales (0–4) and was completed independently by the children (CALI-C) and the parents (CALI-P). Total score ranges from 0 to 84; higher scores indicate *greater limitations*. The psychometric properties of this questionnaire (internal consistency and validity) were documented by Palermo et al. (2008). The Child Pain Anxiety Symptom Scale (CPASS; Pagé et al., 2010) is a 20-item instrument with 6-point Likert scales (0–5) used to measure pain anxiety: the thoughts, feelings, behaviors, and physical sensations that accompany the experience and anticipation of pain. It has four subscales: fear of pain, cognitive anxiety, escape and avoidance behaviors, and physiological symptoms of anxiety. Total score ranges from 0 to 100, and higher scores indicate *higher levels of pain anxiety*. The CPASS has demonstrated good internal consistency and good validity and reliability (Pagé et al., 2010). The Pain Catastrophizing Scale—Child and Parent (PCS-C and PCS-P; Crombez et al., 2003; Goubert et al., 2006) is a 13-item instrument with 5-point Likert scales (0–4) used to measure pain dramatization; it has three subscales: rumination, amplification, and helplessness. Total scores range from 0 to 52, with higher scores indicating *higher levels of pain catastrophizing*. The results of the validation study by Crombez et al. (2003) showed good internal consistency. A parent version was also used to assess the parent's worry and feelings of helplessness in the face of their child's pain (Goubert et al., 2006).

Data Analyses

Acceptability analyses were based on the rate of enrollment in the study and of completed questionnaires, percentage of attendance at yoga and VR sessions and use of abdominal breathing outside the sessions, during the intervention and 2 months later. Feasibility analyses were based on the frequency of headaches during the sessions. For VR alone, technical feasibility measures were used to evaluate simulator sickness (paired *t* tests were conducted) and the feeling of presence in the virtual environment (qualitatively compared to reference means). Preliminary efficacy analyses were tested with repeated-measures ANOVAs on three conditions (WL, yoga, and VR-delivered biofeedback) × 2 times (pre and post). A priori orthogonal contrast analyses were performed comparing pre–post changes between (a) WL and VR-delivered biofeedback and (b) WL and yoga. These contrast analyses were performed for all variables given that a priori orthogonal contrast analyses can be performed independently of the results of repeated-measures ANOVAs (Furr, 2008). The longitudinal effect of the intervention was analyzed with repeated-measures ANOVAs for 2 conditions (yoga, VR-delivered biofeedback) × 3 times (pre, post, 2-month follow-up). Planned a priori orthogonal contrast analyses comparing pre and 2-month follow-up, and then post and 2-month follow-up were conducted separately for the yoga and VR-delivered biofeedback conditions to document changes over time in each condition. It was expected that the pre to 2-month follow-up contrast analyses would be statistically significant and conducted with sufficient statistical power. Stabilization of improvements was expected between post and 2-month follow-up, although the sample size was too small to have enough power to reach conclusions in the absence of statistically significant differences. Effect sizes were calculated using partial eta squared (Lakens, 2013). Despite the small sample, parametric statistical tests were used after confirming the convergent results with nonparametric statistical tests. Analyses were done with SPSS V.26.

