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Heart Rate Variability biofeedback therapy for children and adolescents with chronic pain: A pilot study

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ABSTRACT

Purpose: As a brief, noninvasive, cost-effective, and technology-driven therapy, biofeedback is a promising and welcomed clinical intervention for children and adolescents with pediatric chronic pain conditions. The aim of this pilot study was to explore the application of a brief Heart Rate Variability (HRV) biofeedback intervention supplemented by at-home breathing practice as a tool for reducing symptomatology associated with chronic pain in a pediatric urban hospital setting.

Design and methods: Twenty-one participants aged 10–17 years ($M = 14.05$, $SD = 1.91$; 76% female) and their caregivers completed the study. Participants were randomized to either 1) receive immediate biofeedback treatment including at-home breathing practice or 2) to be placed on a 4-week waitlist and then enrolled in the biofeedback treatment. Study outcomes included self-reported pain intensity, health-related quality of life (HRQOL), and anxiety sensitivity. HRV data were obtained from biofeedback sessions. Results: Following biofeedback treatment, participants achieved significant reductions in self-reported pain intensity, higher levels of self-reported school functioning, and increased HRV, as measured by Blood Volume Pulse (BVP) amplitude. Participants in the waitlist group experienced an increase in pain intensity during the waitlist period.

Conclusion: Further research is needed to understand the mechanisms underlying HRV biofeedback and its treatment of pediatric chronic pain.

Practice implications: Nurses are ideal practitioners for biofeedback given their training in physiology and background in healthcare and should be encouraged to explore training in this area. Suggested biofeedback-related apps and mobile devices to share with patients at bedside are provided.

Introduction

Pain is essential to our survival and usually advantageous: to signal injury and to activate a protective response. However, for children with chronic pain, pain signals remain active long after one has recovered from illness or injury and can occur in areas without nociceptors (e.g., phantom limb pain) (Friedrichsdorf et al., 2016; Zeltzer & Schlank, 2005). Chronic pain can also occur when an underlying medical condition (e.g., arthritis, sickle cell) cannot be adequately managed, there is a recurrence or flare-up, or the medical condition has caused changes in the nervous system (Friedrichsdorf et al., 2016). Children with chronic pain are underserved, likely due to misconceptions about pain experienced by children, the complexity involved with assessing pediatric pain, limited treatment research, and varied individual and cultural perspectives on pain (Cohen, 2007; Friedrichsdorf et al., 2016; Liossi & Howard, 2016; Zeltzer & Schlank, 2005). Conservatively estimated to affect 20% of children and adolescents worldwide (King et al., 2011; Friedrichsdorf et al., 2016;), pediatric chronic pain warrants more attention.

Children and adolescents suffering from chronic pain experience significant impairment in health-related quality of life, sleep quality, and family functioning (Gold, Mahrer, et al., 2009; Gold, Yetwin, et al., 2009; Palermo et al., 2007; Vetter, 2008). Due to a large number of pain-related school absences, children with chronic pain often resort to home-schooling or attending school part-time (Vetter, 2008). This experience is further isolating and hampers a child's ability to socialize

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and to form sufficient peer relationships. Not surprisingly, pediatric chronic pain is often comorbid with mental health problems such as depression and anxiety (Konijnenberg et al., 2006).

Pediatric chronic pain involves a complex interplay of biological, psychological, developmental, and sociocultural factors (Force A.P.S.P.C.P.T, 2012). As such, it is best understood in the context of the biopsychosocial model, which necessitates an interdisciplinary treatment approach including complementary approaches like biofeedback (Force A.P.S.P.C.P.T, 2012; Kashikar-Zuck, 2006; Kozlowska et al., 2008; Liossi & Howard, 2016; Zeltzer & Schlank, 2005). Biofeedback enhances an individual's awareness of the mind-body connection by monitoring physiological processes and providing immediate visual or auditory feedback on a computer or other feedback device (Spirito & Kazak, 2006; Zeltzer & Schlank, 2005). For children with chronic pain, biofeedback offers a non-invasive alternative to medication and injections. By teaching a child to become aware of physiological responses to different experiences and increasing his/her internal locus of control, biofeedback can lead to significant reductions in pediatric chronic pain, especially headache activity (Spirito & Kazak, 2006). For children with chronic pain, who do not feel in control of their body, biofeedback provides them with the opportunity to establish a more positive relationship with their body. This intervention is also cost-effective, as treatment gains for pediatric pain have been demonstrated in as few as five sessions of biofeedback supplemented by at-home practice (Allen & Elliott, 2002).

Biofeedback is considered a "promising" and "probably efficacious" treatment for pediatric chronic pain due to a lack of randomized clinical trials, small sample sizes, and heterogeneous diagnoses (Spirito & Kazak, 2006). There are several forms of biofeedback corresponding to the physiological reaction being targeted, with thermal and electromyographic biofeedback being the most commonly studied (Hermann & Blanchard, 2002). These biofeedback modalities have demonstrated promise with pediatric populations experiencing migraine (Baumann, 2002; Hermann & Blanchard, 2002; Scharff et al., 2002), episodic tension-type headache (Blume et al., 2012; Bussone et al., 1998; Grazzi et al., 2001), and recurrent abdominal pain (Humphreys & Gevirtz, 2000; Masters, 2006; Sowder et al., 2010).

