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Review Article

Heart Rate Variability Biofeedback to Treat Fibromyalgia: An Integrative Literature Review

Marcelaine Reneau, MSN, FNP-BC

Department of Anesthesia, Pain Clinic, Veterans' Health Administration, Charleston, South Carolina

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ABSTRACT

Objectives: Fibromyalgia (FM) is associated with debilitating pain and a reduced heart rate variability (HRV), reflecting decreased emotional adaptability and resistance to stress. Common pharmacological treatments are ineffective, and opioids are highly addictive and cause an estimated 15,000 overdose deaths per year. Effective recommendations include patient-centered interventions like physical activity, cognitive behavioral therapy, and biofeedback. Heart rate variability biofeedback (HRVB) may be effective in improving HRV, thus increasing stress resistance and emotional adaptability and reducing pain.
Design: This integrative literature review was conducted to examine the relationship between HRVB and FM-related chronic pain using the Theory of Symptom Self-Management and to identify available HRVB technology.
Data Sources: We searched PubMed, EBSCOhost, and Google Scholar electronic databases for relevant publications. Manuscripts were selected using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses strategy, and study quality was assessed using the Critical Appraisal Skills Programme guidelines. The relationship between HRVB and FM was analyzed and evaluated based on the methodological framework proposed by Whittemore and Knafl.
Review/Analysis Methods: We reviewed 22 articles and included six in this review. Five reported HRVB as a treatment for chronic pain, and one for FM pain.
Results: Overall, the articles in this review support the claim that HRVB is related to decreased pain. The researchers evaluated five HRVB programs, three on handheld devices and two on desktop computers.
Conclusions: The reviewed studies had methodological flaws. However, HRVB is a promising treatment for chronic pain. Larger, randomized controlled studies are needed to thoroughly evaluate the relationship between HRVB and FM pain.

Fibromyalgia (FM), a complex chronic pain syndrome, affects 10 million individuals in the United States (Center for Disease Control, 2017). Unlike other chronic pain-related conditions, FM involves an incoherent heart rate variability (HRV) and a dysfunctional autonomic nervous system (ANS) (Cohen et al., 2000; Dworkin & Fields, 2005; Martínez-Lavín & Hermosillo, 2000). HRV, the change in time intervals between heartbeats, reflects heart–brain interaction and ANS function (Cho et al., 2011; Kang, Chen, Chen, & Jaw, 2012; Meeus et al., 2013; Mostoufi, Afari, Ahumada, Reis, & Wetherell, 2012). When HRV is incoherent, chaotic, or insufficient, ANS is also dysfunctional, contributing to the chronic pain, decreased physical functioning, and poor quality of life that are associated with fibromyalgia (Cohen et al., 2000; Kang et al., 2012; Meeus et al., 2013). Optimal or coherent HRV is associated with improved physical functioning, improved stress regulation, improved emotional arousal, and improved stress resistance (De jonckheere, Ibarissene, Flocteil, & Logier, 2014; Kapitza, Passie, Bernateck, & Karst, 2010; Lehrer & Gevirtz, 2014; McCraty & Shaffer, 2015).

Heart rate variability biofeedback (HRVB), a form of cardiorespiratory feedback training (Lehrer & Gevirtz, 2014), is a self-management strategy that induces a vagal response as the individual slows their breathing rate to 4-6 breaths per minute (McCraty & Shaffer, 2015). The decreased rate of breathing during HRVB will induce a slower heart rate, allowing more time between heartbeats and an improvement in HRV coherence (McCraty & Shaffer, 2015). Additionally, repeated sessions of HRVB can sustain HRV coherence for longer periods of time (McCraty & Shaffer, 2015). It is hypothesized that routine use of HRVB can decrease pain, improve stress

Address correspondence to Marcelaine Reneau, MSN, FNP-BC, 388 Oak Park St., Summerville, SC 29486.
E-mail address: hairem@musc.edu.

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resistance and emotional adaptability, and increase overall well-being (Cohen et al., 2000; McCraty & Shaffer, 2015).

The purpose of this integrative literature review was to examine studies that reported on the relationship between HRVB and FM-related chronic pain using the Theory of Symptom Self-Management as the theoretical framework. Additionally, we sought to identify which HRVB technology has been used and any comparisons among devices. However, we were able to identify only one study devoted solely to FM-related chronic pain. To fully evaluate HRVB as a treatment for pain, we included other forms of chronic pain in our literature review.

Theoretical Framework

The Theory of Symptom Self-Management (TSSM) has been used to assist individuals to reduce, prevent, relieve, or decrease the timing of unpleasant symptoms, such as chronic pain, through self-management-enhancing interventions (Fu, LeMone, & McDaniel, 2004; Hoffman, 2013), such as biofeedback (Burckhardt, 2004; Vancleef, 2011) and HRVB (McCraty & Shaffer, 2015; Moss & Shaffer, 2017; Wheat & Larkin, 2010). The central tenet of TSSM that guided this review is that functional and cognitive performance outcomes, such as quality of life and functional status, are improved by optimizing self-directed, self-management, perceived self-efficacy (PSE)—enhancing interventions, such as HRVB (Hoffman, 2013; Lorig & Holman, 2003). The key concepts of TSSM are as follows: 1) PSE for symptom self-management, 2) actual symptom self-management, 3) patient characteristics, 4) symptoms, 5) performance outcomes and PSE-enhancing interventions (Hoffman, 2013).

