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Is heart rate variability biofeedback useful in children and adolescents? a systematic review

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Abstract

Background: Heart rate variability (HRV) is considered as an index of both physical and emotional health, and biofeedback aiming to increase the level of HRV has demonstrated extensive beneficial effects. Although HRV is commonly and reliably applied in adults, the use of HRV biofeedback, alone or in addition to other treatments, in children and adolescents has not been widely explored to date. **Methods:** This systematic review following PRISMA guidelines covers all human studies using HRV biofeedback in children and adolescents. A literature search was conducted in PsycINFO, PubMed, and Scopus, and a standardized methodological quality assessment was performed. **Results:** Results showed the efficiency of HRV biofeedback sessions with children and adolescents to reduce physical and mental health-related symptoms and enhance well-being. **Conclusions:** These findings underline the therapeutic value of using HRV biofeedback as a complement to more conventional behavioural and cognitive interventions to help children to manage stress and/or pain. Capitalizing on the identified strengths and shortcomings of available results, we propose research avenues as well as evidence-based clinical guidelines for using HRV biofeedback in clinical paediatric settings.

Keywords: Heart Rate Variability; Biofeedback; Cardiac Coherence; Stress; Children

1. Introduction

While heart rate corresponds to the number of heart beats per minute, heart rate variability (HRV) is a measure of the naturally occurring beat-to-beat changes in heart rate (McCraty & Shaffer, 2015). A healthy heart is not a metronome as its oscillations are complex and constantly changing, thus allowing the cardiovascular system to adjust rapidly to sudden physical and psychological challenges to homeostasis. HRV is therefore an excellent indicator for assessing the activity of the autonomic nervous system, both at the peripheral and central levels, as well as the balance between the two branches of the sympathetic and parasympathetic nervous systems (Thayer, Åhs, Fredrikson, Sollers, & Wager, 2012).

Various metrics are used to quantify HRV through electrocardiographic (ECG) signals or photoplethysmography (PPG). Time-domain indices of HRV quantify the amount of variability in measurements of the interbeat interval (e.g., standard deviation of differences in interbeat intervals, root mean square of successive interbeat intervals), while frequency-domain measurements estimate the distribution of absolute or relative power into frequency bands (e.g., high-frequency power). While a wide amplitude of HRV is associated with better emotion regulation and the use of adapted coping strategies or resilience (Fabes & Eisenberg, 1997), a significant decrease in it is a sign of vulnerability to stress, and has been reported in different populations of patients with psychiatric or behavioural disorders, such as severe depression, post-traumatic stress disorder or generalized anxiety (Lehrer, 2007; Servant, Logier, Moustier, & Goudemand, 2009; Wheat & Larkin, 2010).

HRV biofeedback is considered a simple and non-invasive technique to act upon autonomic activity, mainly through the regulation of breathing in response to external feedback, to enhance heart-brain synchronization and facilitate the maintenance of a physiologically efficient inner state (Prinsloo, Derman, Lambert, & Rauch, 2013). Overall, biofeedback is a training technique that teaches individuals to recognize and learn how to modify their body's physiological signals to help improve health and performance (Schwartz & Andrasik, 2017). Various physiological parameters (e.g., heart rate, electrodermal activity, brain activity) can be

HRV Biofeedback in children and adolescents

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measured and visualized in real time. The immediate feedback helps individuals to gain voluntary control over the various physiological processes and to bring about favourable changes (Yu, Funk, Hu, Wang, & Feijs, 2018). The main aim of HRV biofeedback is to increase cardiac vagal tone. The subject receives feedback regarding their current HRV and, depending on the intervention protocol used, they learn how to handle different techniques (e.g., slow breathing or resonant frequency diaphragmatic breathing) to achieve their optimal individual HRV level (Prinsloo, Rauch, & Derman, 2014). HRV biofeedback can be provided by handheld devices (e.g., emWave2 or Stress Eraser), computer-based interactive programs (emWave desktop or Journey to Wild Divine), or with professional ECG recording equipment. The number of HRV biofeedback applications for smartphones is also increasing (Prinsloo et al., 2014). Most individuals effortlessly achieve high-amplitude oscillations in HRV after a few minutes of training, and almost everyone can master the technique within one to four sessions of coaching. HRV is thus easily and rapidly learned and can be implemented at little cost.

The effectiveness of HRV was confirmed by recent meta-analyses (Goessl, Curtiss, & Hofmann, 2017; Lehrer et al., 2020), demonstrating that HRV biofeedback is associated with a variety of health benefits in both healthy and pathological adult populations. Levels of anxiety and depressive stress-related symptoms were significantly reduced (e.g., Caldwell & Steffen, 2018; Tan, Dao, Farmer, Sutherland, & Gevirtz, 2011) and various kinds of human performance including cognitive, physical, and creative activities were improved (e.g., Paul & Garg, 2012; Sutarto, Wahab, & Zin, 2013; Wells, Outhred, Heathers, Quintana, & Kemp, 2012). Alone or combined with other relaxation or breathing techniques, HRV biofeedback has proved very useful and has become increasingly used by psychotherapists in several adult pathological populations (Lehrer, 2018; Leyro, Buckman, & Bates, 2019). However, its use and health benefits in children and adolescents have received little attention to date. This is all the more surprising given that children are ideal potential users (e.g., Attanasio et al., 1985; Culbert, Kajander, & Reaney, 1996): (1) having a naturally higher HRV level, they are very sensitive to guided paced breathing; (2) in general, they can easily control their physiological

parameters (e.g., peripheral temperature, breathing and heart rate) via biofeedback techniques; (3) thanks to their enhanced brain plasticity, they can easily learn new emotional self-regulation techniques; and (4) they are also very familiar with and curious about new technologies as well as the use of biofeedback video games systems.

The main objective of the present study was to propose the first systematic review specifically focusing on the use of HRV biofeedback in children and adolescents. Following Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines, it reports the effectiveness of HRV biofeedback, alone or combined with other methods such as psychoeducation or relaxation, to reduce physical and mental health-related symptoms and enhance well-being, by comparing the results from published studies investigating HRV biofeedback in children and adolescents with or without physiological and/or mental disorders. The methodological quality of the intervention studies including a direct comparison with a control group was also evaluated by a quality assessment tool developed by the National Heart, Lung and Blood Institute (NHLBI, 2014). Based on the collected data and the observed results and conclusions, the second objective was to propose directions for future research and clinical applications of HRV in children and adolescents.