In the past two decades, there has been increased interest in the efficacy of Heart Rate Variability (HRV) biofeedback in the treatment of pediatric chronic pain. In HRV biofeedback, also termed "resonant frequency biofeedback therapy," participants are guided in discovering their natural resonant frequency for breathing and HRV (Gevirtz & Lehrer, 2003), that is optimal for autonomic regulation. Autonomic dysregulation, the nervous system's inability to correctly process stimulation, is believed to contribute to the development and maintenance of chronic pain. For example, children with chronic pain have been found to have significantly lower (i.e., less optimal) HRV compared to healthy controls (Evans et al., 2013), meaning that their nervous systems will have a harder time adjusting to stressors and changes. By targeting a specific aspect of autonomic regulation, HRV biofeedback may prove to be more advantageous for treating chronic pain than other forms of biofeedback (Gevirtz, 2003; Huss et al., 2009; Lehrer et al., 2004). Two pilot studies demonstrated that HRV biofeedback can improve pain and functional outcomes for pediatric chronic headache (Shiri et al., 2013) and functional abdominal pain (Stern et al., 2014). Research has also supported the efficacy of HRV biofeedback to improve aspects of HRV autonomic functioning, including vagal tone (Sowder et al., 2010) and cardiopulmonary functioning (Fahrenkamp & Benore, 2019), in youth with chronic pain. In a recent systematic review of all pediatric studies involving HRV biofeedback therapy, biofeedback treatment yielded positive treatment outcomes for the majority of investigations and effect sizes tended to be medium to large (Dormal et al., 2021). Though the results of HRV biofeedback for pediatric chronic pain are promising, previous studies have lacked comparisons to a control group and have failed to include both measures of HRV and clinical outcomes.

The current pilot study explores the application of HRV biofeedback supplemented by at-home breathing practice for the treatment of pediatric chronic pain at an outpatient pain management clinic. This pre-post, waitlist control study adds to the literature by examining both physiological and clinical outcomes and comparing results to both baseline levels and a control group. The primary aim was to examine the effects of HRV biofeedback, in conjunction with participants' current pain management therapies, on pain and pain-related impairment. The study also examined changes in HRV across the biofeedback treatment to test whether the treatment had the intended physiological effect. We expected that there would be improvements following HRV biofeedback treatment in pain intensity, health-related quality of life, and anxiety sensitivity, which would not be observed in the waitlist attention control group. Further, we anticipated that participants' HRV would increase across biofeedback sessions.

Methods

Participants

Eligible participants were English-speaking children and adolescents between the ages of 8–17 years, who were not currently receiving biofeedback treatment, and one of their caregivers. Child participants were permitted to continue with their current pain management treatments, including pain medication and alternative therapies (e.g., acupuncture), to ethically provide the usual standard of care/treatment for patients with chronic pain. Concurrent treatments included: individual therapy (treatment group: $n = 5$; control group: $n = 6$), group therapy (control group: $n = 2$), family therapy (treatment group: $n = 1$), pain medication (prescribed and/or over-the-counter; treatment group: $n = 6$; control group: $n = 8$), acupuncture (treatment group: $n = 5$; control group: $n = 5$), and massage (treatment group: $n = 1$; control group: $n = 3$). For both treatment groups, children were involved with an average of two concurrent treatments. Participants were excluded if they had a developmental, cognitive, or neurological deficit that impaired their ability to complete study questionnaires and procedures. Exclusion criteria also included alcohol or drug dependency and acute psychiatric distress, as indicated by suicidality, homicidality, or psychosis.

Twenty-one participants between the ages of 10 and 17 years ($M = 14.05$, $SD = 1.91$) and their caregivers comprised the final sample (see Fig. 1 for participant flow diagram). With the exception of a biological grandmother and one father, the remaining caregivers in this study were the participants' biological mothers. The majority of child participants were female (76%) and all five male participants were randomized to the treatment group. The sample came from a variety of ethnic backgrounds, which is consistent with the patient population in the Pediatric Pain Management Clinic at Children's Hospital Los Angeles (CHLA): 38% Caucasian, 29% Latino/a, 19% African-American, and 14% from mixed backgrounds. A third of the children were enrolled in regular classes, 30% had a combination of regular and special education classes, and the remaining children participated in alternative schooling programs (e.g., home instruction, independent study). All reported living with their biological mother but only 37% of the participants reported living with their biological father as well. Eighty-one percent of the sample had a history of recurrent pain in more than one location and 67 % reported experiencing pain on a daily basis at the start of the study. Fifty-seven percent of participants (treatment group: $n = 4$; control group: $n = 8$) that completed the study had diagnoses of comorbid medical conditions (e.g., Juvenile Rheumatoid Arthritis, Sickle Cell Disease). Only three children had a history of biofeedback treatment, ranging from one to five prior sessions.

Procedures

This study was approved by the Institutional Review Boards at CHLA and the primary author's graduate school. Staff and clinicians involved with the Pediatric Pain Management Clinic at CHLA were informed about eligibility criteria and provided referrals to study investigators.