Perceived Self-Efficacy for Symptom Self-Management

Self-efficacy influences how a person thinks, feels, motivates him- or herself, and performs actions (Bandura, 1994). PSE is the belief or confidence one has in oneself to perform or execute the actions required to produce the desired effects or outcomes (Bandura, 1994). PSE for symptom self-management is a patient's ability to implement specific behaviors to attain established treatment goals or desired outcomes (Hoffman, 2013).

Symptom Self-Management

Symptom self-management encompasses self-directed active behaviors that may prevent or relieve symptoms such as pain or decrease their frequency or intensity, allowing the patient to reach optimal performance outcomes (Hoffman, 2013). Self-management with biofeedback has been shown to be an effective treatment for FM pain (Macfarlane et al., 2017). The symptom self-management behaviors analyzed in this review are the consistent and correct use of biofeedback. Use is considered correct if the patient engages in HRVB as often and for as long as prescribed, following the prescribed breathing rate and depth while following along with the electronic signals emitted by the feedback device.

Patient Characteristics

Patient characteristics include the physiological and psychological factors that influence outcomes and may include severity of illness, comorbidities, age, mental state or mood status, personal beliefs, affective reaction to illness or disease, and degrees of uncertainty (Hoffman, 2013). The patient physiological and psychological characteristics analyzed in this review are mental health status, sleeping difficulties, gender, marital status, and employment status. Depression and mood disturbance, commonly seen in FM (Cohen, 2017; Macfarlane et al., 2017), are significant factors in pain management and are influencing factors on self-management (Fu et al., 2004). Fatigue or unrefreshing sleep is a hallmark symptom of FM (Wolfe et al., 2010) and can also greatly influence self-management (Cohen, 2017; Fu et al., 2004; Rosso & Maddali-Bongi, 2016). Work absenteeism and disability are considered the cause of an average of 26% of the indirect costs associated with FM and 42% of the costs of unemployment owing to FM disability (Chandran et al., 2012; Ghavidel-Parsa, Bidari, Amir Maafi, & Ghalebaghi, 2015; Schaefer et al., 2015). Women comprise 86%-96% of the population of FM patients and have a higher divorce rate when compared to those suffering from other chronic pain diseases (Wolfe, Ross, & Anderson, 1995).

Symptoms

Symptoms are the subjective experiences of a perceived threat to health or wellness, or are signs of an undesirable outcome (Hoffman, 2013). Symptoms of FM can be diffuse and multifocal, and they can wax and wane daily. The symptoms analyzed in this review are chronic pain, fatigue, depression, and low HRV. FM-related pain is often characterized as a widespread ache with multiple diffuse, exquisitely tender muscle points (Wolfe et al., 2010).

Performance Outcomes

Performance outcomes are the effects of a person's symptom self-management experience (Hoffman, 2013). Desired outcomes of self-directed behaviors, such as HRVB, include decreased symptoms of pain, depression, and fatigue, less symptom distress, and fewer symptom occurrences (Fu et al., 2004; Hoffman, 2013). These outcomes have a direct effect on quality of life (Cohen, 2017; Fu et al., 2004; Macfarlane et al., 2017), sleep (Cohen, 2017; Rosso & Maddali-Bongi, 2016), and functional status (Cohen, 2017). The performance outcomes analyzed in this review are functional status and quality of life.

Perceived Self-Efficacy—Enhancing Interventions

A patient's ability to perform PSE-enhancing interventions is developed through activity performance along with social or verbal persuasion by others, which determines how the individual will think, feel, self-motivate, and perform (Hoffman, 2013). The building blocks of PSE-enhancing interventions include mastery of the activity by performing it oneself, observing others perform the activity successfully, being persuaded by others that the activity is possible, and perceiving one's self as possessing the strength to achieve the goal (Hoffman, 2013). The following were analyzed in this review: mastery of HRVB skills via observation of trainers and frequently performing the skill oneself, being socially persuaded to perform the activity, and self-interpretation one's HRVB skills as good or adequate.

Methods

Design

This integrative review was guided by the methodological framework proposed by Whittemore & Knafl (2005). The five stages include 1) identifying a gap in the literature about HRVB as a treatment for FM-related chronic pain, 2) searching in the literature for studies supporting the use of HRVB to treat FM, 3) evaluating data using the Critical Appraisal Skills Programme (CASP) scoring system, 4) analyzing data using the TSSM as a framework, and 5) visually presenting a review matrix (Whittemore & Knafl, 2005).

Search Methods

In September 2017, a reference librarian at an academic medical center was consulted to assist in finding the most appropriate approach in searching the literature for applicable studies. The literature was systematically selected to be included in the sample using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (see Fig. 1). We searched PubMed, EBSCOhost, and Google Scholar electronic databases for relevant publications. We searched each database for the following terms: [heart rate variability OR heart rate variability biofeedback OR heart rate coherence biofeedback OR heart rate coherence OR biofeedback] AND [fibromyalgia] AND [chronic pain]. The terms evolved from concept maps used in the development of the aims of this review. We included primary studies of any research design in the review. We reviewed reference lists from included manuscripts to identify literature not found in the initial database searches manually.

The original planned study inclusion criteria were: 1) articles that included fibromyalgia pain in the outcome measures, 2) articles reporting HRVB as an intervention, 3) peer-reviewed articles in the English language, and 4) adult participants (>17 years). Exclusion criteria were: 1) non-FM pain, 2) literature reviews, and 3) non-HRVB biofeedback. This search returned only one study. The search criteria were expanded to include other forms of chronic pain. During the review, studies involving cancer pain were eliminated; this search yielded 21 more studies. We did not set a time limit because of the novelty of the subject matter as well as an interest in historical findings.