2. Methods

2.1. Identification of articles and selection procedure

This systematic review was carried out following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA). The PRISMA statement includes a checklist of 27 items and a flow diagram (Moher, Liberati, Tetzlaff, Altman, & Prisma Group, 2009). To identify eligible studies, a literature search was performed in PubMed, Scopus, and PsycINFO. We focused on peer-reviewed articles published in English between January 1st, 1999 and January 1st, 2020. The search strategy used the following syntax: ("heart rate variability biofeedback" OR "HRV biofeedback" OR "heart rate coherence biofeedback" OR "heart rate coherence" OR "cardiac coherence" OR "respiratory sinus arrhythmia

biofeedback") AND ("child*" OR "adolescen*"). The initial search identified 145 articles (47 in Pubmed, 44 in Scopus, 48 in PsycINFO, and 6 in other sources). The articles to be included in the review were then selected according to the PRISMA procedure (Figure 1): First, duplicates were removed, leading to the identification of 63 unique papers. Second, remaining records were individually screened and articles presenting one of the following exclusion criteria were removed: (1) No HRV biofeedback intervention; (2) No peer-reviewed experimental data or case reports presented (i.e., review, reply, editorial, erratum, conference proceedings, dissertation); (3) No sample of children or adolescents. This procedure ended up in the inclusion of 18 articles in the systematic review process.

Insert Figure 1 about here

2.2. Methodological quality assessment

The methodological quality of each study including control group comparisons (n=10) was assessed using the "quality assessment of controlled intervention studies" scale developed by the NHLBI (2014). The scale comprises 14 items with a binary answer (Yes/No), leading to a maximum score of 14. For each study, a score (i.e., percentage of items with a "Yes" answer) was computed, leading to a global quality rating (i.e., poor for scores below 50%, fair for scores between 50 and 69%, good for scores between 70% and 79%, and strong for scores of 80% and beyond, adapted from Black et al., 2017). When an item was not directly relevant to the study or when the information contained in the paper did not allow a clear decision regarding an item to be made, the term "not applicable" (NA) or "not reported" (NR), respectively, was used and the item was excluded from the computation of the global quality rating. Supplementary Table 1 reports detailed scores obtained for each study on each item and global quality ratings.

2.3. Data extraction and synthesis

Regarding the 18 studies using HRV biofeedback intervention in children and adolescents, a systematic data extraction procedure was used to determine the main characteristics of each article. Four categories of variables were reported, adapted from the PICOS procedure (Liberati et al., 2009): (1) Participants (population, sample size, mean age, age range, and gender ratio); (2) Intervention (HRV biofeedback, other interventions, number of sessions, duration of a session, HRV measures, assessment tools, time measurement, follow-up); (3) Comparison (control group, matching variables); (4) Outcomes (main results, reported limitations, conclusion, methodological quality). A comprehensive synthesis of the data extracted from each study is presented in Table 1.

3. Results

3.1. Quality assessment

Among the 10 studies with a control group comparison included, only 1 was considered as presenting strong quality, 1 good quality, and 8 fair quality, according to the assessment criteria selected (Supplementary Table 1). Most of the studies reported good adherence to the intervention protocols in both experimental and control groups and the overall dropout rate was quite low across studies and did not differ greatly between treatment groups. Before conducting the intervention trial, most studies generated hypotheses, reported the outcomes to be measured, and prespecified the groups to be analysed. The implementation and assessment of clinical and physiological outcomes were good, all studies using valid and reliable methods, tasks, or questionnaires to do so, and all participants were analysed according to the group they were assigned to (e.g., intervention or control group). However, half of the studies (i.e., 5 out of 10) reported an adequate randomization method and only one study was double-blind (i.e., neither participants nor investigators were aware of the condition assigned to the participants). Most studies attempted to match the experimental and control groups on the main sociodemographic variables (e.g., age, gender), but several studies did not manage to constitute equivalent groups. Finally, most studies did not justify their sample size based on a priori power computation or previous experiments.

3.2 Main outcomes

Each of the included studies focused on the benefits derived from HRV biofeedback intervention in children and adolescents without any disturbance or disorder (n=3), or presenting either physiological (n=6) or mental health disorders (n=9). These studies are described below and their main characteristics are synthesized in Table 1.

Insert Table 1 about here

3.2.1 HRV biofeedback in healthy children and adolescents

Two studies evaluated the beneficial influence of a classroom-based emotional self-regulation program, which included several sessions of HRV biofeedback in a school setting (Bradley et al., 2010; McCraty, Atkinson, Tomasino, Goelitz, & Mayrovitz, 1999). Middle school children were enrolled in an emotional competence intervention (16 hours given over 2 weeks) during which they had to learn a series of tools and strategies to help them to reduce stress, to improve communication skills, to maintain focus on academic contents, and to enhance relationships with others (McCraty et al., 1999). In the first group (n=32), psychological and behavioural changes were examined one week before and one week after the training program. The results of this study showed several significant improvements among trained students such as better management of stress and anger, higher levels of motivation and concentration, and enhanced leadership and communication skills. Interestingly, most of these changes were still observed 6 months later. In a second phase, the impact of the training on children's autonomic responses was assessed before, during, and after a stressful interview. Half of the participants followed the intervention course (i.e., experimental group; n=30), while the other half did not (i.e., passive control group; n=30). Compared to controls, physiological

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3 measurements revealed that trained children had higher HRV levels during the recovery
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5 period, suggesting an increase in parasympathetic activity in response to stressful events.
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8 The second study investigated the effect of a similar emotion self-regulation program
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10 (Test Edge) in a class of high-school students on measures of test anxiety, socioemotional
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12 functions, test performance, and HRV (Bradley et al., 2010). During this program, students
13
14 learned how to generate a psychophysiological state of coherence through HRV biofeedback
15
16 exercises. A controlled pre- and post-intervention laboratory experiment using
17
18 electrophysiological measures on a random stratified sample (n=136) was carried out to
19
20 assess whether students were able to apply self-regulation techniques learned during the Test
21
22 Edge program. Participants had to complete a computerized version of the Stroop test to
23
24 simulate the stressful conditions of taking an academic test while different electrophysiological
25
26 measures were recorded. Larger significant pre-post differences, showing reduced test anxiety
27
28 and negative affect, and increased psychophysiological coherence after the intervention, were
29
30 observed in the trained students group compared to controls. These findings suggest that they
31
32 had learned how to better manage their emotions and regulate their psychophysiological
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34 activation level under stressful conditions.
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38 Finally, a group of basketball and football players attended a series of HRV biofeedback
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40 training sessions to assess their benefits on their anxiety level and other psychophysiological
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42 parameters (Dziembowska et al., 2016). After 10 twenty-minute sessions, a significant
43
44 decrease in the mean anxiety score was observed in the experimental group as well as
45
46 improvements in their HRV measures, indicating better flexibility of their autonomic nervous
47
48 system that could potentially lead to better athletic performance.
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51 *3.1.2 HRV biofeedback in children and adolescents with physical and/or mental health* 52 53 *disorders* 54 55