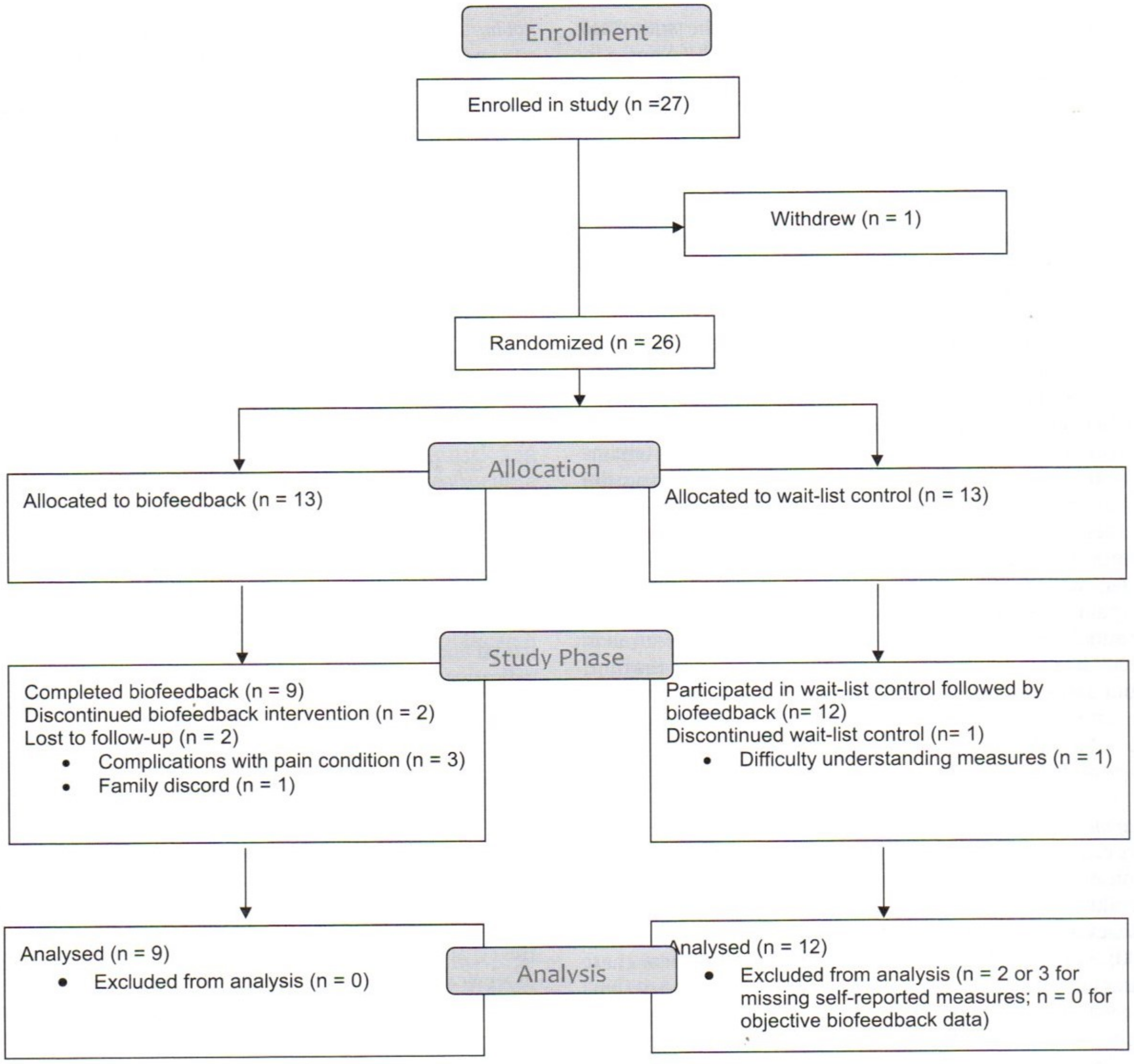

Fig. 1. Participant flow diagram.

Eligible participants were also recruited from the Pediatric Pain Management Clinic and the Division of Rheumatology. Following consent, study investigators introduced participants to the biofeedback equipment and conducted an assessment to determine their optimal breathing rate (i.e., resonant frequency). Participants were then randomized to receive either 1) four biofeedback treatments supplemented by at-home breathing practice or 2) to be placed on a 4-week waitlist. On two occasions, participants switched assignment immediately following randomization due to scheduling conflicts. Throughout the investigation, participants were asked to complete questionnaires measuring study outcomes (please refer to Table 1 for the timing of administration for each measure). All participants randomized to the waitlist attention control group were permitted to participate in the biofeedback and breathing treatment after completion of the waitlist period and posttest measures.

The 5-session (i.e., the consent session with the breathing assessment plus four treatment sessions) HRV biofeedback protocol was originally developed by Phillip A. Hughes, Ph.D., who provided ongoing

Table 1
Time of assessment for study measures.

	Time of Consent	WL 1	WL 2	WL 3	WL 4	End of WL	BFB 1 Pre Post	BFB 2 Pre Post	BFB 3 Pre Post	BFB 4 Pre Post	End of BFB
Demographic Questionnaire	X					X					X
FPS-R	X	X	X	X	X	X	X X	X X	X X	X X	X
PPQ	X					X					X
PedsQL™	X					X					X
CASI	X					X					X

Note. FPS-R = Faces Pain Scale – Revised; PPQ = Varni-Thompson Pediatric Pain Questionnaire; PedsQL™ = PedsQL™ 4.0 Generic Core Scales (for health-related quality of life); CASI = Childhood Anxiety Sensitivity Index; WL # = week during waitlist control period; BFB # = number of biofeedback treatment session.

supervision in biofeedback to study investigators during the study. Two study investigators, a pre-doctoral psychology intern at CHLA and a licensed clinical social worker on the CHLA Pediatric Pain Management team, carried out the biofeedback treatment sessions. The biofeedback sessions lasted approximately 30–60 min and were conducted in a private room at CHLA using a computerized Nexus-10 (10-channel) wireless Bluetooth biofeedback system connected to a laptop personal computer. The computer displayed information about the participant's breathing and heart rate and the participant was guided through various exercises designed to gain more control over these bodily functions, as well as to increase HRV by synchronizing breathing and heart rates while achieving resonant frequency. The StressEraser, a handheld FDA-regulated biofeedback device from Helicor, Inc., was introduced in the final sessions for 5 min of practice to further reinforce these skills. The StressEraser is no longer in production but was slightly smaller than an iPhone. Participants would place their index finger in to a pulse sensor located on top of the device and then try to synchronize their breathing with the HRV wave that appeared on the screen. During the treatment phase of the study, participants were asked to practice breathing at their resonant frequency for 10 consecutive minutes per day by listening to a BreathSync CD (BK Specialties, Inc.) that paced their breathing. Per self-report, participants who completed the study practiced for approximately 5–10 min and averaged the following number of practices: 1.86 ($SD = 2.17$) before the first biofeedback treatment, 4.33 ($SD = 3.53$) by the second treatment, 5.83 ($SD = 2.80$) by the third treatment, and 3.71 ($SD = 2.90$) by the fourth and final biofeedback treatment.