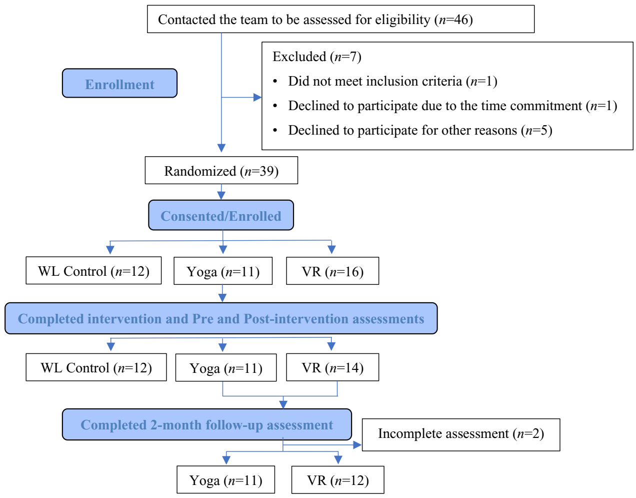
Results

Feasibility and Acceptability

Of the 46 children who contacted us to be enrolled in the study, seven withdrew prior to randomization (Figure 1); one child changed her mind about participating because she no longer had headaches, five children declined to continue before the randomization, for reasons not mentioned and one child declined to continue participating after assenting to the study, due to the time commitment. All participants completed pre and post intervention surveys, and only two participants did not complete follow-up surveys. Regarding compliance, 100% participation at all sessions was observed in the VR-delivered biofeedback intervention. In the yoga intervention, the level of participation was a mean of 6.55 times out of eight ($SD = 1.13$) for the group sessions: three children and their parent participated in all sessions (27% of subjects), two participated in 7/8 sessions (18%), four participated in six/eight sessions (36%), and two participated in five/eight sessions (18%).

During the VR-delivered biofeedback intervention, eight out of 14 children (57%) declared that they had used abdominal breathing to

Figure 1
Modified Consolidated Standards of Reporting Trials Flow Diagram Describing Recruitment and Enrollment



Note. WL Control = waiting list control; VR = virtual reality. See the online article for the color version of this figure.

manage headaches outside the sessions: six used it often and two every time they had a headache. At the 2-month follow-up, eight out of 12 children (67%) said they had used abdominal breathing during headaches: occasionally ($n = 1$), often ($n = 6$), or every time ($n = 1$). One child reported having no headaches during this period and not having used abdominal breathing for this reason. During the yoga intervention, eight out of 11 children (72%) said they had used the strategy they learned to manage headaches: occasionally ($n = 2$), often ($n = 6$), or every time ($n = 1$). At the 2-month follow-up, eight out of 11 children (72%) reported having used the strategy during headaches: occasionally ($n = 1$), often ($n = 2$), or every time ($n = 5$).

No child reported a headache during the various yoga sessions or until at least one hour afterward. Only one child reported a headache during a VR immersion session, and breathing exercises helped to relieve this headache significantly. For the VR-delivered biofeedback intervention, the feelings of presence experienced were between 61.48 and 69.30 (*SD* between 24.13 and 30.22), and can be considered satisfactory. Paired *t* tests were conducted for the questionnaire measuring simulator sickness before and after each VR immersion. Significant differences were observed only at Immersions 2, $t(13) = -2.46$, $p = .029$, and 7, $t(13) = -2.88$, $p = .013$; details in the online supplemental materials. However, the simulator sickness scores obtained at each session can be considered low.

Preliminary Efficacy

Preintervention, no significant difference was observed between conditions in terms of sex, age, and headache scores (*p* between .901 and .204; details in the online supplemental materials). Descriptive data of the variables studied are in Table 1.

Repeated-measures ANOVAs were conducted with headache and activity limitation outcome measures pre and postinterventions. The Time and interaction effects were statistically significant (Table 2). The planned a priori orthogonal contrast analyses on change scores were conducted separately for the VR-delivered biofeedback and yoga conditions against the WL condition. For the VR-delivered biofeedback condition, the contrast was statistically significant for the headache score, $F(1, 24) = 7.52$, $p = .011$, $\eta_p^2 = .24$, and close to statistical significance for CALI-C and CALI-P scores, $F(1, 24) = 4.09$, $p = .054$, $\eta_p^2 = .15$; $F(1, 24) = 2.80$,

Table 1

Descriptive Statistics of Children With Headaches Participating in a Pilot Randomized Clinical Trial Comparing to Yoga or VR-Delivered Biofeedback Interventions to a Waiting List