56 A first series of studies investigated the potential use of HRV biofeedback in addition to
57
58 conventional pharmaceutical treatments to relieve pain in children. Using a case series design,
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3 Fahrenkamp and Benore (2019) reported changes in respiration rate and HRV in 4 adolescents
4 with chronic pain who underwent a brief protocol of HRV biofeedback training (i.e., only 3 or 4
5 sessions). Post-intervention results showed expected improvements in cardiopulmonary
6 functioning and self-regulation abilities, supporting the benefits of using this type of technique,
7 even for short periods, to improve pain management in paediatric populations with chronic
8 pain. In the same vein, another study analysed archived data of 24 children diagnosed with
9 irritable bowel syndrome or functional abdominal pain to evaluate the clinical utility of HRV
10 biofeedback in treating these conditions (Stern, Guiles, & Gevirtz, 2014). After completing
11 approximately 8 thirty-minute sessions of HRV biofeedback, most participants reported partial
12 or even complete remission. Confirming the interest of using HRV biofeedback to help children
13 manage pain, another study compared the regulatory performance of the autonomic system in
14 a group of 20 children with functional abdominal pain before and after 6 sessions of HRV
15 biofeedback training (Sowder, Gevirtz, Shapiro, & Ebert, 2010). A comparison of baseline
16 performance with a control group of healthy children showed the presence of autonomic
17 dysregulation (i.e., lower vagal tone) in children who had functional abdominal pain. After the
18 intervention program, children with functional pain demonstrated a significant reduction in pain
19 frequency and intensity, and an increase in their autonomic balance. Taken together, these
20 results seem to demonstrate the significant contribution of HRV biofeedback for this type of
21 pathology, which, by improving the regulation of the autonomic system, enables children to
22 better manage their associated pain.
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46 As the HRV biofeedback including guided breathing techniques is directly related to
47 increased cardiopulmonary capacities, a case series study reported the results of 20 children
48 suffering from asthma who followed 13 to 15 biofeedback sessions coupled with an abdominal
49 breathing protocol (i.e., Smetankin method; Lehrer, Smetankin, & Potapova, 2000). The
50 preliminary uncontrolled results of this study showed mild improvement in two spirometric
51 parameters after the protocol, and plead for the use of this type of non-pharmacological
52 intervention in larger-scale studies of asthmatic children.
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HRV Biofeedback in children and adolescents

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3 Like pain management programs, it has been suggested that attending biofeedback
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5 HRV sessions could be useful in helping children to cope with stress and anxiety, whether
6
7 these are generated by external events (such as medically invasive procedures; Shockey et
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9 al., 2013), are associated with other physical conditions (Slutsker, Konichezky, & Gothelf,
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11 2010), or are one of the core symptoms of various mental health disorders (Kenien, 2015;
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13 Knox et al., 2011; Mc Ausland & Addington, 2018; Pop-Jordanova, 2009; Thurstone & Lajoie,
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15 2013). For example, children suffering from cancer undergo many painful and stressful
16
17 invasive procedures. To determine whether HRV biofeedback could help them to cope, a 4-
18
19 session intervention biofeedback coupled with relaxation was tested in a group of 12 children
20
21 diagnosed with cancer (Shockey et al., 2013). Compared to baseline, children after the
22
23 biofeedback intervention reported a global decrease in their anxiety level and improvements
24
25 in their HRV coherence scores were also observed, suggesting that these combined
26
27 interventions may help children to manage their procedural distress. By addressing two pivotal
28
29 etiological factors, namely autonomic dysregulation and anticipatory anxiety, a case report
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31 study demonstrated the positive impact of HRV biofeedback in the treatment of a 13-year-old
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33 boy with cyclic vomiting syndrome not responding to medication (Slutsker et al., 2010). After
34
35 16 sessions combining psychoeducation, cognitive behavioural therapy and HRV biofeedback
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37 training, the patient had better HRV scores and was free of vomiting episodes even 4 months
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39 after the intervention.
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44 Several studies have investigated the benefits of biofeedback HRV in groups of children
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46 with mental health disorders specifically characterized by high levels of stress and anxiety. A
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48 group of 24 children and adolescents aged between 9–17 who were referred for treatment of
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50 anxiety were assigned to either a game-based biofeedback group or a waiting list comparison
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52 group (Knox et al., 2011). The eight-session biofeedback intervention included
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54 psychoeducation and used computer-based gaming technology to teach and practice
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56 relaxation. Significant differences between the two groups were observed at post-test, the
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58 intervention group showing reduced anxiety and depression scores on standardized tests.
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HRV Biofeedback in children and adolescents