Measures

Sociodemographics

Caregivers completed a questionnaire about their demographics at the time of consent (e.g., age, educational background) and information about their child's background, including his/her previous experience with biofeedback and pain history. Additional information about child participants' medical history was gleaned from their medical chart after obtaining informed consent. Caregivers also provided brief updates about their children's ongoing pain treatments throughout the study.

Pain

Pain intensity was assessed via self-report throughout the study by the Faces Pain Scale – Revised (FPS-R) at the time of consent, once a week during the waitlist period (if applicable), and before and after each biofeedback treatment session. An additional measure administered only at the time of consent, the Varni-Thompson Pediatric Pain Questionnaire (PPQ), gathered information about the patient's pain intensity and descriptive characteristics of pain.

The FPS-R consists of six faces with expressions representing increasing levels of pain intensity (Hicks, von Baeyer, Spafford, van Korlaar and Goodenough, 2001). Children are told that the faces show "how much something can hurt," with the first face demonstrating *no pain* and the last face expressing *very much pain*. Reporters are instructed to circle the face representing how much pain they are currently experiencing. This instrument was adapted from the Faces Pain Scale (Bieri et al., 1990) and exhibits a high correlation with visual analog scales of pain intensity ($r = 0.92$ for the Visual Analog Scale and 0.84 for Colored Analogue Scale) for ages 4–16 years (Hicks et al., 2001). The FPS-R has well-established concurrent validity (0.84–0.99) and inter-rater reliability (0.84–0.99).

The PPQ (1985) is a comprehensive assessment of chronic pain that measures pain intensity, location, and the affective qualities of pain. Only a portion of this measure was analyzed for this investigation: the two visual analogue scales (VAS) that measure pain intensity for "how you feel now" and for the worst pain experienced during the week. The VAS lines are flanked on one side by a smiley face with the words *not hurting, no discomfort, no pain* and with a frowning face on the opposite end with the words *hurting a whole lot, very uncomfortable, severe pain*. Participants are asked to mark a spot on each line reflecting their pain intensity levels. The PPQ has well-established psychometric properties, including convergent validity (0.27–0.68), inter-rater correlations (0.40–0.85) and test-retest reliability (0.29–0.41) (Cohen et al., 2019).

Health-related quality of life (HRQOL)

Children's HRQOL was assessed by self-report on the PedsQL™ 4.0 Generic Core Scales (Varni et al., 1999), at the time of consent, at the conclusion of the waitlist period (if applicable), and after completing the biofeedback treatment. This measure is comprised of three scales measuring the core dimensions of health (i.e., physical, emotional, and social functioning), as defined by the World Health Organization, and one scale assessing school functioning. A Total HRQOL Score is derived from the average of these four subscales. The PedsQL™ 4.0 Generic Core Scales contain 23 items: eight for physical functioning and five for each of the three remaining scales. The PedsQL™ employs a 5-point Likert scale in which reporters are asked to rate the extent to which an item has posed a challenge over the past 7 days: 0 = *never a problem*, 1 = *almost never a problem*, 2 = *sometimes a problem*, 3 = *often a problem*, and 4 = *almost always a problem*. Items are reverse-scored and linearly transformed to a scale of 0–100 with higher scores indicative of greater HRQOL (Varni et al., 1999; Varni et al., 2002). The PedsQL™ has established reliability (Total Scale Score: $r = 0.88$ for child self-report and 0.90 for parent proxy-report) and is able to distinguish between healthy children and those with acute and chronic health illness (Schwimmer et al., 2003; Varni et al., 2003).

Anxiety sensitivity (fear of physiological arousal)

Children were administered the Childhood Anxiety Sensitivity Index (CASI(Silverman, Fleisig, Rabian and Peterson, 1991), an 18-item instrument adapted from the Anxiety Sensitivity Index(Peterson and Reiss, 1987)) at the time of consent, at the conclusion of the waitlist period (if applicable), and after completion of the four biofeedback treatments. Anxiety sensitivity is a stable predisposition toward fearing anxiety-related bodily sensations, arising from beliefs that these sensations have harmful somatic, psychological or social consequences (Reiss & McNally, 1985). According to Reiss and McNally (1985), anxiety sensitivity includes a variety of anxiety symptoms, not only physical symptoms (e.g., rapid heartbeat), but also mental symptoms (e.g., racing thoughts) and observable physical symptoms (e.g., stomach growling). Each item contains one statement (e.g., "It scares me when I feel like I am going to throw up.") and children are asked to endorse sensitivity in the following manner: 1 = *none*, 2 = *some*, and 3 = *a lot*. A total score for anxiety sensitivity is obtained from adding up points for each item of the scale. Internal consistency and test-retest reliability have been demonstrated in nonclinical and clinical samples, respectively (internal consistency: 0.76–0.87 and 0.87–0.88; test-retest: 0.76 and 0.79) (Silverman et al., 1991). There is also evidence of concurrent, predictive, and convergent validity for this measure (Holmbeck et al., 2008).

HRV during biofeedback

HRV data were recorded during biofeedback treatment sessions. Blood Volume Pulse (BVP) amplitude was used to measure HRV during the biofeedback treatment (Zeltzer & Schlank, 2005). BVP corresponds to the amount by which the blood vessels were opening up during the session. An increase in BVP amplitude is associated with increased vasodilation and peripheral temperature and can signify moments of deep relaxation (Peper et al., 2007). Data for BVP amplitude were obtained from the two-minute interval of the initial breathing assessment corresponding to the participant's resonant frequency and from the last two minutes of a resonant frequency reinforcement exercise in the fourth (i.e., final) biofeedback treatment session.