	M (*SD*)		
Conditions	Pre	Post	Follow-up (2 months)
Headache score			
Waiting list	5.17 (1.53)	5.58 (1.89)	
Yoga	5.18 (1.17)	4.27 (1.01)	2.64 (1.96)
VR-delivered biofeedback	6.07 (2.67)	4.21 (3.58)	4 (3.26)
CALI-C			
Waiting list	36.67 (20.56)	33.75 (19.76)	
Yoga	46.45 (17.21)	24.27 (18.10)	14.45 (11.34)
VR-delivered biofeedback	46.29 (20.72)	27.21 (21.16)	17.33 (12.56)
CALI-P			
Waiting list	20.17 (20.53)	18.25 (20.69)	
Yoga	40.18 (21.42)	17.64 (13.63)	10.27 (9.12)
VR-delivered biofeedback	37.71 (26.84)	25.50 (23.80)	21.42 (22.81)

Note. VR = virtual reality; CALI-C = Child Activity Limitations Interview-21—Child; CALI-P = Child Activity Limitations Interview-21—Parent.

$p = .107$, $\eta_p^2 = .10$. For the yoga condition, the contrasts were statistically significant for CALI-C and CALI-P scores, $F(1, 21) = 7.134$, $p = .014$, $\eta_p^2 = .25$; $F(1, 21) = 11.48$, $p = .003$, $\eta_p^2 = .35$, and close to statistical significance for the headache score, $F(1, 21) = 2.87$, $p = .105$, $\eta_p^2 = .12$.

For the results at follow-up, repeated-measures ANOVAs revealed significant Time effects for all three variables (Table 2). The planned a priori contrast analyses comparing pre and 2-month follow-up, and then post and 2-month follow-up times were conducted separately for VR-delivered biofeedback and yoga. For the VR-delivered biofeedback condition, the repeated contrasts between pre and 2-month follow-up were statistically significant for the headache score, $F(1, 10) = 5.541$, $p = .035$, $\eta_p^2 = .30$, CALI-C, $F(1, 10) = 23.564$, $p = .001$, $\eta_p^2 = .68$, and CALI-P, $F(1, 10) = 5.366$, $p = .037$, $\eta_p^2 = .29$: scores were lower at the 2-month follow-up than preintervention. Scores at the follow-up continued to decrease in severity in the VR-delivered biofeedback condition. The repeated contrasts between post and 2-month follow-up were close to statistical significance for the CALI-C, $F(1, 10) = 3.872$, $p = .075$, $\eta_p^2 = .26$, and not significant or clinically significant ($\eta_p^2 \leq .02$) for the headache score, $F(1, 10) = 0.083$, $p = .777$, $\eta_p^2 = .01$, or CALI-P, $F(1, 10) = 0.092$, $p = .766$, $\eta_p^2 = .01$. For the yoga condition, the repeated contrasts between pre and 2-month follow-up were statistically significant for the headache score, $F(1, 10) = 14.627$, $p = .003$, $\eta_p^2 = .59$, CALI-C, $F(1, 10) = 32.442$, $p < .001$, $\eta_p^2 = .76$, and CALI-P, $F(1, 10) = 20.539$, $p = .001$, $\eta_p^2 = .67$. Scores continued to decrease in severity at the follow-up, and the repeated contrasts between the post and 2-month follow-up times were statistically significant for the headache score, $F(1, 10) = 5.400$, $p = .042$, $\eta_p^2 = .35$, CALI-C, $F(1, 10) = 6.054$, $p = .034$, $\eta_p^2 = .38$, and CALI-P, $F(1, 10) = 6.328$, $p = .031$, $\eta_p^2 = .39$.