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3 Biofeedback-assisted relaxation training with a video game format thus appeared to be
4 effective in reducing anxiety among children and adolescents. A similar HRV biofeedback
5 intervention program with a 4-week trial was proposed to a group of 20 adolescents (aged from
6 13 to 22 years old) at a clinically high risk of psychosis (Mc Ausland & Addington, 2018). Post-
7 intervention results revealed significant changes in improving impaired tolerance to normal
8 stress and dysphoric mood as well as in good overall adherence to treatment. However, no
9 change in self-reported measures of anxiety and distress was observed. Although the
10 effectiveness of the intervention was not fully established, HRV biofeedback constitutes a
11 feasible treatment option to deal with anxiety symptoms in children and adolescents.
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23 In another study, Pop-Jordanova (2009) attempted to evaluate the impact of
24 biofeedback sessions on HRV level in some common mental health disorders in children. HRV
25 changes were measured before and after the completion of 15 biofeedback training sessions
26 of 16 minutes each, notably in children with anxious phobic symptoms (n=15), somatoform
27 problems (n=15), obsessive-compulsive manifestations (n=7), or conduct disorders (n=12).
28 Interestingly, biofeedback training had a positive impact on most groups, with maximum HRV
29 changes observed in children with obsessive-compulsive, conduct, and anxiety disorders. By
30 using archival data, a recent study (Kenien, 2015) explored whether a self-induced state of
31 coherence through HRV biofeedback specifically improved executive functions in a group of
32 children (aged between 7 and 14 years old) with emotional disturbances. The intervention
33 group (n=30) received 12 weeks of cardiac coherence training (20 sessions of 20 minutes),
34 while the control group (n=30) did not receive any intervention. The children's executive
35 functioning (i.e., inhibition, working memory, emotional control, and shifting) was assessed on
36 a scale (i.e., Behaviour Rating Inventory of Executive Function; Gioia, Isquith, Guy, &
37 Kenworthy, 2000) by their teachers 1 week before and 1 week after the intervention. For both
38 groups, no statistically significant improvements in the four executive processes evaluated
39 were reported after the intervention, suggesting that HRV biofeedback training did not have a
40 direct impact on the executive abilities of children with severe emotional disorders. Finally, a
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3 case study by Thurstone and Lajoie (2013) investigated the contribution of HRV biofeedback
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5 in improving the treatment of an adolescent with substance abuse problems. In addition to his
6
7 cognitive behavioural therapy sessions, the 17-year-old teenager was also invited to attend 6
8
9 sessions of 10-minute HRV biofeedback. While the pre-intervention patient's HRV tracing
10
11 measures showed numerous irregularities, the post-intervention results showed an improved
12
13 amplitude and coherence level, reflecting better functioning of the parasympathetic nervous
14
15 system. Furthermore, he also reported a significantly lower perceived level of stress than his
16
17 baseline level, indicating that he felt calmer and more confident. These preliminary results are
18
19 encouraging for the complementary use of this type of training to improve substance abuse
20
21 treatment in young patients.
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25 Finally, a series of studies investigated the benefits of HRV biofeedback in children with
26
27 developmental behavioural issues and/or learning disabilities. First, an uncontrolled
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29 experimental study compared the contribution of HRV biofeedback alone, as well as in
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31 combination with neurofeedback sessions, in a group of 15 children with autism (Goodman et
32
33 al., 2018). The pre-post intervention differences showed significant improvements in emotional
34
35 regulation and social behaviours in all children who received HRV biofeedback. In an attempt
36
37 to find alternatives to classical pharmaceutical treatment, the benefit of therapeutic
38
39 interventions including HRV biofeedback sessions has also been explored in several studies
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41 in children with attention-deficit/hyperactivity disorder (ADHD; Amon & Campbell, 2008;
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43 Groeneveld et al., 2019; Lloyd, Brett, & Wesnes, 2010; Pop-Jordanova, 2009). In a
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45 retrospective study (Groeneveld et al., 2019), the results of behavioural and physiological pre-
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47 and post-intervention evaluations of 39 adults and 100 children diagnosed with ADHD were
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49 compared. Participants benefited from a 30-minute session of combined neurofeedback and
50
51 HRV biofeedback. Physiological parameters changed significantly after treatment, and both
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53 statistically and clinically meaningful improvements in ADHD symptoms were observed,
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55 suggesting that this type of combined intervention holds promise for treating symptoms of
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57 ADHD. In a study investigating the contribution of HRV biofeedback in several groups of
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children with different mental health disorders, Pop-Jordanova (2009) included a group of children with ADHD (n=10). However, after 15 training sessions, no significant change in physiological levels could be demonstrated in this group. Nevertheless, in two different controlled clinical trial studies (Amon & Campbell, 2008; Lloyd et al., 2010), HRV biofeedback therapy was also administered to children with ADHD. The first study focused on the benefits of HRV biofeedback at behavioural level, measured by online questionnaires completed by parents at different phases of the intervention (i.e., pre-intervention, after 1 month, after 2 months, and post-intervention). The second study investigated both behavioural and cognitive changes induced by this type of intervention by evaluating children's performance. Together, these studies demonstrated significant improvements in both behaviour and cognitive functioning after the intervention, suggesting that therapy based on HRV biofeedback is beneficial in children with ADHD.

4. Discussion

While it has been widely and efficiently used in adults (for reviews, see Goessl et al., 2017; Lehrer et al., 2020), HRV biofeedback to improve stress and/or pain management in children and adolescents remains largely unexplored until now. The objective of this systematic review was to identify studies that have used HRV protocols either alone or in combination with other therapies, as well as to evaluate their usefulness and effectiveness in children and adolescents. Based on the findings, suggestions will be made to propose avenues for future research and to recommend clear and comprehensive guidelines for the clinical application of HRV biofeedback protocols in therapeutic interventions in order to obtain optimal results.

Overall, all 18 studies but one (Kenien, 2015) showed the positive contribution of HRV biofeedback sessions in children and adolescents. When they were implemented in a school or sports setting with healthy children (Bradley et al., 2010; Dziembowska et al., 2016; McCraty et al., 1999), the adaptation of physiological responses was better and with a lower level of test anxiety, suggesting that the emotional self-regulation capacities of the participants had