Search Outcomes

The initial database searches yielded 22 articles. We removed 10 duplicates and reviewed the full text of the remaining 12 articles. Three of the articles eliminated were literature reviews of HRVB (Gevirtz, 2013; Moss & Shaffer, 2017; Wheat & Larkin, 2010); these were hand-searched for original studies. However, no additional studies met inclusion criteria.

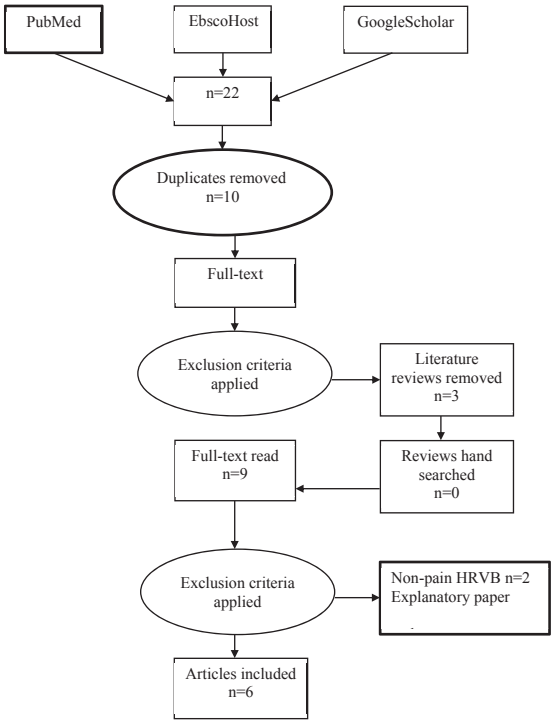

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement

The remaining nine full-text articles were then further assessed for eligibility, yielding six studies. Two of the articles eliminated reported HRVB findings, but not pain treatment (Edwards, 2014; Whited, Larkin, & Whited, 2014). The final one eliminated was an explanatory paper on how and why HRVB works (Lehrer & Gevirtz, 2014). A review of reference lists of the selected articles and the previous literature reviews did not yield any additional studies.

Data Presentation

The resulting data were categorized and presented in table form (Table 1) by reference, interventions, biofeedback technology, population, study design, outcome measures, relevant findings, and grading. The Critical Appraisal Skills Programme (CASP) guided the grading of each randomized controlled and cohort study by addressing three broad questions: 1) Are the results of the study valid? 2) What are the results? and 3) Will the results help locally? (Critical Appraisal Skills Programme, 2018).

Results

Overview of Studies

The six articles reviewed consisted of three randomized pilot studies (Berry et al., 2014; Hallman, Olsson, von Schéele, Melin, & Lyskov, 2011; Weeks, Whitney, Tindall, & Carter, 2015) one non-randomized pilot study (Hassett et al., 2007), one retrospective archival study, (Wilson, 2017), and one retrospective cohort study (Soer, Vos, Hofstra, & Reneman, 2014). The independent variable was HRVB in all studies. The study by Hassett et al. (2007) was the only one which treated FM-related pain solely with HRVB. Hallman et al. (2011) compared two forms of treatment for neck and shoulder pain. Patients in the first group received multiple sessions of HRVB, whereas those in the second group received the same breathing protocol instructions during session one but did not receive instructions on breathing during the remaining sessions. Berry et al. (2014) added HRVB to standard care for chronic pain; however, they did not specify what this care entailed or specifics about pain location. However, they did exclude individuals with diabetes or traumatic musculoskeletal system damage. Soer et al. (2014) added HRVB to Back School, a personalized pain rehabilitation program designed to increase physical capacity and cognitive behavior interventions for chronic back pain. Weeks et al. (2015) compared faded HRVB to full HRVB in nine sessions to treat non-malignant chronic musculoskeletal pain, fibromyalgia, headache, neuropathy, and reflex sympathetic dystrophy over a 3-week period. Faded HRVB consisted of visual feedback during session 1, followed by a systematic reduction of visual biofeedback with each session so that by session nine, the participants were controlling HRV without visual feedback. The control group received visual biofeedback for nine sessions. Wilson (2017) included individuals with neuropathic pain, musculoskeletal pain, and headache. The primary outcomes measured were pain ($n = 6$), functional status ($n = 5$), depression ($n = 3$), HRV ($n = 4$), catastrophizing ($n = 1$), sleep ($n = 1$), anxiety ($n = 1$), somatization ($n = 1$), self-reported health status ($n = 1$), and biofeedback skills ($n = 1$). Only three studies reported study controls: standard care ($n = 1$), Back School ($n = 1$), and full HRVB ($n = 1$). Although none of the studies or reviews articulated the use of any theoretical framework or model, we identified some of the TSSM constructs in some of the studies (see Table 2).