Repeated-measures ANOVAs were conducted with measures of negative pain representation pre and postintervention (pain anxiety and pain catastrophizing). Only the main effects of Time were significant (Table 3). The planned a priori orthogonal contrast analyses were conducted separately for the VR-delivered biofeedback and yoga conditions against the WL condition. For the VR-delivered biofeedback condition, the contrasts were not significant for the CPASS, PCS-C, and PCS-P, respectively, $F(1, 24) = 1.36$, $p = .255$, $\eta_p^2 = .05$; $F(1, 24) = 6.65$, $p = .430$, $\eta_p^2 = .03$; $F(1, 24) = 1.40$, $p = .249$, $\eta_p^2 = .06$. For the yoga condition, the contrasts were statistically significant for the PCS-P, $F(1, 21) = 4.51$, $p = .046$, $\eta_p^2 = .18$, but not for the CPASS and PCS-C, respectively, $F(1, 21) = 1.27$, $p = .272$, $\eta_p^2 = .06$; $F(1, 21) = 1{,}81$, $p = .193$, $\eta_p^2 = .08$.

Repeated-measures ANOVAs were conducted to assess the effects of the intervention at the 2-month follow-up. The main effect of Time was significant for PCS-C and PCS-P scores (Table 3). The planned a priori contrast

Table 2

Inferential Statistics for the Comparison Between a Waiting List and Yoga or VR-Delivered Biofeedback Interventions on the Measures of Headache and Limitations in Activity in Children With Headaches

		Repeated-measures ANOVA		
Variables studied	Analysis times	Time *F* (*df*)	Condition *F* (*df*)	Interaction *F* (*df*)
Headache score	Pre–post analysis	5.48 (1, 34) ($p = .025$, .14[a])	0.29 (2, 34) ($p = .750$, .02[a])	4.08 (2, 34) ($p = .026$, .19[a])
	Pre–post follow-up analysis	10.36 (2, 46) ($p < .001$, .31[a])	0.71 (1, 23) ($p = .409$, .03[a])	1.01 (2, 46) ($p = .374$, .04[a])
CALI-C	Pre–post analysis	20.67 (1, 34) ($p < .001$, .38[a])	0.03 (2, 34) ($p = .969$, .002[a])	3.32 (2, 34) ($p = .048$, .16[a])
	Pre–post follow-up analysis	31.49 (2, 46) ($p < .001$, .58[a])	0.22 (1, 23) ($p = .643$, .01[a])	0.26 (2, 46) ($p = 774$, .01[a])
CALI-P	Pre–post analysis	18.55 (1, 34) ($p < .001$, .35[a])	1.32 (2, 34) ($p = 282$, .07[a])	4.14 (2, 34) ($p = .025$, .20[a])
	Pre–post follow-up analysis	19.70 (2, 46) ($p < .001$, .46[a])	0.77 (1, 23) ($p = .390$, .03[a])	2.76 (2, 46) ($p = .074$, .11[a])

Note. The number of participants and conditions differed between the first (control = 12, yoga = 11, VR-delivered biofeedback = 14) and second (yoga = 11, VR-delivered biofeedback = 12) analyses. VR = virtual reality; ANOVA = analysis of variance; CALI-C = Child Activity Limitations Interview-21—Child; CALI-P = Child Activity Limitations Interview-21—Parent.
[a] Partial eta squared.

analyses comparing the pre and 2-month follow-up and then post and 2-month follow-up times were conducted separately for the VR-delivered biofeedback and yoga conditions. For the VR-delivered biofeedback condition, the repeated contrasts between the pre and 2-month follow-up times were not significant for the CPASS, $F(1, 10) = 0.028$, $p = .869$, $\eta_p^2 = .002$, PCS-C, $F(1, 10) = 2.659$, $p = .127$, $\eta_p^2 = .17$, or PCS-P, $F(1, 10) = 1.136$, $p = .306$, $\eta_p^2 = .08$. The repeated contrasts between the post and 2-month follow-up times were not significant for the CPASS, $F(1, 10) = 0.697$, $p = .419$, $\eta_p^2 = .05$, or PCS-P, $F(1, 10) = 0.238$, $p = .634$, $\eta_p^2 = .02$; they were close to statistical significance for the PCS-C, $F(1, 10) = 3.209$, $p = .097$, $\eta_p^2 = .20$. For the yoga condition, the repeated contrasts between the pre and 2-month follow-up times were not significant for the CPASS, $F(1, 10 = 1.621$, $p = .232$, $\eta_p^2 = .14$, but were statistically significant for the PCS-C, $F(1, 10) = 9.952$, $p = .010$, $\eta_p^2 = .50$, and PCS-P, $F(1, 10) = 21.670$, $p = .001$, $\eta_p^2 = .68$, both of which showed a decrease in scores over time. The repeated contrasts between the post and 2-month follow-up times were not significant for the CPASS, $F(1, 10) = 0.075$, $p = .790$, $\eta_p^2 = .01$, PCS-C, $F(1, 10) = 0.078$, $p = .786$, $\eta_p^2 = .01$, or the PCS-P, $F(1, 10) = 2.457$, $p = .148$, $\eta_p^2 = .20$.