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3 improved. In a clinical context with children who had physical and/or mental health disorders,
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5 HRV biofeedback helped to (1) improve several symptoms, (2) reduce disruptive behaviours,
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7 (3) enhance autonomic and emotional self-regulation, (4) reduce self-reported anxiety and pain
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9 levels, and (5) improve cognitive functioning. Children as young as 5 years old were able to
10
11 synchronize their breathing rhythm, to understand the principles of biofeedback, and to learn
12
13 to control the modulation of their physiological and emotional responses. In addition, they were
14
15 able to reproduce the techniques and use them when faced with new stressful situations.
16
17 Globally, this type of intervention appears to be easy to set up, even in a clinical or school
18
19 context. Children quickly learn the technique after a few coaching sessions, with positive
20
21 behavioural and physiological consequences occurring very quickly, even after only a few
22
23 sessions (e.g., 4 or 5 sessions; Fahrenkamp & Benore, 2019; Shockey et al., 2013). Finally,
24
25 this type of intervention is cost-effective, totally safe and non-invasive, completely compatible
26
27 and complementary with pharmaceutical or psychological treatments already set up, and the
28
29 benefits seem to be generalized and long-lasting, with some changes still observed 6 months
30
31 after the intervention ended.
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35 While all these findings are very encouraging regarding the therapeutic potential of
36
37 HRV biofeedback interventions, most of these studies suffered from significant methodological
38
39 limitations, as demonstrated by the results of our quality assessment (Supplementary Table
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41 1). First, only 10 studies had a control group and matching with the experimental group on
42
43 demographic data was not always performed. In most cases, the control group did not receive
44
45 any intervention at all, with only one study using an active placebo (Lloyd et al., 2010) and one
46
47 using a waiting list (Knox et al., 2011). Consequently, many observed benefits of HRV
48
49 biofeedback interventions might be the consequence of uncontrolled factors. For example, the
50
51 mere presence of an active intervention whatever its HRV content may have played a major
52
53 role in promoting well-being and reducing stress. Second, most studies had limited sample
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55 sizes and very few used randomization to select their samples. The findings are therefore
56
57 difficult to generalize, so larger, double-blind, randomized, better controlled studies are
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3 required. Third, while most studies used validated software and equipment to perform the HRV
4 measurements and biofeedback sessions (often the emWave system developed by
5 Heartmath), the protocols for applying the sessions differed greatly from one study to another.
6
7 The number and duration of sessions varied, as did their frequency. Fourth, some studies used
8
9 HRV biofeedback alone, while others combined it with relaxation or breathing exercises or
10
11 even more traditional cognitive and behavioural therapy sessions. This lack of standardization
12
13 of intervention protocols again hampers the generalization of the results and prevents the
14
15 establishment of clear guidelines for clinicians using this technique. Moreover, when
16
17 therapeutic approaches are combined, it is no longer possible to identify the respective impact
18
19 of the different interventions, and the contribution of HRV biofeedback in particular. Finally, to
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21 demonstrate the impact of HRV biofeedback, pre- and post-intervention measures were
22
23 compared. These measures consisted mostly of self-reported questionnaires, with a few
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25 studies also using observations provided by parents and teachers. Only one study included
26
27 more objective and less biased measures (i.e., neuropsychological standardized tests; Lloyd
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29 et al., 2010), particularly to quantify the modulation of cognitive functions, and not all studies
30
31 confirmed through online physiological measurements that biofeedback had a direct impact on
32
33 the level of HRV.
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40 Considering all these limitations, future experimental studies should adopt better-
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42 defined and controlled protocols to confirm definitively and validly the efficiency of HRV
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44 biofeedback in children and adolescents. Future studies should, therefore, include larger
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46 samples selected using conventional randomization methods, and an active control group
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48 matched at baseline for relevant variables, ideally with a staggered schedule including them in
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50 a waiting list system, or with other alternative placebo interventions. Precise, standardized
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52 physiological measurements during biofeedback sessions should be performed to ensure that
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54 children are adherent and sensitive to this type of intervention. In addition, more objective and
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56 quantitative measurements (e.g., neuropsychological tests, experimental tasks), not just self-
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58 reported ones, should be used to confirm the beneficial effects of biofeedback sessions on
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3 cognitive and affective functioning. Finally, if HRV biofeedback is applied in combination with
4 other therapeutic approaches (e.g., relaxation, cognitive behavioural therapy), it will be
5 important to include groups receiving only these approaches, in order to isolate the specific
6 effects of each.
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12 Although experimental validation remains necessary, the promising results observed
13 following the use of HRV biofeedback in the various studies identified in this systematic review
14 prompt us to formulate a series of clinical recommendations representing the foundations of
15 future guidelines to be applied systematically for the use of this type of intervention. Firstly,
16 who can benefit from HRV biofeedback interventions? As demonstrated in the selected
17 studies, children from 5 years old can benefit from this type of session. Interestingly, HRV
18 biofeedback can have positive consequences both for healthy children and children with
19 physical and/or mental health disorders. When HRV biofeedback is applied in a clinical setting,
20 it has been shown to improve stress and concentration regulation in patients suffering from
21 either anxiety and emotional disorders (e.g., phobia, psychosis) or behavioural and learning
22 disorders (e.g., ADHD, autism). In addition, it can also help in the management of anxiety
23 and/or pain induced by other physical pathologies requiring frequent and invasive tests or
24 interventions (e.g., cancer, functional abdominal pain). Secondly, how can HRV biofeedback
25 be optimally applied? To achieve significant positive effects, the various studies used a
26 protocol with an average of 6 to 15 sessions, at a rate of 1 to 2 sessions per week. Each
27 session lasted about 20 minutes and was often accompanied by breathing and/or relaxation
28 exercises, as well as psycho-educational advice. Equipped with an HRV sensor, children could
29 generally visualize their physiological parameters on a computer screen and learn how to
30 modulate them through video game-based exercises. In addition to arousing children's interest
31 and giving a playful aspect to the breathing exercise, the use of this type of video game seems
32 to promote the learning of regulation techniques and improve compliance with treatment.
33 Furthermore, studies have reported the presence of even greater benefits when children tend
34 to naturally exercise while at home and when parents fully participate in the intervention
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HRV Biofeedback in children and adolescents

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3 program by exercising with their children. Finally, in a clinical context, we advise proposing
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5 HRV biofeedback interventions in combination with more traditional drug and/or therapeutic
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7 treatments. HRV biofeedback sessions are not time-consuming and do not have any disruptive
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9 effects, making them an ideal complement to other therapeutic approaches.
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12 In conclusion, this systematic review demonstrates the feasibility of HRV biofeedback
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14 interventions in children and adolescents and highlights the substantial benefits provided by it
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16 on a variety of physical, behavioural, and cognitive problems. Although methodological
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18 limitations have been identified requiring replication of these results in more controlled
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20 experimental studies, the promising results observed to date pave the way for this type of
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22 intervention in clinical and/or school settings. The development of integrated portable solutions
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24 combining biofeedback on physiological parameters and breathing exercises, and allowing
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26 easy and autonomous use by children wherever and whenever they wish, would be a most
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28 appreciable objective in the short and midterm.
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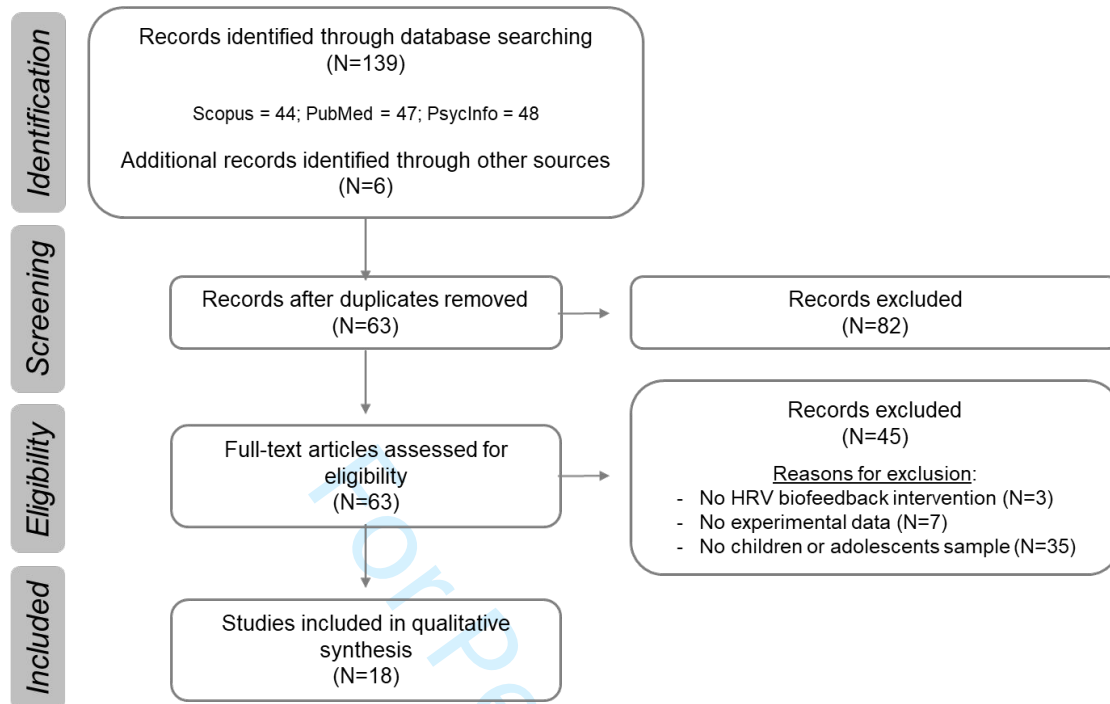
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Figure 1

Figures Legends

Figure 1: PRISMA flow diagram describing process for selecting and reviewing papers included.