Table 1
HRVB Literature Review Outcomes

Reference	Intervention	Biofeedback Technology	Population	Design	Outcome Measures	Relevant Findings	CASP Score
Wilson. (2017)	Heart rate variability biofeedback (HRVB)	"Relaxing Rhythms" from Unyte Health Inc. finger sensor measuring skin conductance levels and HRV	N = 72; 56 F; 15 M; 1 TG	Retrospective archival study (not randomized)	Pain, catastrophizing, depression, anxiety, somatization	Decreased pain $p < .001$, however not sustained across sessions	n/a
Hassett, Radvanski, Vaschillo, et al. (2007)	HRVB	J&JJ-330 unit on computer screen and Cardiosignalizer CS-03 handheld device	N = 12; 12 F	Pilot (not randomized)	Functional status, depression, pain, sleep	Decreased pain $p = .455$ after 10 sessions, $p = .006$ after 3 months; increased functional status $p = .069$ after 10 sessions, $p = .0022$ after 3 months	n/a
Soer, Vos, Hofstra, & Reneman. (2014)	HRVB and mindfulness exercises added to Back School	Freeze-frame by Heart Math, visual biofeedback on a computer screen	N = 170; 71 F; 99 M	A retrospective cohort study comparing the intervention to Back School alone	Pain, pain disability, self-reported health status, HRV	Increased HRV $p < .01$; decreased pain $p = .15$; increased function $p = .02$	8
Berry, Chapple, Ginsberg, Gleichauf, Meyer, & Nagpal. (2014)	HRVB plus standard care	*Quick Coherence*, controlled breathing and self-induction of positive or neutral emotional state	N = 14; 1 F; 13 M	Randomized Pilot comparing the intervention to standard care	Pain, HRV, physical activity limitations	Increased HRV 191% $p = .04$; decreased pain 36% $p < .001$; decreased physical limitations 42% $p < .001$	9
Hallman, Olsson, von Scheele, Melin, Lyskov. (2011)	HRVB	*J&JJ-330-2* visual handheld device	N = 24; 21 F	Randomized Pilot comparing intervention to standard care	Pain, HRV, physical function, depression, vitality, social function	Increased resting HRV, increased LF HRV $p = .016$ interaction effect, no significant HF HRV interaction effect; decreased pain $p = .049$; decreased physical function $p = .27$; decreased depression $p = .78$; increased vitality $p = .005$; increased social function $p = .047$	10
Weeks, Tindall, Carter.(2015)	Faded HRVB	Freeze-frame by Heart Math, visual biofeedback on a computer screen	N = 20; 5 F; 6 M	Randomized Pilot comparing the intervention to full HRVB	HRV, use of BF skills, pain, functional status, kinesophobia	HRV no significant difference between groups; decreased pain $p = .291$ (no difference from the control group), improved functional status $p = .464$ (no difference compared to control group), decreased kinesophobia compared to control group $p = .102$, improved HRVB used $p = .132$ compared to control group	10

BF = biofeedback; F = female; HRV = heart rate variability; HRVB = heart rate variability biofeedback; M = male; T = transgender.

Perceived Self-Efficacy-Enhancing Interventions

Observation

The participants in all studies were instructed and coached by HRVB-trained clinicians or researchers on how to correctly use the respective HRVB device (Hallman et al., 2011; Hassett et al., 2007; Soer et al., 2014; Weeks et al., 2015; Wilson, 2017). The authors did not indicate how these instructions affected the study outcomes.

Frequency

The participants practiced HRVB in weekly sessions that ranged from 10 weeks (n = 2) to 6, 5, and 3 weeks (Berry et al., 2014;

Table 2
Theory of Symptom Self-Management Concepts Included in Studies

Self-Management Concepts	Wilson (2017)	Hassett et al. (2007)	Soer et al. (2014)	Berry et al. (2014)	Hallman et al. (2011)	Weeks et al. (2015)
Patient characteristics						
Age	18-78	18-60	Mean 44	Adult	Mean 42	Mean 58
Gender	56 F; 15 M; 1T	12 F	71F; 99 M	1M; 13F	21 F	5 F; 6M
Mental health status	NR	NR	NR	NR	NR	NR
Sleep quality	NR	NR	NR	NR	NR	NR
Marital status	28 Married; 2 significant other; 23 single; 16 divorced; 2 separated;	NR	NR	NR	NR	NR
Employment status	28 Employed; 30 disabled; 7 unemployed; 7 retired	NR	NR	NR	NR	6 Employed; 5 unemployed
PSE interventions						
Observation	X	X	X	X	X	X
Frequency	More than 3 clinic sessions	10 Weekly clinic sessions; home practice 20 min. twice a day	6 Weekly clinic sessions	4 In clinic session	10 In clinic session; home practice 15 minutes daily, 5 days/week	3 Times a week for 3 weeks in clinic sessions
Verbal or social persuasion	Verbal	Verbal	NR	NR	NR	NR
Self-interpretation of HRVB skills	Light display	Light display	Light display	Light display	Light display	Light display
Symptoms						
Pain severity	X	X	X	X	X	X
Fatigue	NR	▲	NR	NR	NR	NR
Depression	NR	NR	▲	▲	X	NR
Low HRV	NR	X	X	X	X	X
Symptom self-management						
Correct use of HRVB	NR	NR	NR	NR	NR	X
Consistent use of HRVB	NR	NR	NR	NR	NR	X
Performance outcomes						
Functional status	NR	▲	NR	NR	NR	NR
Quality of life	NR	▲	X	NR	X	NR
X reported						
▲indirectly reported						
NR not reported						

F = female; HRV = heart rate variability; HRVB = heart rate variability biofeedback; M = male; NR = not reported; T = transgender.