Discussion

The main objective of this pilot study was to investigate the acceptability and feasibility of two types of innovative approaches, VR-delivered biofeedback and yoga, in the treatment of pediatric headaches. The results were promising. High attendance and low attrition indicate good adherence to treatment and appreciation of the interventions. Poorer attendance was, however, observed in the yoga condition. This result might be explained by the fact that it was a group intervention, which allowed less freedom for individual preferences and placed more constraints on parents' schedules. In future studies, it would be advisable to collect information about children's and parents' schedules to mitigate time and scheduling barriers. Half of the children in the VR-delivered biofeedback condition and more than half in the yoga condition said they had often or always used the strategies outside the sessions when they had a headache.

Table 3

Inferential Statistics for the Comparison Between a Waiting List and Yoga or VR-Delivered Biofeedback Interventions on the Measures of Pain Representation Variables in Children With Headaches

Variables studied	Analysis times	Repeated-measures ANOVA for the		
		Time F (df)	Condition F (df)	Interaction F (df)
CPASS	Pre–post analysis	10.19 (1, 34) (p = .003, .23[a])	0.71 (2, 34) (p = .500, .04[a])	0.93 (2, 34) (p = .403, .05[a])
	Pre–post follow-up analysis	1.12 (2, 46) (p = 334, .05[a])	1.12 (1, 23) (p = .301, .05[a])	0.44 (2, 46) (p = .650, .02[a])
PCS-C	Pre–post analysis	22.01 (1, 34) (p < .001, .39[a])	1.66 (2, 34) (p = .205, .09[a])	0.72 (2, 34) (p = .496, .04[a])
	Pre–post follow-up analysis	12.47 (2, 46) (p < .001, .35[a])	0.44 (1, 23) (p = .514, .02[a])	1.11 (2, 46) (p = .337, .05[a])
PCS-P	Pre–post analysis	12.95 (1, 34) (p = .001, .28[a])	0.32 (2, 34) (p = 728, .02[a])	1.94 (2, 34) (p = .159, .10[a])
	Pre–post follow-up analysis	8.96 (2, 46) (p < .001, .28[a])	0.001 (1, 23) (p = 1.000, .00[a])	1.89 (2, 46) (p = .163, .08[a])

Note. The number of participants and conditions differed between the first (control = 12, yoga = 11, VR-delivered biofeedback = 14) and second (yoga = 11, VR-delivered biofeedback = 12) analyses. VR = virtual reality; CPASS = The Child Pain Anxiety Symptom Scale. ANOVA = analysis of variance; PCS-C = Pain Catastrophizing Scale—Child; PCS-P = Pain Catastrophizing Scale—Parent.
[a] Partial eta squared.

These results suggest that the strategies were acceptable and perceived to be useful. Note that the transfer of skills seems to be greater in the yoga condition, which may be explained by the presence of parents at the sessions. The parents might have encouraged their children to use relaxation exercises in daily life, as several studies have shown (e.g., Coakley & Wihak, 2017). It could also be beneficial to involve parents in the VR-delivered biofeedback intervention, by having them actively participate in some sessions.

