Exercise Heart Rate Monitors for Anxiety Treatment in a Rural Primary Care Setting:
A Pilot Study

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BACKGROUND AND OBJECTIVES: Rural patients with anxiety often lack access to traditional biofeedback modalities. Exercise heart rate monitors (HRMs) are tools used in the fitness industry to provide athletes with feedback on heart rate and regulatory breathing strategies. HRMs are inexpensive, discrete, and publicly accessible. This randomized controlled pilot study explored whether use of HRMs for biofeedback during guided mindfulness, diaphragmatic breathing, and progressive muscle relaxation techniques could facilitate anxiety reduction as compared to these techniques alone.

METHODS: Fifty-three rural anxiety patients were randomized to HRM or control groups for four weekly 20-minute, scripted sessions with a non-behaviorist wherein they practiced these techniques; the HRM group received feedback on their heart rate response.

RESULTS: The HRM group had significantly greater improvement in state anxiety (State-Trait Anxiety Inventory) and self-efficacy (General Self Efficacy Scale), and a greater percentage of the group indicated that they "felt in control of their anxiety."

CONCLUSIONS: This pilot study demonstrates that this novel, inexpensive, and accessible tool may be a useful clinical intervention for anxiety and can be easily incorporated by both behaviorists and non-behaviorist primary care clinicians into individual or group biofeedback treatment for patients with anxiety. This tool has additional potential for patients to use for anxiety self-management. Further study with a larger sample and blinded design is warranted.

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Anxiety is among the most common presenting complaints in primary care and causes significant functional impairment to patients.[1] Family medicine clinicians, particularly those practicing in settings without extensive behavioral health resources, often find themselves seeking effective treatments to best serve their patients, including complimentary modalities such as biofeedback. The utility of clinical biofeedback for the treatment of anxiety and a variety of other medical conditions is well-supported in the literature.[2,3] Biofeedback is a process whereby patients are presented with precise, real-time measurements of physiological variables such as heart rate, body temperature, or neuromuscular activity and are taught to regulate these variables through self-correction. They then learn to link these changes with their cognitive, emotional, and behavioral states.[4,5] We know that perception of voluntary control over heart rate, specifically, is important for anxiety patients.[6-8] Heart rate can be regulated with respiratory strategies,[9,10] isometric muscle contractions,[11] and even mindful attention.[12] Biofeedback, then, can be used to teach patients these strategies for regulating heart rate, which they can then generalize to other contexts and improve the quality of their everyday lives.

While rural anxiety patients' access to biofeedback has not been specifically assessed, we know that some rural populations experience barriers to accessing specialized mental health practitioners and mental health technology.[13-15] There have been attempts to seek alternatives to traditional biofeedback for health care settings without behavioral health resources and for direct patient use. For example, a previous pilot study demonstrated

the efficacy of a portable respiratory device in reducing anxiety in an urban population,[16] and the concept has been applied to several commercially available home computer programs such as the well-studied HeartMath® series.[17] That said, the cost ($160–$180) and technological sophistication of these devices may render them inaccessible to some patients in rural communities.

Exercise heart rate monitors (HRMs), commonly used in the fitness industry by both recreational and competitive athletes and coaches, are used during training to provide feedback on exertional intensity as manifested by heart rate. In so doing, HRMs also provide feedback on performance strategies that regulate heart rate, such as breathing techniques. HRMs have been used in research settings to reliably measure heart rate.[18-20] HRMs are discrete (consisting of a chest strap worn beneath clothing and a wrist watch receiver), as inexpensive as $30–$50, and readily available at sporting goods stores or online retailers.

This pilot study explored whether using this non-medical device, the exercise HRM, during widely accepted effective mind-body techniques for anxiety reduction (mindfulness, diaphragmatic breathing, progressive muscle relaxation) decreases anxiety as compared to these techniques alone. We also investigated whether using HRMs during these exercises increases "self-efficacy," individuals' belief in their ability to effectively manage life's challenges. We predicted that decreased anxiety is associated with increased self-efficacy, a potential mediating variable for HRMs' impact on anxiety.

These specific mind-body techniques were selected because of their ease for non-behaviorists to learn and incorporate; in fact, our study visits were performed by a non-behaviorist. By integrating an inexpensive, user-friendly, non-medical device into techniques that do not require extensive behavioral health expertise, we sought to demonstrate an intervention that could be easily generalized to a variety of settings without behavioral health resources.