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Table 1. Description and main results of HRV biofeedback intervention studies with healthy and pathological children and adolescents

Authors (year)	Participants					Intervention								Comparison	Outcomes		
	Population	Sample (N)	Mean Age (\pm SD)	Age Range	Gender ratio (% males)	HRV Biofeedback Intervention	Coupled with (other interventions)	Number of sessions	Duration of each session	HRV measures	Assessment tools	Time measurement	Follow-up	Control group	Main results	Limitations reported	Key conclusions
Healthy Populations																	
Bradley et al. (2010)	High-school students	Experimental group: n = 77; Control group: n = 59	Experimental group: M = 15.3 \pm 0.44; Control group: M = 15.3 \pm 0.44	NR	Experimental group: 53; Control group: 40	Freeze-framer interactive learning system	TestEdge program	NR	NR	RR intervals; SD of RR intervals; High and Low frequency power; Total power; Coherence ratio	Test Anxiety Inventory; Test performance; Stroop Test	Twice: pre- and post-intervention; two phases of measures: Resting baseline and Stress preparation period	None	Yes (no intervention)	Experimental group showed lower test anxiety and increased psychophysiological coherence after intervention. Students with high test anxiety exhibited increased HRV and heart rhythm coherence even during resting baseline condition.	Lack of baseline equivalence between the two groups; No information about native language; Stroop Test was not an achievement test	Students in intervention group appeared to have effectively learned, practiced and integrated the emotion self-regulation skills taught in program.
Dziembowska et al. (2016)	Young male athletes	Biofeedback group: n = 20; Control group: n = 21	M = 18.34 \pm 1.36	16-21	100	emWave PC stress relief system	No	10 in 3 weeks	20 minutes	HRV and EEG recordings; Coherence Index	State-Trait Anxiety Inventory (STAI); Rosenberg self-esteem Scale (SES)	Pre- and post-intervention	None	Yes (no intervention)	Biofeedback group showed changes in both EEG and HR measures.	Small sample size; No generalisation for both genders; Only short-term effects evaluated	HRV biofeedback is a simple and powerful tool for sport psychology.
McCraty et al. (1999)	Middle-school students	Year 1: n = 32; Year 2: Experimental group n = 30, Control group n = 30	Year 1: M = 12.2; Year 2: M = 13.2	Year 1: 12-13; Year 2: 12-14	Year 1: 56.25; Year 2: Experimental group = 36.67, Control group = 30	Freeze-framer interactive learning system	Heart Smart program	NR	NR	RR intervals; SD of RR intervals; High and Low frequency power; Total power; Coherence ratio	The Achievement Inventory Measurement (AIM)	Year 1: One week before and one week after the completion of the program + follow-up; Year 2: HRV recordings before, during and after a stressful interview	After 6 months post-intervention	Yes (no intervention)	AIM assessment: Significant improvement in 11 of 19 subscales following intervention. Many of these changes were sustained over the following 6 months. Physiological assessment: Significant increase in heart rate, standard deviation of RR intervals, total power and VLF power in trained group.	Small sample size; no appropriate controls; no simultaneous measurement of behavioural and physiological changes	Results provide support for integration in school curricula of courses designed to teach effective self-management skills to children.
Populations with physical and/or mental health disorders																	
Amon & Campbell (2008)	Children with ADHD	Experimental group: n=24 (17 in group 1; 7 in group 2); Control group: n = 12 (10 in group 1; 2 in group 2)	Experimental group: M = 9.5; Control group: M = 8.75	5-15	Experimental group: 62.5; Control group: 75	The Wild Divine biofeedback video game	/	Group 1: 12 sessions (once a week); Group 2: 24 or 36 sessions (twice or three times a week)	45 minutes	/	ADHD questionnaires; Strengths and Difficulties Questionnaire (SDQ); Questionnaire on the Wild Divine Video game	Parents completed an online questionnaire 4 times: T1 Pre-intervention, T2 after the 1 st month, T3 after the 2 nd month, T4 after the 3 rd month	None	Yes (no ADHD)	Both experimental and control group had significant reductions on SDQ and ADHD questionnaire, resulting in improvement in behaviour by final session.	Small and uneven sample size; no random group allocation	The Wild Divine protocol showed potential in teaching breathing and relaxation techniques to reduce disruptive behaviours in children with ADHD.
Fahrenkamp & Benore (2019)	Adolescents with chronic pain	n = 4	M = 16 \pm 1	15-17	25	Nexus 10 biofeedback system (BioTrace)	Interdisciplinary program	3 or 4	NR	Respiration rate; HRV (%LF)	/	Pre- and post-intervention	None	None	All 4 adolescents showed lower respiration rates and directional increases in %LF after biofeedback training sessions compared with initial assessment.	Small sample size; no gold standard for objectively measuring biofeedback outcomes and conducting biofeedback protocols in children; benefits of biofeedback were not examined within the context of treatment outcomes from larger interdisciplinary program	Adolescents using a brief protocol of HRV biofeedback training demonstrated expected changes in cardiopulmonary functioning and self-regulation.
Goodman et al. (2018)	Children with diagnosis of Autism Spectrum Disorder (ASD)	n = 15	M = 12.4 \pm 2.5	9-18	86.7	Thought Technology Ltd. (Quebec, Canada) equipment and software (BioGraph Infinity 6.0)	Group 1: HRV biofeedback alone - Group 2: HRV Biofeedback + Mu Rhythm Synchrony Neurofeedback (MRS-NFB)	Preliminary Training = 4 sessions + Training = 12 sessions	1 hour	Quantitative EEG; Mu Suppression Index; Standard deviation of normal-to-normal wave intervals; Square root of the mean squared difference of successive normal-to-normal intervals; HF spectrum	Social Responsiveness Scale-2 (SRS-2); Emotion Regulation Checklist (ERC); Spence Children's Anxiety Scale (SCAS - Parent report); Autism Treatment Evaluation Checklist (ATEC)	Pre- and post-intervention	None	None	No difference between the two groups over time in social behaviour, autistic symptoms, emotion regulation, anxiety or HRV; Group 1: Significant pre-post improvement in emotion regulation and social behaviour; Group 2: Significant pre-post improvement in emotional lability/negativity, autistic symptoms and HRV.	Small sample size; Lack of no-treatment control group; Demand characteristics and parents' optimism; Modifications during course of training	This study was the first to suggest that HRV biofeedback can positively affect symptoms of ASD.
Groeneveld et al. (2019)	Children with ADHD	n = 100	M = 10.6 \pm 2.9	6-17	72	Finger Blood Volume Pulse (BVP) sensor and respiration	Neurofeedback (NFB) breathing exercise;	30	3 to 5 minutes	HRV; Breathing Rate and QEEG	ADHD Symptoms and behaviour via Achenack System of Empirically Based Assessment	Pre- and post-intervention	None	None	Decrease in ASEBA score and increase in IVA score after treatment. Significant changes in	Retrospective experimental design; not randomized sample; One treatment condition (no comparison)	After 30 sessions, both statistically significant, and clinically meaningful improvements in ADHD symptoms were observed.