Our results also support the feasibility and safety using VR and yoga in this population based on the absence or infrequency of headaches during the sessions for both interventions. Unwanted negative side effects induced by immersion in VR (Bouchard et al., 2021) were absent or very low. It should be mentioned that precautions were taken to limit as much as possible the discomfort associated with the use of this tool (immersion for less than 10 min, seated position, adjustment of helmet, and vision). Subjective reports from clinicians and children about engagement, immersion, and enjoyment of the process were encouraging and consistent with previous work (Griffin et al., 2020). For the yoga intervention, precautions were also taken to minimize discomfort (all poses requiring the head to be lower than the torso were modified). Participants' subjective reports indicated that the poses they practiced did not create discomfort. Moreover, this approach was appreciated, as indicated by positive informal comments by parents and children on the yoga experience.

Regarding clinical outcomes, the data suggest a potential benefit in terms of reduced headache frequency and further limitations in activities following both the yoga and VR-delivered biofeedback interventions. A significant difference in improvement in the frequency headaches was observed between the VR-delivered biofeedback condition and the WL. Results were marginally significant for the difference between yoga and the WL. A significant difference in activity limitations was observed between the yoga condition and the WL. Results were marginally significant for the difference between VR-delivered biofeedback versus the WL. The longitudinal effects of these interventions were maintained two months after the interventions. In the VR-delivered biofeedback condition, we observe a stabilization of effects two months later, while in the yoga condition, participants seemed to continue improving significantly up to two months after the intervention. These results suggest that it would be appropriate to track changes both in future research (e.g., RCTs) and in clinical practice.

For pain representation variables (pain anxiety and pain catastrophizing), no difference in improvement was observed between the WL and the two interventions. These results suggest an improvement in measures regardless of the condition investigated. We hypothesize that expecting to receive an intervention could lead to a modification of negative representations of pain, such as the feeling of powerlessness, in the control group. Furthermore, these variables are largely cognitive aspects of the pain experience and therefore less likely to be affected by our interventions, whose target was not cognitive. However, when we looked at the long-term effects of the two interventions, we found that children's and parents' pain catastrophizing seemed to improve in the yoga condition two months later, but pain anxiety did not. This could be partially explained by the fact that this concept is more complex than pain catastrophizing. The latter concerns the cognitive representation of pain, whereas pain anxiety concerns multifactorial aspects, such as cognitive, emotional, behavioral, and physiological reactions to the anticipation and/or experience of pain (Pagé et al., 2010). Pain anxiety assessment by the CPASS may not be a relevant target in view of the scope of this study's interventions and their specific goals. Moreover, the long-term effects on parents' and children's pain catastrophizing, only in the yoga condition, might be explained by the parents' active participation in this intervention. In the literature, links are also observed between children's and parents' pain catastrophizing (Caruso et al., 2021). In our study, the improvement in the beliefs of one party may have influenced those of the other.

Regarding the usefulness of VR for treating chronic pain, our results concur with those of previous studies, although this topic is currently in the early phases of research in adults (Chuan et al., 2021). Several studies have highlighted this tool's potential to manage chronic pain through distraction by stimulating the visual, auditory, and proprioception senses (e.g., Pourmand et al., 2018). However, the analgesic effects after the VR session were short-lived. This finding is not surprising. In order to achieve long-term pain management, it is probably necessary to learn strategies that can be used without being immersed with a headset (Ahmadpour et al., 2019). To our knowledge, this is the first study to use VR with a biofeedback device to deliver an intervention that aims to train relaxation skills in children with chronic pain. Although the method has not yet been studied for chronic disease, a few studies suggest that VR is useful to teach self-regulation techniques to children and adolescents, such as deep breathing relaxation (Bossenbroek et al., 2020; Cook et al., 2021). In our study, the intervention combined VR with biofeedback in ways that are consistent with the holistic model for VR program design developed by Ahmadpour et al. (2020). This model postulated that the way a VR product is perceived by users (product aspects), the experience and emotions elicited (experience aspects), and the intervention goals for managing pain (intervention aspects) all influence its efficiency. The product itself was associated with a good feeling of presence in the different environments. In terms of the experience, users were able to develop their feelings of autonomy and competence to manage their pain. The use of biofeedback gave children virtual visual feedback informing them about their state of relaxation, which facilitated active self-regulation of their breathing. Relaxation was practiced in virtual environments depicting stressors from daily life. The effects observed in this study might be partly explained by an increase in perceived self-efficacy to relax in conditions similar to reality.