Statistical analyses

Data analyses were conducted using IBM™ SPSS™ statistical software. Descriptive statistics were computed to determine mean scores for study outcome measures. Independent *t*-tests (e.g., age) and chi-square analyses (e.g., ethnicity) were conducted to explore possible demographic differences across treatment groups. Data were inspected to ensure approximately normal distributions and an alpha level of 0.05 was adopted to indicate statistical significance. One-way within-subjects ANOVAs were conducted on outcomes for the waitlist group to examine possible maturation effects in pain and pain-related impairment from the time of consent to the end of the waitlist period. Mixed ANOVAs were used to compare study outcomes (pain intensity, HRQOL, anxiety sensitivity) between the treatment and waitlist attention control group across time and to examine changes in study outcomes across biofeedback treatment in both groups. Trend analyses for pain intensity scores over time, comparing the biofeedback and waitlist attention control groups and across biofeedback treatment in both groups, were evaluated using one-way repeated-measures ANOVAs. Finally, mixed ANOVAs were conducted to examine changes in BVP amplitude in response to HRV biofeedback treatment in both groups. Post-hoc power analyses using G*Power showed that with the current sample size, we had adequate power (0.80) to detect a very large effect (f = 0.65). Therefore, any significant results indicated large effect sizes.

Results

Preliminary analyses

There were no significant differences between treatment groups for age, ethnicity, current or last completed grade in school, type of schooling, frequency of pain symptoms, pain intensity at consent, worst pain experienced in the week before consent, comorbid medical diagnoses, prior experience with biofeedback, amount of breathing practice prior to each biofeedback treatment session, number of other treatments used during the study (e.g., acupuncture), and the type of concurrent treatment used during the study. Participants in the treatment group reported missing more school days in the month before study enrollment than their waitlist counterparts ($M = 5.83$ and 1.82, respectively), but the difference was not statistically significant, $t(18) = 1.938$, $p = .069$. There were significant differences between treatment groups in terms of gender, as no boys were randomized to the waitlist group, $\chi^2(1, N = 21) = 8.750$, $p < .01$. At the time of consent, no significant differences were found between treatment groups on all self-report outcomes, including subscales.

Maturation

One-way within-subjects ANOVAs were conducted on all self-report outcomes to examine possible maturation effects for the waitlist attention control group from the time of consent to the end of the waitlist period. The results indicated a significant time effect for the CASI total score, Wilk's $\Lambda = 0.498$, $F(1, 9) = 9.067$, $p = .015$, with anxiety sensitivity decreasing significantly during the waitlist period.

Waitlist attention control vs. treatment

Mixed ANOVAs were conducted with a two-level within-subjects factor of time (i.e., pre- and post-treatment/waitlist) and examined for possible interaction effects to identify between-groups differences in behavior on study outcomes across time. All pre-treatment scores were obtained from the consent session. Post-treatment scores for the waitlist group were obtained from the conclusion of the waitlist period. Descriptive statistics for these analyses are summarized in Table 2. The results indicated a significant interaction between time and treatment group for current pain intensity on the FPS-R (Wilk's $\Lambda = 0.654$, $F(1, 17) = 8.991$, $p = .008$) and on the PPQ (Wilk's $\Lambda = 0.636$, $F(1, 17) = 9.739$, $p = .006$). There was a significant difference between the groups in their report of pain intensity over time, with reports of pain reductions for the treatment group but pain increases for the waitlist group.

There was also a significant interaction between time and treatment group for PedsQL™ school functioning, Wilk's $\Lambda = 0.782$, $F(1, 17) = 4.729$, $p = .044$. The treatment group experienced a large improvement in self-reported school functioning by the end of treatment, while the waitlist group experienced a negligible improvement when the waitlist period concluded (see Table 2).

Biofeedback treatment

Mixed ANOVAs were conducted on all self-report outcomes to evaluate the effect of biofeedback treatment across time in both groups (i.e., participants randomized to biofeedback and participants randomized to waitlist attention control followed by biofeedback). The within-subjects factor of time had two levels: pre-treatment and post-treatment. Pre-treatment scores were obtained from the consent session for the treatment group and from the conclusion of the waitlist period (just prior to biofeedback treatment) for the waitlist group. Descriptive statistics for these analyses are summarized in Table 3. The results indicated a significant time effect for current pain intensity on the FPS-R (Wilk's $\Lambda = 0.531$, $F(1, 17) = 15.037$, $p = .001$) and on the PPQ (Wilk's $\Lambda = 0.574$, $F(1, 17) = 12.607$, $p = .002$). Pain intensity scores for both groups decreased over the course of treatment. A significant time effect was also found for school functioning on the PedsQL™

Table 2
Scale descriptive statistics comparing the waitlist attention control to the treatment group.

Variable	Waitlist Group ($n = 10$)[a]		Treatment Group ($n = 9$)	
	Pre-waitlist *M* (*SD*)	Post-waitlist *M* (*SD*)	Pre-treatment *M* (*SD*)	Post-treatment *M* (*SD*)
Pain				
Current pain (FPS-R)**	2.40 (2.07)	3.60 (2.63)	3.00 (2.45)	1.33 (2.65)
Current pain (PPQ)**	3.00 (2.28)	3.79 (2.82)	4.48 (2.76)	1.70 (2.71)
Worst pain (PPQ)	6.82 (2.49)	5.65 (3.38)	6.56 (1.77)	5.80 (2.93)
Total HRQOL	59.13 (14.76)	61.63 (13.84)	59.30 (13.46)	67.75 (17.05)
Physical Functioning	50.63 (20.67)	50.31 (15.69)	61.81 (21.52)	63.19 (20.24)
Emotional Functioning	62.00 (23.71)	68.50 (23.93)	52.22 (18.22)	66.11 (16.16)
Social Functioning	75.50 (19.21)	80.00 (15.81)	72.22 (14.60)	81.11 (15.57)
School Functioning*	53.50 (9.73)	54.50 (14.03)	49.44 (14.88)	63.33 (23.18)
Anxiety Sensitivity	31.90 (8.17)	28.60 (7.55)	29.78 (7.48)	28.67 (7.26)

Note. FPS-R = Faces Pain Scale – Revised; PPQ = Varni-Thompson Pediatric Pain Questionnaire; HRQOL = Health-related Quality of Life.
[a] Two participants in the waitlist group did not complete measures for the conclusion of the waitlist period and were excluded from these analyses.
* $p < .05$ (interaction).
** $p < .01$ (interaction).