Hallman et al., 2011; Hassett et al., 2007; Soer et al., 2014; Weeks et al., 2015; Wilson, 2017). Sessions lengths varied, ranging from 10 minutes (n = 2) to 20 minutes (n = 1) to 45-60 minutes (n = 1) to a full hour (n = 1). Berry et al. (2014) did not provide the length of time per session. Hassett et al. (2007) and Hallman et al. (2011) added recommendations for daily home practice, 20 minutes twice daily and 15 minutes 5 times a week, respectively.

Verbal or Social Persuasion

Hassett et al. (2007) and Wilson (2017) reported additional verbal coaching to improve respiration rates and prevent participant hyperventilation. None of the study participants had the opportunity to observe their peers using HRVB.

Self-Interpretation of HRVB Skills

PSE can be enhanced when individuals are able to self-interpret skill mastery. All the HRVB devices reviewed provided visual feedback that allowed the participants to track HRV coherence while they breathed at the prescribed rate and depth. The *Relaxing Rhythms* training program displayed an image of a staircase on a screen when HRV was coherent and disappeared when incoherent; as the participant advanced in skill level and continued with optimal HRV, the staircase evolved into a bridge (Wilson, 2017). Blinking lights advanced from red (no synchronization) to blue (advancing synchronization) to green (optimal synchronization) on the *emWave* desktop HRVB program (Heart Math, 2004). The J&J I-330 HRVB device projected a light display onto a computer screen that moved up as the target respiratory frequency was achieved, and down as the target was lost (J&J Engineering). Only Soer et al. (2014) reported that the participants were required to demonstrate basic HRVB skill before they were able to use HRVB during stress-inducing events. The participants in the Hassett et al. (2007) study reported that the HRVB device was easy to use, and that they benefited from the biofeedback training and would recommend the treatment to others. None of the other studies provided anecdotal reports or qualitative data about the participants' self-reported experiences with HRVB.

Patient Characteristics

The ratio of women to men in the studies reviewed was almost 2:1 (62:36), and only 1 transgender individual was included. Soer et al., (2014) linear regression analysis did not report any significant relationship between a change in HRV coherence score and gender. The remaining studies did not report a relationship between gender and measured outcomes.

Depression, anxiety, and negative moods were outcomes measured in most of the studies (Berry et al., 2014; Hallman et al., 2011; Hassett et al., 2007; Soer et al., 2014; Wilson, 2017). However, none of the studies reported how mental health status might have affected pain. Only Hassett et al. (2007) reported sleep quality. They administered the Pittsburg Sleep Quality Index, a 19-item self-rated questionnaire, and reported improved sleep quality ($p = .0148$) that was not sustained at the 3-month postintervention follow up.

Wilson (2017) was the only researcher to report marital status: 28 married, 2 with significant others, 23 single, 16 divorced, and 2 legally separated participants. There was no reported association between marital status and HRV outcomes.

Employment status was only reported in two studies (Weeks et al., 2015; Wilson, 2017). Most individuals were either employed (n = 34) or disabled (n = 30); the remaining participants were unemployed (n = 12) and retired (n = 7). Neither author reported how employment status might have affected the outcomes.

Symptoms

The symptoms of fibromyalgia covered in this review are pain, fatigue, depression, and HRV. Methods of pain measurement varied greatly between each study and are detailed in Table 1. Most studies reported a statistically significant reduction in pain with HRVB (Berry et al., 2014; Hallman et al., 2011; Soer et al., 2014; Weeks et al., 2015; Wilson, 2017). However, there was no statistically significant difference in pain reduction between the treatment and control groups ($p = .049$, $p = .15$) in the two RCTs (Hallman et al., 2011; Soer et al., 2014). Hassett et al., (2007) reported that although pain reduction was not statistically significant ($p = .0455$), it was sustained at the 3-month follow-up ($p = .006$).

Only one study measured fatigue as an outcome. Hassett et al. (2007) administered the Fibromyalgia Impact Questionnaire (FIQ), a 19-item self-reported questionnaire designed to measure fatigue among other physical impairments, and reported an improved FIQ score ($p = .0686$) at the end of session 10 compared to session 1, which was sustained at the 3-month follow-up ($p = .0022$).

Overall depression scores were decreased after HRVB (see Table 1; Berry et al., 2014; Hallman et al., 2011; Hassett et al., 2007; Soer et al., 2014). Soer et al. (2014) reported improved self-rated mental health scores in the HRVB group ($p = .38$), but they were not statistically different from those of the control group ($p = .39$).

HRV changes were reported in all but one of the studies. Overall, there was a statistically significant improvement ($p < .01$-$p = .023$) in HRV coherence (see Table 1).

Symptom Self-Management

Weeks et al. (2015) reported that participants in the faded HRVB group demonstrated improved use of unassisted biofeedback after three weeks of practice of faded visual feedback compared to full visual HRVB training. The researchers concluded that faded HRVB improved biofeedback skills because the participants were able to optimize their HRV without the use of HRVB at the end of the study.

Performance Outcomes

Functional status and quality of life were measured by Hassett et al. (2007) with the FIQ. In their study, FM patients reported improved scores ($p = .0686$) on the FIQ after HRVB training, which were significantly sustained ($p = .0022$) 3 months postintervention (Hassett et al., 2007). Hallman et al. (2011) and Soer et al. (2014) administered the SF-36, a 36-item questionnaire designed to assess health-related quality of life. They reported improved physical functioning, improved vitality, and improved social functioning after HRVB training.