Methods

Overview
In this randomized controlled trial, participants from a rural primary care practice were randomized into either experimental (wearing a HRM) or control (not wearing a HRM) groups. Both groups participated in four weekly guided meditation-based individual sessions featuring mindfulness, progressive muscle relaxation, and diaphragmatic breathing. Subjects assigned to the HRM group received feedback on their heart rate. Both groups completed baseline and end-of-study measures of anxiety and self-efficacy. The study was approved by the University of Vermont College of Medicine Institutional Review Board.

Participants and Setting
Prospective participants were recruited during June and July 2011 at The Health Center, a rural federally qualified health center (FQHC) in Plainfield, VT, where study visits were conducted in August 2011. Inclusion criteria were: (1) age > 18, (2) subjectively reported anxiety symptoms most days in the past month, and (3) ability to potentially wear a chest strap HRM and participate in all study visits and telephone calls. Exclusion criteria included (1) psychotic spectrum disorders or obsessive compulsive disorder (which we regarded as a distinct clinical entity from other anxiety disorders) or (2) changes to concurrent anxiety treatment regimen or additional medications expected to affect the sympathetic nervous system (ie, antihypertensives) 30 days prior to enrollment.

Potential participants were recruited with flyers in examination rooms and waiting areas and were provided the incentive that participants who completed the study would be entered into a lottery to win $100. Sample size was selected based on achieving 80% power to detect 10% difference in state anxiety improvement between the groups, based on statistical parameters of a previous similar study.[21] Of 55 participants screened, two were excluded: one had recent change in medications; the other refused to wear a HRM chest strap. Fifty-three eligible individuals were scheduled for four weekly appointments (5–9 days apart) to meet individually with investigator MMH.

Randomization
Anticipating enrollment of 54 participants, we used GraphPad QuickCalc randomization software to generate two lists of 27 numbers, which were designated to treatment and control groups. We then prepared 1x1 inch paper cards bearing the numbers 1–54, stored in an opaque envelope. After completing baseline measures at Visit 1, participants were instructed by investigator MMH to blindly draw a card. The investigator identified the card number on the pair of lists and assigned the participant to the corresponding condition.

Study Visits
The intervention was modeled on the techniques of mindfulness,[22,23] progressive muscle relaxation,[24] and diaphragmatic breathing,[25] all of which have been supported in the literature for the treatment of anxiety. Based on protocols from Greenberg,[26] each visit was scripted to standardize participants' experiences.

Participants allocated to the HRM group wore a Polar FS2 HRM, which detects heart rate with an accuracy of 1 beat per minute.[27] The receiver remained on a table between participant and investigator MMH, visible by both. At 5-minute intervals during each session, MMH provided the participant with verbal feedback as displayed on the HRM watch, delivered in terms of change from baseline (ie, "You are seven beats lower than when you started"). Feedback on heart rate change, as opposed to absolute heart rate, was provided as it would be more meaningful to lay participants and more relevant to the experimental hypotheses in

that participants would learn whether their heart rate changed in response to various stimuli.

Visit #1 (20 minutes)

The script began with an explanation of advantages and disadvantages of being in both groups, in efforts to minimize directional expectations. Those in the HRM group received additional instruction on wearing the HRM transmitter and the logistics of feedback as described above. The first session included guided mindfulness practice in the seated position, "paying attention . . . on purpose"[28] to the breath in the present moment. Participants were instructed that each time a thought entered their awareness, they should "catch it, acknowledge it, and let it go—returning attention to the breath." The script reflected language and concepts of mindfulness, such as "beginners' mind," acceptance, patience, and nonjudgmental observation.[29-31] Participants were guided through "body scan" and progressive muscle relaxation techniques. The session concluded with 5 minutes of silent mindfulness.

Visit #2 (20 minutes)

This visit focused on directed diaphragmatic breathing.[32,33] Based on literature identifying so-called "relaxation-induced anxiety,"[34,35] our script included an introductory caution that diaphragmatic breathing may induce sensations of sleepiness, fluttering, or other novel sensations and that participants should feel empowered to stop at any time. Participants were taught and practiced extended-exhalation breathing, diaphragmatic breathing, and three-part yoga breathing.

Visit #3 (20 minutes)

This visit focused on breathing strategies for specific situations: (1) anxiety warning signs: extended exhalations to trigger the parasympathetic nervous system, (2) full-blown anxiety or panic: mindfulness-type breathing—finding the breath in the present moment and focusing on it

without attempting to change it;[36] (3) maintenance: diaphragmatic breathing. After this psychoeducation, participants practiced transitioning between breathing techniques.