Table 3
Scale descriptive statistics before and after four sessions of biofeedback treatment.

Variable	Waitlist Group (n = 10)[a]		Treatment Group (n = 9)		All (n = 19)[a]	
	Pre M (SD)	Post M (SD)	Pre M (SD)	Post M (SD)	Pre M (SD)	Post M (SD)
Pain						
Current pain (FPS-R)**	3.60 (2.63)	1.60 (1.84)	3.00 (2.45)	1.33 (2.65)	3.32 (2.50)	1.47 (2.20)
Current pain (PPQ)**	3.79 (2.82)	2.44 (2.21)	4.48 (2.76)	1.70 (2.71)	4.12 (2.74)	2.09 (2.42)
Worst pain (PPQ)	5.65 (3.38)	5.64 (3.48)	6.56 (1.77)	5.80 (2.93)	6.08 (2.71)	5.72 (3.15)
Total HRQOL	61.63 (13.84)	61.02 (14.33)	59.30 (13.46)	67.75 (17.05)	60.53 (13.33)	64.21 (15.62)
Physical Functioning	50.31 (15.69)	46.56 (18.13)	61.81 (21.52)	63.19 (20.24)	55.76 (19.07)	54.44 (20.47)
Emotional Functioning	68.50 (23.93)	69.33 (24.74)	52.22 (18.22)	66.11 (16.16)	60.79 (22.44)	67.81 (20.61)
Social Functioning	80.00 (15.81)	78.50 (19.30)	72.22 (14.60)	81.11 (15.57)	76.32 (15.35)	79.74 (17.20)
School Functioning*	54.50 (14.03)	58.50 (20.96)	49.44 (14.88)	63.33 (23.18)	52.11 (14.27)	60.79 (21.56)
Anxiety Sensitivity	28.60 (7.55)	28.00 (6.96)	29.78 (7.48)	28.67 (7.26)	29.16 (7.33)	28.32 (6.91)

Note. FPS-R = Faces Pain Scale – Revised; PPQ = Varni-Thompson Pediatric Pain Questionnaire; HRQOL = Health-related Quality of Life.
[a] Two participants in the waitlist group did not complete measures for the conclusion of the waitlist period and were excluded from these analyses.
* $p < .05$ (time effect).
** $p < .01$ (time effect).

with both groups increasing from pre- to post-treatment: Wilk's Λ = 0.763, $F(1, 17) = 5.282$, $p = .035$.

Pain ratings over time

Trend analyses were conducted to examine changes in pain intensity scores (FPS-R) over time. Mixed ANOVAs were conducted with a two-level within-subjects factor of time (i.e., pre- and post-treatment). The first mixed ANOVA compared the waitlist attention control group during the waitlist period with the treatment group during the treatment period (see Fig. 2). All pre-treatment (i.e., baseline) scores were obtained from the consent session. Post-treatment scores for the waitlist group were obtained from the conclusion of the waitlist period. Follow-up polynomial contrasts indicated a significant linear effect for the interaction of Treatment Group x Time of Measurement, $F(1, 16) = 7.617$, $p = .014$, partial $\eta^2 = 0.323$. The FPS-R scores decreased in a linear fashion for the treatment group over time but increased linearly for the waitlist group during the waitlist period.

The second mixed ANOVA examined changes in the FPS-R pain intensity scores across biofeedback treatment in both groups (see Fig. 3). Pre-treatment (i.e., baseline) scores were obtained from the consent session for the treatment group and from the conclusion of the waitlist period for the waitlist group. Mauchly's test indicated that the assumption of sphericity had been violated, χ^2 (9) = 20.622, p = .015, therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity, $\varepsilon = 0.555$. The results indicated a significant time effect, $F(2.22, 35.49) = 6.643$, $p = .003$, partial $\eta^2 = 0.293$.

Follow-up polynomial contrasts indicated a significant linear effect with means decreasing over time, $F(1, 16) = 13.751$, $p = .002$, partial $\eta^2 = 0.462$. Neither the main effect of Treatment Group nor the interaction of Treatment Group x Time of Measurement was significant, indicating that FPS-R scores decreased in a linear fashion over the five times of measurement in a similar manner for both groups across biofeedback treatment.

HRV during biofeedback

The results from a mixed ANOVA examining change in BVP amplitude during biofeedback treatment indicated a significant time effect, Wilk's $\Lambda = 0.663$, $F(1, 19) = 9.642$, $p = .006$. BVP amplitude increased for both groups over the course of treatment, providing evidence of physiological changes in the expected direction during biofeedback (Table 4).

Discussion

The current pilot study is the first controlled evaluation of a brief HRV biofeedback treatment protocol for pediatric chronic pain in a pediatric, urban, academic teaching hospital. As hypothesized, participants demonstrated improvement in both clinical and physiological outcomes following HRV biofeedback therapy. Children achieved significant reductions in current pain intensity and experienced an increase in their self-reported school functioning at the conclusion of a brief HRV

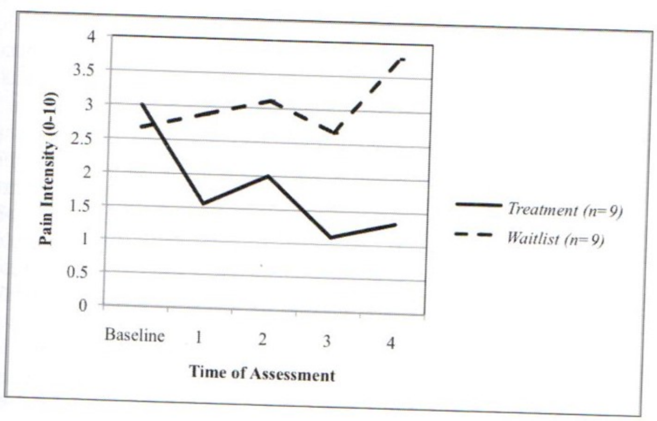

Fig. 2. Trend analysis for pain intensity scores (FPS-R) comparing the waitlist group during the waitlist period with the treatment group during biofeedback treatment. Three participants in the waitlist group were excluded from the analyses due to missing data.