1						belt; Fluctuation of HR inter-beat intervals presented on a monitor	Psycho-education				(ASEBA) and Integrated Visual and Auditory Continuous Performance Test (IVA); ADHD Medication use				physiological parameters after treatment.	between NFB and HRV); no sham-control placebo group		
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7	Kenien (2015)	Children with emotional disturbances	Treatment group: n = 30; Control group: n = 33	NR	7-14	87	emWave desktop HRV biofeedback	/	20 sessions over 12 weeks	20 minutes	/	Behaviour Rating Inventory of Executive Function (BRIEF): 4 Subscales = Inhibition, Working Memory, Emotional Control and Shift	Completed by teachers 1 week prior to and 1 week post-intervention	None	Yes (no intervention)	No significant difference between pre-test and post-test within intervention or control group on all subscales.	Secondary data analysis of a quasi-experimental study design; No participant selection on specific inclusion and exclusion criteria; Wide age range; no randomization selection for control and treatment groups; minority of females	More objective measures and qualitative assessment are needed.
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16	Knox et al. (2011)	Children with anxiety	Total n = 24 (Intervention group: n = 12; Control group: n = 12)	M = 12.88 ± 2.42	9-17	62.5	Heart Math Freeze-Framer system 2.0 and Journey to the Wild Divine	Psycho-education exercises	8	NR	Changes in HRV and skin conductance level	Multidimensional Anxiety Scale for Children (MASC); State/Trait Anxiety Scale for Children (STAIC); Children's Depression Inventory (CDI)	Pre- and post-intervention	None	Yes (waiting-list)	Significant differences between intervention and control group at post-test on different measures (MASC, STAIC Trait, and CDI).	Small sample size; Non-random assignment to groups	Biofeedback-assisted relaxation training with a video game format is effective in reducing anxiety in children and adolescents.
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26	Lehrer et al. (2000)	Children with asthma	n = 20	M = 12.4 ± 3.4	9-16	60	KC-01 Cardiosignalizer	Relaxed abdominal pursed-lips breathing	13-15 sessions	20 minutes	/	Spirometry measures: forced expiratory volume (FEV1) and forced expiratory flow (FEF50%)	Pre- and post-intervention	None	None	Moderate but significant improvement in FEV1 and FEF50% after 13 to 15 daily biofeedback sessions.	No control condition; Possible ceiling effect	This study demonstrates that the Smetankin protocol can be administered to asthmatic children, and that small but salutary effects accompany its clinical use.
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36	Lloyd et al. (2010)	Children with ADHD	Total n = 38 (only biofeedback group: n = 14; both biofeedback and placebo: n = 22; only placebo group: n = 2)	NR	9-13	89.7	emWave Desktop System	/	One daily session over 6 weeks	20 minutes	/	Cognitive Drug Research (Cognitive efficiency computer-based assessment); Strength and difficulties Questionnaire; Interviews with 32 parents	T1: pre-intervention; T2: post-intervention (biofeedback or placebo); T3: post-intervention (only for placebo groups)	None	Yes (active placebo)	Participants demonstrated significant improvements in various aspects of cognitive functioning such as delayed word recall, immediate word recall, word recognition, and episodic secondary memory. Significant improvements in behaviour were also found.	Self-reported questionnaires	The intervention offers a physiologically based program to improve cognitive functioning and behaviours in children with ADHD.
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45	Mc Ausland & Addington (2018)	Young people at clinical high risk for developing psychosis	n = 20	M = 16.7 ± 2.3	13-22	30	emWave 2 devices	Anxiety education	4-week trial	Minimum 1 hour per week	/	DSM IV; K10 (anxiety and depressive symptoms); Social Interaction Anxiety Scale (SIAS); Zung SAS (general anxiety)	Pre- and post-intervention + follow-up	After 4 weeks post-intervention	None	Significant decrease in unusual thought content, grandiose ideas and symptom scores. Significant change over time on impaired tolerance to normal stress and dysphoric mood. Trend for improvement in SAS scores.	Single group; Small sample size; Concurrent treatment; Use of self-reported measures; Use of biofeedback on their own; No objective measure of HRV	Observed improvements in scores, adherence and participant's feedback indicate that this type of intervention is well-tolerated and may be a feasible and useful option for young patients in reducing some presenting concerns.
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52	Pop-Jordanova (2009)	Children with mental health disorders (6 groups: (1) Children with anxious phobic symptoms; (2) children with somatoform problems; (3) children with obsessive-compulsive manifestations; (4) children with ADHD; (5) children with conduct disorders; (6) control	(1) n = 15; (2) n = 15; (3) n = 7; (4) n = 10; (5) n = 12; (6) n = 15	(1) M = 12.5 ± 2.25; (2) M = 10.92 ± 2.06; (3) M = 14.5 ± 2.2; (4) M = 10.5 ± 1.8; (5) M = 11.5 ± 1.52; (6) M = 10.18 ± 1.33	NR	NR	Heart Math Freeze-Framer system (basic recordings + 2 games)	/	15 training sessions	16 minutes	HRV spectra: % of low, medium and high HRV	Eysenck Personality questionnaire and inventory	Pre- and post-intervention	None	Yes (but no direct comparison)	Maximum HRV changes obtained for obsessive-compulsive, conduct disorders, and anxiety. Children with ADHD did not manage to change high part of HRV.	/	HRV as a peripheral biofeedback could be good choice especially for introvert children manifesting common mental health problems.
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	Shockey et al. (2013)	Children diagnosed with cancer	n = 12	M = 11 ± 2.08	8-14	58.3	Heart Math emWave	Relaxation (belly breathing)	3	30 minutes	HR and HRV Coherence score	Faces Scale (anticipatory fear); State/Trait Anxiety Scale for Children (STAIC); Satisfaction with the intervention program (Likert scale)	Pre- and post-intervention	None	None	Decrease in state and trait anxiety from baseline to final session; Improvement in coherence scores in sessions 3 and 4.	Small sample size; No control group comparison; One-to-one interaction with the investigator; Faces scale modifications are not appropriate	This combination intervention of relaxation and biofeedback served as a tool to increase participants' awareness of the connection between emotions, physiological changes, and self-regulation.
	Slutsker et al. (2010)	One boy with cyclic vomiting syndrome (CVS)	n = 1	13	NA	100	emWave program	Cognitive behavioural therapy (CBT)	16 sessions over 4 months	NR	Low/high frequency ratio	Symptoms	Pre- and post-intervention + follow up	After 4 months post-intervention	None	Better HRV low/high ratio and symptom-free after intervention.	/	HRV biofeedback is possible to assist the patient regulate autonomic dysregulation.