Visit #4 (30 minutes)

Participants were guided through the practice of the aforementioned skills, with the addition of guided imagery.[37]

Outcome Measures

Self-report measures of anxiety and self-efficacy were administered at baseline and end of study: the State-Trait Anxiety Inventory-Form Y (STAI-Y)[38] and the General Self-Efficacy Scale (GSE),[39] respectively. The STAI-Y trait (general) anxiety subscale was used only to assess baseline equivalency between the treatment and control groups; change in state ("in the moment") anxiety was used to assess the effect of our intervention.

Investigator MMH contacted participants by telephone 24–48 hours after Visit 4 and administered the GSE and STAI-Y. MMH initiated the administration by instructing participants to write down the options for the Likert responses to mimic the instrument's visual analog format. Participants were also asked three subjective questions according to a script and instructed to respond on a 5-point Likert scale:

• My anxiety has lessened or improved after this study.

• I feel in control of my anxiety.

• I feel in control of the way I respond to challenge or stress.

Results

Data analysis was performed using SPSS version 20 on an intention-to-treat basis. For four subjects lost to follow-up, we estimated end-of-study data using the last observation carried forward (LOCF) method.

Characteristics of Study Participants

Fifty-three participants were enrolled (ages 20–73). Forty-nine participants completed the study: three

participants withdrew due to scheduling conflicts; one completed all visits but not end-of-study measures. As demonstrated in Table 1, the groups did not differ in terms of age, sex, whether or not subjects were on concurrent treatment, panic history, baseline trait and state anxiety, or self-efficacy. Concurrent treatment included psychotherapy and pharmacotherapy, including selective serotonin reuptake inhibitors, tricyclic antidepressants, and scheduled (not "as needed") benzodiazepines.

Post-Intervention Outcomes

All participants' heart rates decreased during study visits. End-of-study state anxiety and self-efficacy data are reported in Table 2.

Anxiety

The HRM group had a greater mean change score on the STAI-State subscale than the control group, which was statistically significant ($P=.042$).

Self-Efficacy

The HRM group had a greater mean change score on the GSE; however, this difference was nonsignificant. After suspecting a ceiling effect on this limited-range instrument (baseline mean score was 28.85, with impairment reflected by a score less than 30 yet with a maximum score of only 40), we instead compared the presence or absence of response between the groups. Fisher's exact test demonstrated that a statistically significant greater proportion of the HRM group improved in self-efficacy as compared to control ($P=.039$).

Subjective Questions

This analysis only included responses from those participants who completed the study, as these questions were only posed at end of study. The mean response to all three questions trended higher in the HRM group; this difference was statistically significant only for the item "I feel in control of my anxiety after this study" ($P=.004$). For the same item, when responses on the 5-point Likert scale (from strongly disagree to

Table 1: Characteristics of Enrolled and Completed Participants

Variable	Enrolled Participants (n=53)			Completed Participants (n=49)		
	Group		P Value	Group		P Value
	HRM (n=26)	Control (n=27)		HRM (n=25)	Control (n=24)	
Age, mean (SD)	48.77 (12.3)	47.96 (15.3)	.830	48.24 (12.2)	47.46 (16.0)	.850

Sex, n (%)
  Male
  Female
	
	5 (19.2%)
	21 (80.8%)
		
		8 (29.6%)
		19 (70.4%)
			.530	
				5 (20.0%)
				20 (80.0%)
					
					6 (25%)
					18 (75%)
						.740

Concurrent treatment, n (%)
  Medication
  Psychotherapy
  Any (including other)
	
	19 (73.1%)
	6 (23.1%)
	21 (80.8%)
		
		17 (63.0%)
		7 (25.9%)
		19 (70.4%)
			
			.559
			1.000
			.526
				
				18 (72.0%)
				6 (24.0%)
				20 (80.0%)
					
					15 (62.5%)
					6 (25.0%)
					17 (70.8%)
						
						.551
						1.000
						.520

Prior history of panic attacks, n (%)	12 (46.2%)	10 (37.0%)	.580	12 (48.0%)	8 (33.3%)	.390
Baseline self-efficacy score, mean (SD)	28.42 (3.06)	29.26 (4.60)	.438	28.40 (3.122)	29.33 (4.80)	.426
Baseline State Anxiety score, mean (SD)	47.92 (12.31)	43.70 (11.37)	.201	48.24 (12.46)	43.17 (12.0)	.153
Baseline Trait Anxiety score, mean (SD)	48.35 (10.53)	49.22 (9.24)	.749	48.28 (10.7)	48.21 (8.84)	.980

2-tailed unpaired t test used to compare mean ages. 2-tailed Fisher's exact test used to compare all other variables.