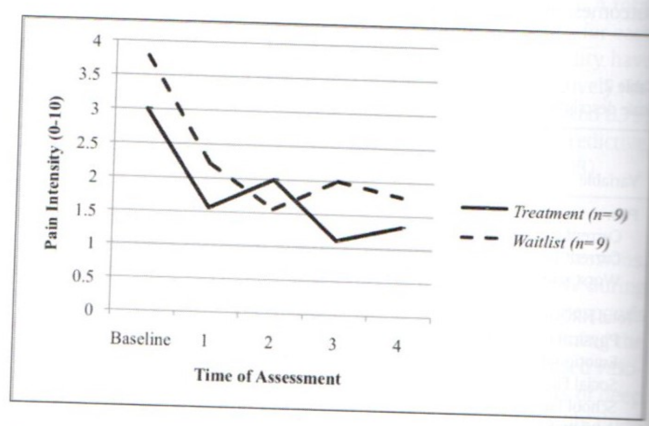

Fig. 3. Trend analysis for pain intensity scores (FPS-R) over the course of biofeedback treatment for both groups. Baseline scores for the waitlist group were obtained from the conclusion of the waitlist period. Three participants in the waitlist group were excluded from the analyses due to missing data.

Table 4
Descriptive statistics for Heart Rate Variability (HRV) as measured by Blood Volume Pulse (BVP) amplitude during biofeedback.

	Waitlist Group ($n = 12$)	Treatment Group ($n = 9$)	All
Time of Assessment	BVP Amplitude *M* (SD)	BVP Amplitude *M* (SD)	BVP Amplitude *M* (SD)
Initial Breathing Assessment	39.28 (20.38)	48.31 (22.28)	43.15 (21.17)
Final Biofeedback Session	69.32 (21.63)	64.75 (36.19)	67.36 (28.05)

biofeedback treatment. Participants also achieved significant increases in BVP amplitude by the end of treatment, demonstrating physiological effects and providing some evidence of skill mastery for the HRV biofeedback protocol. These effects of the HRV biofeedback treatment are strengthened by the comparison with a waitlist attention control group. Specifically, participants in the waitlist control group experienced increases in pain intensity and no change in school functioning while waiting to start the biofeedback treatment.

Unexpectedly, the waitlist attention-control group reported a significant reduction in anxiety sensitivity at the conclusion of the waitlist period. Given the nature of the waitlist-attention-control with weekly telephone "check-ins" to assess current pain intensity and current pain management treatments, patients' overall anxiety sensitivity may have declined as a function of attention to symptoms and pain management strategies, as well as general contact with a healthcare provider. Given the routine misconceptions about pain and especially pain without a known etiology to be considered a result of psychological concerns, exaggeration, or malingering (Edmond & Keefe, 2015; Turk & Okifuji, 2000), patients may have benefited in a variety of ways from the attention-control, in that questions validated the patient's pain experience. Therefore, general anxiety and specifically anxiety sensitivity symptoms may decline. Future studies should examine pain validation and other mechanisms that may explain this decrease in anxiety and anxiety sensitivity symptoms.

This study highlights the benefits of biofeedback therapy for pain reduction and school functioning. Results suggest that participants mastered the biofeedback skills and therefore had more control over their pain and stress, which may have enabled them to attend school more consistently. Historically, patients experiencing chronic pain suffer from significantly missed school days (Vetter, 2008). Clinically it's recognized that missed school days have significant ramifications on other critical child health outcomes, such as mood, sleep patterns, peers, extracurricular activities, and academic success (Kashikar-Zuck et al., 2010; Logan et al., 2008). While most clinicians attempt to theoretically reduce pain in patients, it's universally recognized that increased functioning is inversely related to pain. Therefore, it would be expected that increasing school functioning would lead to reduced pain experiences and improved functional outcomes. The current findings support both a reduction in pain intensity and a "return" to school functioning. This brief HRV biofeedback protocol proved to be a viable treatment option for children and adolescents in our outpatient pediatric pain management clinic due to its brevity, portability, and non-invasive technique. The further development and validation of a brief HRV protocol has numerous advantages for delivering services to patients with chronic pain. Routinely, patients are referred for non-pharmacological interventions, yet there remains a paucity of evidence-based interventions for this population. The current study begins to lend evidenced-based support for the current protocol, with robust initial findings suggesting a brief HRV protocol impacts both clinical and physiological outcomes. These initial findings are encouraging and lend support for future trials with larger samples, sound methodology, and the utility of validated psychometrics. Similarly, previous pediatric biofeedback studies (Allen & Elliott, 2002) demonstrated that clinicians with brief training in biofeedback were able to provide successful treatment. Additionally, caregivers did not provide any feedback or documentation suggesting concerns about the biofeedback intervention. All clinicians and scientists working with patients with chronic pain recognize a high level of school absenteeism and the associated negative sequelae for other significant pediatric health outcomes (Chalkiadis, 2001). The current brief HRV protocol lends support for improving school functioning and patients can continue to practice learned exercises long after study completion via an app on their smartphone.