HRVB Technology

The HRVB technology across all studies used visual biofeedback projected onto a screen. Freeze Frame, manufactured by HeartMath, was used in two studies (Soer et al., 2014; Weeks et al., 2015). The J&JJ-330 unit, a visual handheld device, was used by Hassett et al. (2007) and Hallman et al. (2011). Wilson (2017) used *Relaxing Rhythms* from Unyte Health, Inc. None of the authors provided reliability or validity data to support the results. None of the authors reported any contraindications to using HRVB. However, some did report participant use of beta blockers and a diagnosis of coronary artery disease as an exclusion criterion (Berry et al., 2014; Hallman et al., 2011; Soer et al., 2014).

Discussion

The purpose of this review was to examine the relationship between HRVB and FM-related pain through the lens of the TSSM and to identify the HRVB technology used to treat FM pain. However, as discussed earlier, we included studies of chronic musculoskeletal pain. When pain management was evaluated against the central tenet of TSSM, that functional and cognitive patient outcomes are improved by enhancing self-directed and self-management behaviors, significant gaps were identified.

PSE-Enhancing Interventions

Interventions that include self-management skills support self-efficacy and improve self-care (Fu et al., 2004). Lehrer et al. (2013) developed a protocol and manual for HRVB training and recommended five in-office sessions for participant instruction and home practice 20 minutes twice daily for 3 months, followed by 20-minute practice sessions every 2-3 days to maintain benefits. The frequency and duration of HRVB practice reported in this review were inconsistent, making it difficult to determine how much practice is ideal for skill mastery and optimal outcomes. The researchers and clinicians taught the participants how to use HRVB; however, we do not know how this affected the outcomes or if the participants truly understood the instructions.

Patient Characteristics

Physiological, psychological, and contextual patient characteristics significantly influence performance outcomes such as quality of life and functional status (Hoffman, 2013; Iversen, 2003). Although FM patients are more likely to suffer from depression and sleep disturbances than those with other chronic pain disorders (Cohen, 2017), the studies reviewed did not include these variables. The studies reviewed did include sex as a variable but did not report how this may have affected the outcomes. The female-to-male ratio of FM sufferers in the general population is 2:1; however, the female-to-male ratio was almost 1:1 in the studies reviewed. This review thus may not be an accurate representation of FM patient outcomes. Psychosocial issues like marital status and employment status may contribute to FM symptoms (Cohen, 2017) and are associated with increased divorce rates (Wolfe et al., 1995); nevertheless, these factors were underrepresented and their significance was not discussed in the studies reviewed.

Symptoms

Overall, there was a statistically significant reduction in pain after HRVB compared to control groups in all but one study, supporting the current recommendations for patient-centered non-pharmaceutical pain treatment (Babu, Mathew, Danda, & Prakash, 2007; Cohen, 2017; Gevirtz, 2013) and self-management enhancing interventions (Fu et al., 2004; Hoffman, 2013). However, sustained pain reduction was evaluated in only two of the six studies and seen in only one 3-month follow-up study. Four of the studies demonstrated a statistically significant increase in HRV, but this did not translate into decreased pain, increased resilience, improved emotional state, or improved stress resistance. None of the studies discussed pharmacological treatment or its effects on pain. Sleep disturbance and fatigue are known triggers for FM pain (Clauw, 2014; Wolfe et al., 2010) and should be included as outcomes in future studies. Overall, mood improved with HRVB. Depression scores decreased (Hallman et al., 2011; Hassett et al., 2007), negative mood improved (Berry et al., 2014), and self-rated mental health scores increased, indicating improved mental health (Soer et al., 2014).

Symptom Self-Management

HRVB is designed to provide patients with a self-directed active behavior to self-manage pain. Once the patient has demonstrated adequate HRVB skills in the clinic setting, he or she may receive a prescription from the clinician for home use. The patient can then self-determine the correct use of HRVB by following the prompts from the device. Consistent and correct use of the HRVB training device can allow the patient to self-manage his or her pain. Clinicians can verify consistent and correct use outside of the clinic setting by reviewing the reports generated by the software of the HRVB device. However, only one study, Weeks et al. (2015) reported that participants who used HRVB at the prescribed frequency reported decreased pain postintervention.

Performance Outcomes

Functional status and quality of life are the performance outcomes evaluated in this review. Again, Hassett et al. (2007), the only study involving FM patients, measured outcomes with the FIQ. The FIQ is a reliable instrument used to measure quality of life and functional status (Iversen, 2003). Although the researchers reported improved scores, the improvement was not statistically significant. However, Soer et al. (2014) and Hallman et al. (2011) administered the SF-36, a questionnaire that measures quality of life by evaluating self-report of physical function, vitality, and social function. Both studies reported an increase in these measures post-HRVB intervention. These instruments would be appropriate for future studies.

HRVB Technology

This review demonstrated that there are several biofeedback devices available on the market for HRV modulation**.** The authors did not provide reliability or validity data about the HRVB devices, making it challenging to support their use in future studies. The monetary cost of the devices was not given, and there was no discussion of software or device problems reported during the study. Although there was no discussion of any contraindication to HRVB, it can be assumed that participants with coronary artery disease could face risks from HRVB.

Strengths and Limitations

There were several limitations in this review. First, the pilot studies were small and not guided by power analyses; second, the larger studies were retrospective non-randomized controlled trials. None of the studies compared HRVB to sham or other biofeedback. Second, only one of the studies was on FM exclusively, so other chronic pain studies were included, although it has been established in the literature that the pain caused by FM is different from that of other disorders (Clauw, 2014; Wolfe et al., 2010). None of the studies evaluated stress resistance, a marker of optimal HRV and a functional ANS (Cho et al., 2011; Kang et al., 2012; Meeus et al., 2013; Mostoufi et al., 2012). Additionally, no qualitative or mixed-method studies were identified. Such studies could enhance our knowledge of the effects HRVB may have on chronic pain, quality of life, and functional status. Lastly, we did not search the literature for different biofeedback devices; this may have yielded additional studies.