Concerning the beneficial effect of yoga, the results of this study are consistent with others in the literature (Anheyer et al., 2020). Our yoga intervention included poses, breathing, and visualization practices. We assume the observed outcomes could be related to the multidimensional effects of this intervention, which acted through both central and peripheral mechanisms, including physical, biochemical and psychological pathways implicated in pain activation. Indeed, yoga may allow users to reduce body tension and loosen stiff muscles, which can trigger headaches (Kumar et al., 2020). Yoga practice is also believed to improve vagal tone and decrease sympathetic effects, thereby improving cardiac autonomic balance, which in turn reduces the frequency and intensity of headaches (Kisan et al., 2014). Neuroimaging studies provide evidence that yoga has an effect on various brain regions: hippocampus, dorsolateral prefrontal cortex, anterior cingulate gyrus, striatum, thalamus, pons, and cerebellum, which is altered in migraine (Lou et al., 2005). Finally, it should be mentioned that parents were directly involved through their active participation in the sessions. Although several studies highlight the benefit of including parents in intervention programs (e.g., Coakley & Wihak, 2017), we cannot isolate the specific contribution of their presence in this study. Nevertheless, it is possible to assume that their involvement had beneficial effects, which will require investigation. Finally, it is interesting to observe the potential complementary effects of the two interventions. VR-delivered biofeedback and yoga were associated with statistically significant changes in different outcome variables (e.g., headache frequency for VR-delivered biofeedback vs. CALI for yoga). A program combining both interventions may be an interesting avenue to tackle all outcome measures used in this study.

These preliminary results are promising and suggest that these two nonpharmacological interventions have potential for use in treating pediatric chronic headaches, although the clinical effects obtained in this study should be interpreted with caution given the sample size. This study has also several limitations. First, we do not have information on (a) the total number of children who were exposed to the advertisement or approached by their doctors before they expressed an interest in registering for the study, and (b) the experience of participating (e.g., whether participants would recommend this to others, the most appreciated sessions, or the burden they experienced). These indices would have allowed a fuller assessment of the interventions' feasibility and acceptability. Second, this was a small-scale pilot study with only 37 participants. A larger sample could have allowed more statistical power to detect more effects. Third, there was no 2-month follow-up for the WL group, which precluded us from effectively assessing the long-term effects of the interventions. Fourth, data were based on retrospective recall of headache frequency, activity limitations, and frequency of using relaxation skills in daily life. These data may be subject to reporter bias and are less reliable than systematic self-monitoring. Finally, this study did not investigate predictors of changed outcomes. A next step would be to undertake a larger trial powerful enough to assess efficacy and identify the characteristics of the interventions but also of the children and parents that are associated with a positive response to treatment.

Conclusion and Future Studies

Although the pharmacological approach has shown its efficacy in treating chronic pain, it must be accompanied by nonpharmacological interventions. Our study provides preliminary evidence indicating that VR relaxation exercises combined with biofeedback and yoga exercises may be feasible and acceptable interventions for the effective treatment of pediatric migraines and tension headaches. Given the existing literature and our findings, we believe that further examination is warranted, using a larger randomized controlled trial or partially randomized preference trials (Wasmann et al., 2019), possibly combined with a noninferiority design (Walker, 2019). Further studies are also needed to determine whether these approaches have robust long-term effects.

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