1																Four months after therapy, no vomiting was reported.		
2	Sowder et al. (2010)	Children with Functional Abdominal Pain (FAP)	Intervention group: n = 20; Control group: n = 10	Intervention group: M = 12.6 ± 3.03; Control group: M = 14.4 ± 2.86	5-17	Intervention group: 45; Control group: 50	J&J Engineering I-330 C-2 Portable 6-Channel Physiological Monitoring System	/	6	At least 10 minutes	Vagal tone; % of LF	Visual Analog Scale of pain severity	Pre- and post-intervention	None	Yes (children without FAP; no intervention)	A significant increase in %LF and a significant decrease in pain frequency and intensity observed after intervention in FAP group.	No intervention in control group; Experimenter effect	HRV biofeedback would be efficacious in treating FAP.
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15	Stern et al. (2014)	Children with Irritable Bowel Syndrome (IBS) and Functional Abdominal Pain (FAP)	Total: n = 24 (IBS: n = 13; FAP: n = 11)	IBS: M = 10.69 ± 3.4; FAP: M = 12.18 ± 3.06	6-17	IBS: 46; FAP: 36	J&J Engineering C2+ hardware and USE3 Software	/	Mean = 8 (between 3 and 18 sessions; stop when remission)	30 minutes	HR and respiration rate	Self-reported symptom frequency and severity	Pre- and post-intervention	None	None	IBS: 69.2% of full remission and 30.8% of partial remission; FAP: 63.6% of full remission and 36.4% of partial remission.	Small sample size; Single self-reported measure for clinical outcomes; no record of HRV data during baseline and stress task; Treatment compliance not assessed; Clinical outcomes assessed 2 weeks post-treatment; no long-term follow-up; no control group	The results support the clinical utility of HRVB in the treatment of IBS and FAP in paediatric outpatients.
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22	Thurstone & Lajoie (2013)	Adolescent with cannabis use	n = 1	17	NA	100	emWave Desktop Stress Relief	Cognitive behavioural therapy (CBT)	6	10 minutes	HRV amplitude and power spectrum	Perceived Stress Scale	Pre- and post-intervention	None	None	After treatment, improved amplitude and coherence HRV; Better score on perceived stress scale.	No control group; Single-case study	This case shows promise results for HRV biofeedback to augment individual CBT for adolescent substance treatment.
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Legend: ADHD, Attention-deficit hyperactivity disorder; DSM, Diagnostic and Statistical Manual of Mental Disorders; EEG, Electroencephalogram; HF, High frequency; HR, Heart rate; HRV, Heart rate variability; LF, Low frequency; NR, Not reported; QEEG, Quantitative electroencephalogram; RR intervals, intervals between successive heartbeats; SD, Standard deviation; VLF, Very low frequency.

For Peer Review

Supplementary Table 1. Comparison group studies scoring using adapted quality assessment tool for controlled intervention studies (NHLBI, 2014).

	Authors	Date	Score for each item														% score
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Healthy populations	Bradley et al.	2010	Y	Y	Y	N	N	N	Y	Y	Y	NA	Y	N	Y	Y	69
	Dziembowska et al.	2016	Y	Y	Y	N	N	Y	Y	Y	Y	NA	Y	N	Y	Y	77
	McCraty et al.	1999	Y	Y	Y	N	N	N	NR	NR	NR	NA	Y	N	Y	Y	50
Populations with physical and/or mental health	Amon & Campbell	2008	N	NA	NA	NA	N	N	Y	Y	Y	NA	Y	N	Y	Y	60
	Goodman et al.	2018	Y	Y	Y	N	N	Y	N	Y	Y	NR	Y	N	Y	Y	69
	Kenien	2015	N	N	NA	NA	NA	N	NR	NR	NR	NA	Y	Y	Y	Y	57
	Knox et al.	2011	N	N	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	64
	Lloyd et al.	2010	Y	Y	Y	Y	Y	NR	Y	Y	Y	Y	Y	N	Y	Y	92
	Pop-Jordanova	2009	N	N	NA	NA	NA	Y	NR	NR	NR	NR	Y	N	Y	Y	57
	Sowder et al.	2010	N	N	NA	NA	NA	Y	N	N	Y	NA	Y	Y	Y	Y	60

Legend: N, No; Y, Yes; NA, Not applicable; NR, not reported.

Note: Question related to each item:

(1) Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT?

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- 3 (2) Was the method of randomization adequate (i.e., use of randomly generated assignment)?
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- 5 (3) Was the treatment allocation concealed (so that assignments could not be predicted)?
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- 7 (4) Were study participants and providers blinded to treatment group assignment?
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- 10 (5) Were the people assessing the outcomes blinded to the participants' group assignments?
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- 12 (6) Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors,
- 13 co-morbid conditions)?
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- 17 (7) Was the overall dropout rate from the study at endpoint 20% or lower than the number allocated to treatment?
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- 19 (8) Was the differential dropout rate (between treatment groups) at endpoint 15 percentage points or lower?
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- 21 (9) Was there high adherence to the intervention protocols in each treatment group?
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- 24 (10) Were other interventions avoided or similar in the groups (e.g., similar background treatments)?
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- 26 (11) Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
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- 28 (12) Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between
- 29 groups with at least 80% power?
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- 33 (13) Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?
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- 35 (14) Were all randomized participants analysed in the group to which they were originally assigned (i.e., did they use an intention-to-
- 36 treat analysis)?
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