Conclusion

FM is a debilitating, painful condition affecting 2% of the population (Wolfe et al., 1995) with relatively few effective treatments available (Macfarlane et al., 2017). Current recommendations for FM treatment by the European League Against Rheumatism and the Canadian Pain Society include non-pharmacological therapies such as biofeedback (Clauw, 2014; Macfarlane et al., 2017). Although HRVB is a promising treatment modality for chronic pain, only one study was found that evaluated the relationship between HRVB and FM pain (Hassett et al., 2007). Future research is needed to thoroughly evaluate the relationship between FM and HRVB.

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References

Babu, A., Mathew, E., Danda, D., & Prakash, H. (2007). Management of patients with fibromyalgia using biofeedback: A randomized control trial. *Indian Journal of Medical Sciences, 61*, 455–461.

Bandura, A. (1994). Self-efficacy. In V. S. Ramachaudran (Ed.), *Encyclopedia of human behavior, 4* pp. 71–81). New York: Academic Press.

Berry, M. E., Chapple, I. T., Ginsberg, J. P., Gleichauf, K. J., Meyer, J. A., & Nagpal, M. L. (2014). Non-pharmacological intervention for chronic pain in veterans: A pilot study of heart rate variability biofeedback. *Global Advances In Health And Medicine, 3*(2), 28–33.

Burckhardt, C. S. (2004). Fibromyalgia: Novel therapeutic aspects...International MYOPAIN Society's (IMS) Sixth World Congress, MYOPAIN 2004, Munich, Germany, July 18-22, 2004. *Journal of Musculoskeletal Pain, 12*(3/4), 65–72.

Center for Disease Control. (2017). Fibromyalgia. Retrieved from cdc.gov/arthritis/basics/fibromyalgia.htm. (Accessed 12 January 2017).

Chandran, A., Schaefer, C., Ryan, K., Baik, R., McNett, M., & Zlateva, G. (2012). The comparative economic burden of mild, moderate, and severe fibromyalgia: Results from a retrospective chart review and cross-sectional survey of working-age U.S. adults. *Journal of Managed Care Pharmacy, 18*(6), 415–426.

Cho, D. S., Choi, J. B., Kim, Y. S., Joo, K. J., Kim, S. H., Kim, J. C., & Kim, H. W. (2011). Heart rate variability in assessment of autonomic dysfunction in patients with chronic prostatitis/chronic pelvic pain syndrome. *Urology, 78*(6), 1369–1372.

Clauw, D. J. (2014). Fibromyalgia: A clinical review. *JAMA, 311*(15), 1547–1555.

Cohen, H. (2017). Controversies and challenges in fibromyalgia: A review and a proposal. *Therapeutic Advances in Musculoskeletal Disease, 9*(5), 115–127.

Cohen, H., Neumann, L., Shore, M., Amir, M., Cassuto, Y., & Buskila, D. (2000). Autonomic dysfunction in patients with fibromyalgia: Application of power spectral analysis of heart rate variability. *Seminars in Arthritis and Rheumatism, 29*(4), 217–227.

Critical Appraisal Skills Programme. Retrieved from https://casp-uk.net. (Accessed 2 May 2018).

De jonckheere, J., Ibarissene, I., Flocteil, M., & Logier, R. (2014). A smartphone-based cardiac coherence biofeedback system. *Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, 4791–4794.