Clinical implications can be derived from study results regarding the treatment of pediatric chronic pain, particularly in light of the COVID-19 pandemic. Though biofeedback has traditionally been delivered face-to-face, newer technologies and applications are beginning to emerge that can be leveraged for remote treatment. Although research on biofeedback administered via telehealth is limited, there have been a handful of recent investigations that have noted positive outcomes, such as improved sleep (Cortoos et al., 2010), improved ergonomics (Golebowicz et al., 2015), reduced pain (Golebowicz et al., 2015; Tan et al., 2013), and decreased depression (Tan et al., 2013). More rural areas, such as Alaska and Hawaii, have been utilizing telehealth for biofeedback for the past two decades and have found it vital in serving their communities (Folen et al., 2001). Just as clinicians have quickly begun to adopt telehealth for routine medical and psychotherapy appointments, it is important to explore and adapt biofeedback for remote purposes using smartphone applications and affordable and reliable/valid HRV devices, as it may have particular benefit for youth with chronic pain. While the inclusion of biofeedback as a telehealth modality is in its naissance, the authors believe there are tremendous opportunities to deliver non-medication evidenced-based biofeedback interventions to a young and tech savvy population who is suffering from significant daily pain.

The current findings highlight the importance of non-medication interventions for children and adolescents with chronic pain. The current pilot study lends further support for a multidisciplinary treatment that targets pain, but clearly impacts a variety of critical outcomes that are focused on improving function (e.g., returning to school), rather than pain intensity alone. Additionally, recommendations have been leveraged regarding tele-biofeedback and some of the clear advantages of this proposed methodology, given the COVID-19 pandemic. Recognizing the devastating effect of chronic pain on the patient, their family, and society, investigators and clinicians need to continue to explore interventions that are brief, cost-effective, and non-invasive.

Practice implications

The integration of non-pharmacological interventions for pediatric pain is critical. When youth with chronic pain are admitted to the hospital, nurse practitioners often serve as the gatekeepers of their comprehensive care. As such, they may wish to inform their patients about biofeedback as a potential treatment option after learning about the feasibility and efficacy of this treatment. Nurses are also ideal practitioners of biofeedback, given their training in physiology and medicine, that they spend a lot of time with patients at the bedside, and that they tend to have a large presence in hospital settings. As such, nurses should be encouraged to gain training and certification in this area. For those interested in pursuing biofeedback training, including HRV biofeedback, there are programs designed specifically for healthcare professionals like the one offered by HeartMath, as well as programs accredited by the Biofeedback Certification International Alliance (BCIA) (https://bcia.memberclicks.net/assets/BFCommonDocs/BF%20Didactic%20Training%20Programs.pdf).

For nurses seeking additional tools for patients at the bedside or for themselves, biofeedback-related smartphone apps and relaxation videos are especially useful. Some apps use the cellphone's own technology for biofeedback, such as Belly Bio (https://apps.apple.com/us/app/bellybio-interactive-breathing/id353763955), which monitors diaphragmatic breathing using the iPhone's accelerometer. Other apps are useful for teaching paced breathing, such as Kardia Deep Breathing (https://apps.apple.com/us/app/kardia-deep-breathing/id998569123). Additionally, there are apps that require the purchase of an additional sensor like eSense™ for handwarming training (https://www.mindfield.de/en/Biofeedback/Products/Mindfield%C2%AE-eSense-Skin-Response.html) and Inner Balance™ (https://www.heartmath.org/store/products/inner-balance/), which is specifically for HRV biofeedback.

Limitations

The conclusions that can be made from this pilot study are limited by a small sample size, a heterogeneous pain sample, the lack of control for supplemental pain management practices used by participants during the study, and the absence of a follow-up assessment period. Trends toward significance were observed for improvement in social and emotional functioning (of HRQOL) following biofeedback treatment, suggesting that a larger sample may have yielded significant results. The study sample was heterogeneous regarding pain condition, which may have decreased power by increasing the likelihood of error. If a larger sample were recruited for participation, it would be beneficial to explore the relationship between pain condition and study outcomes following HRV biofeedback treatment. Given that biofeedback therapy was administered in conjunction with participants' standard pain management practices during this study, we cannot conclude that children and adolescents in our sample achieved significant reductions in pain intensity and improvements in HRQOL solely as a function of our HRV biofeedback protocol (though randomization and comparison to a waitlist attention-control group also engaged in other treatments strengthens study conclusions). While participants demonstrated increased BVP amplitude, a physiological index associated with relaxation (Peper et al., 2007), we were unable to demonstrate the presence of other meaningful physiological changes during biofeedback treatment due to the structure of our HRV biofeedback protocol. Finally, without further follow-up assessment period, it is unclear whether treatment gains would have been maintained over time. Future research with larger samples should control for supplemental pain management therapies, incorporate longitudinal outcomes, include longer durations of continuous biofeedback recordings (e.g., by using fitness and health wearables like WHOOP and Polar), and evaluate additional outcomes including mood, sleep, and relevant biological outcomes, to better understand the effects of HRV biofeedback on multiple outcomes associated with pediatric chronic pain.

Conclusion

Given the direct and indirect benefits of biofeedback for patients and nurses, integrating biofeedback therapy into the management of pediatric chronic pain and chronic health conditions is invaluable. Training nurses in biofeedback to offer additional tools to these patients or using biofeedback to support nurses' own physical and mental health is a worthwhile investment.

As patients continue to struggle with chronic pain and the associated negative health sequelae, biofeedback is a viable non-pharmacological treatment option. Educating and training nurses and other health practitioners about these interventions will increase patients' access to care and lead to improved health outcomes for patients suffering from chronic pain. While the literature on biofeedback is still in its infancy, it continues to show promise, especially HRV biofeedback for targeting and enhancing autonomic nervous system function.

CRediT authorship contribution statement

Alexis K. Yetwin: Conceptualization, Formal analysis, Methodology, Investigation, Writing – original draft, Writing – review & editing. **Nicole E. Mahrer:** Formal analysis, Writing – review & editing. **Terece S. Bell:** Conceptualization, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **Jeffrey I. Gold:** Conceptualization, Methodology, Writing – review & editing.

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