Dworkin, R. H., & Fields, H. L. (2005). Fibromyalgia from the perspective of neuropathic pain. *The Journal of Rheumatology, 75*, 1–5.
Edwards, S. D. (2014). Evaluation of heart rhythm coherence feedback training on physiological and psychological variables. *South African Journal of Psychology, 44*(1), 73–82.
Fu, M. R., LeMone, P., & McDaniel, R. W. (2004). An integrated approach to an analysis of symptom management in patients with cancer. *Oncology Nursing Forum, 31*(1), 65–70.
Gevirtz, R. (2013). The promise of heart rate variability biofeedback: Evidence-based applications. *Biofeedback, 41*(3), 110–120.
Ghavidel-Parsa, B., Bidari, A., Amir Maafi, A., & Ghalebaghi, B. (2015). The iceberg nature of fibromyalgia burden: The clinical and economic aspects. *The Korean Journal of Pain, 28*(3), 169.
Hallman, D. M., Olsson, E. M., von Schéele, B., Melin, L., & Lyskov, E. (2011). Effects of heart rate variability biofeedback in subjects with stress-related chronic neck pain: A pilot study. *Applied Psychophysiology and Biofeedback, 36*(2), 71–80.
Hassett, A. L., Radvanski, D. C., Vaschillo, E. G., Vaschillo, B., Sigal, L. H., Karavidas, M. K., & Lehrer, P. M. (2007). A pilot study of the efficacy of heart rate variability (HRV) biofeedback in patients with fibromyalgia. *Applied Psychophysiology and Biofeedback, 32*(1), 1–10.
Heart Math. (2004). *emWave stress relief system. J&J Engineering (n.d.). J&J I-330 neurofeedback*.
Hoffman, A. J. (2013). Enhancing self-efficacy for optimized patient outcomes through the theory of symptom self-management. *Cancer Nursing, 36*(1), E16–E26.
Iversen, M. D. (2003). Fibromyalgia: The fibromyalgia Impact questionnaire (FIQ). *Arthritis Care & Research, 49*(S5), S210–S213.
Kang, J. H., Chen, H. S., Chen, S. C., & Jaw, F. S. (2012). Disability in patients with chronic neck pain: Heart rate variability analysis and cluster analysis. *Clinical Journal of Pain, 28*(9), 797–803.
Kapitza, K. P., Passie, T., Bernateck, M., & Karst, M. (2010). First non-contingent respiratory biofeedback placebo versus contingent biofeedback in patients with chronic low back pain: A randomized, controlled, double-blind trial. *Applied Psychophysiology and Biofeedback, 35*(3), 207–217.
Lehrer, P., Vaschillo, B., Zucker, T., Graves, J., Katsamanis, M., Aviles, M., & Wamboldt, F. (2013). Protocol for heart rate variability biofeedback training. *Biofeedback, 41*(3), 98–109.
Lehrer, P. M., & Gevirtz, R. (2014). Heart rate variability biofeedback: How and why does it work? *Frontiers in Psychology, 5*, 756.
Lorig, K. R., & Holman, H. (2003). Self-management education: History, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine, 26*(1), 1–7.
Macfarlane, G. J., Kronisch, C., Dean, L. E., Atzeni, F., Häuser, W., Fluß, E., & Jones, G. T. (2017). EULAR revised recommendations for the management of fibromyalgia. *Annals of the Rheumatic Diseases, 76*(2), 318–328.
Martínez-Lavín, M., & Hermosillo, A. G. (2000). Autonomic nervous system dysfunction may explain the multisystem features of fibromyalgia. *Seminars in Arthritis and Rheumatism, 29*(4), 197–199.
McCraty, R., & Shaffer, F. (2015). Heart rate variability: New perspectives on physiological mechanisms, assessment of self-regulatory capacity, and health risk. *Global Advances in Health and Medicine, 4*(1), 46–61.
Meeus, M., Goubert, D., De Backer, F., Struyf, F., Hermans, L., Coppieters, I., & Calders, P. (2013). Heart rate variability in patients with fibromyalgia and patients with chronic fatigue syndrome: A systematic review. *Seminars in Arthritis & Rheumatism, 43*(2), 279–287.
Moss, D., & Shaffer, F. (2017). The application of heart rate variability biofeedback to medical and mental health disorders. *Biofeedback, 45*(1), 2–8.
Mostoufi, S. M., Afari, N., Ahumada, S. M., Reis, V., & Wetherell, J. L. (2012). Health and distress predictors of heart rate variability in fibromyalgia and other forms of chronic pain. *Journal of Psychosomatic Research, 72*(1), 39–44.
Rosso, A. D., & Maddali-Bongi, S. (2016). Mind body therapies in rehabilitation of patients with rheumatic diseases. *Complimentary Therapies in Clinical Practice, 22*, 6.
Schaefer, C., Mann, R., Masters, E. T., Cappelleri, J. C., Daniel, S. R., Zlateva, G., & Staud, R. (2015). The comparative burden of chronic widespread pain and fibromyalgia in the United States. *Pain Practice, 16*(5), 565–579.
Soer, R., Vos, D., Hofstra, B., & Reneman, M. F. (2014). Heart coherence training combined with Back School in patients with chronic non-specific low back pain: First pragmatic clinical results. *Applied Psychophysiology and Biofeedback, 39*(3), 259–267.
Vancleef, L. M. (2011). The influence of perceived control and self-efficacy on the sensory evaluation of experimentally induced pain. *Journal of Behavior Therapy and Experimental Psychiatry, 42*(4), 511–517.
Weeks, D. L., Whitney, A. A., Tindall, A. G., & Carter, G. T. (2015). Pilot randomized trial comparing intersession scheduling of biofeedback results to individuals with chronic pain: Influence on psychologic function and pain intensity. *American Journal of Physical Medicine & Rehabilitation, 94*(10 Suppl 1), 869–878.
Wheat, A. L., & Larkin, K. T. (2010). Biofeedback of heart rate variability and related physiology: A critical review. *Applied Psychophysiology and Biofeedback, 35*(3), 229–242.
Whited, A., Larkin, K. T., & Whited, M. (2014). Effectiveness of emWave biofeedback in improving heart rate variability reactivity to and recovery from stress. *Applied Psychophysiology and Biofeedback, 39*(2), 75–88.
Whittemore, R., & Knafl, K. (2005). The integrative review: Updated methodology. *Journal of Advanced Nursing, 52*(5), 546–553.
Wilson, A. M. (2017). *Heart rate variability biofeedback training as an intervention for chronic pain*. Dissertation. Marquette University. e-Publications@Marquette, Marquette, Michigan. Retrieved from http://epublications.marquette.edu/cgi/viewcontent.cgi?article=1750&context=dissertations_mu Google Scholar database. (Accessed 14 September 2017).
Wolfe, F., Clauw, D. J., Fitzcharles, M., Goldenberg, D. L., Katz, R. S., Mease, P., & Russell, A. S. (2010). The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care and Research, 62*(5), 600–610.
Wolfe, F., Ross, K., & Anderson, J. (1995). The prevelance and characteristics of fibromyalgia in the general population. *Arthritis & Rheumatology, 38*, 19–28.