Table 2: Improvement in Self-Efficacy and State Anxiety

	HRM Group (n=26)	Control Group (n=27)	P Value
Number of points change in self-efficacy score on GSE instrument, mean (SD)	4.65 (3.64)	3.30 (4.02)	.204 (2-tailed unpaired t test)
Number of participants improving in self-efficacy (% of group)	24 (92.3%)	18 (66.7%)	.039* (2-tailed Fisher's exact test)
Number of points change in state anxiety score on STAI-S instrument, mean (SD)	-8.35 (14.78)	-0.07 (14.07)	.042* (2-tailed unpaired t test)

Note: Improvement is defined by negative change-scores on STAI-S (decreased anxiety) and positive change-scores on GSE (increased self-efficacy).
HRM—heart rate monitor
GSE— General Self-Efficacy Scale
SD—standard deviation
STAI-S—State-Trait Anxiety Inventory-State Anxiety subscale

strongly agree) were coded as "agree" or "strongly agree" versus "neutral," "disagree," or "strongly disagree," Fisher's exact test supported that a statistically significant greater proportion of the HRM group agreed or strongly agreed (P=.023) (Table 3).

Self-Efficacy as a Mediating Variable for Improvement in Anxiety
Linear regression analysis demonstrated that percent improvement in STAI-S was predicted by percent improvement in GSE (P=.002).

Analysis of covariance (ANCOVA) of percent GSE improvement by percent STAI-S improvement by group demonstrated the relationship between improvement in GSE and STAI-S was the same in both groups (P=.884).

Table 3: Participants' Responses to Subjective Questions

	Mean Response on 5-Point Likert Scale (SD)		P Value (2-Tailed Unpaired t Test)	Number of Participants Responding "Agree" or "Strongly Agree" n (% of group)		P Value (2-Tailed Fisher's Exact Test)
	HRM	Control		HRM	Control	
"My anxiety has decreased during this study."	4.56 (.583)	4.21 (.658)	.053	24 (96.0%)	21 (87.5%)	.349
"I feel in control of my anxiety after this study."	4.36 (.569)	3.83 (.637)	.004*	24 (96.0%)	17 (70.8%)	.023*
"I feel in control of the way I respond to challenge or stress."	4.24 (.663)	4.04 (.751)	.330	23 (92.0%)	20 (83.3%)	.417

HRM—heart rate monitor

Selected Quotations From Participants
Participants in the HRM group reported the following:

> I didn't think I had control over anything in my life. But that monitor told me otherwise. It's so empowering.

> I had no idea I could change so much, just by changing the way I breathe.

> That thing [the HRM] doesn't lie. Look at what I can do. It's amazing. And so easy.

Discussion

This randomized controlled study found that using an exercise HRM—an accessible, affordable, user-friendly tool—during in-office guided mindfulness, diaphragmatic breathing, and progressive muscle relaxation techniques improved state anxiety and self-efficacy in patients with anxiety in a rural primary care setting. That we would detect this effect even in a small sample, with such brief exposure to the intervention without home practice, is encouraging. Of interesting note, we were able to detect benefit even while administering end-of-study measures in the aftermath of Hurricane Irene in 2011, an anxiogenic influence that caused extensive property damage and chaos throughout our study population's community. This pilot accomplished its goal of demonstrating that this novel tool warrants further study.

The mechanism by which HRMs decrease anxiety is subject to conjecture at this point. Our results suggest that self-efficacy may be involved, although a larger sample is necessary to confirm this. We propose several explanations for the role of biofeedback via HRM in anxiety reduction. First, when participants receive positive feedback that their lengthened exhalations result in lowered heart rate, for example, they repeat the behavior as a consequence of operant conditioning. Since we know that slowed exhalations decrease anxiety,[40,41] the HRM may facilitate the repetition of this known effective behavior. Providing objective evidence that these breathing techniques actually do reduce heart rate may stimulate patients' "buy in" for utilizing these techniques. Second, more broadly, individuals develop a sense of mastery over a task after receiving consistent validation, learning that they have control over their own physiology, which, in turn, may reduce anxiety. Third, by fixating on a gadget, individuals acquire an additional focal point to distract them from ruminative thinking. This is one of proposed mechanisms for mindfulness' efficacy in anxiety and mood disorders.[42] Further study is necessary, requiring creativity in devising proper control groups in order to ascertain the HRM's mechanism for anxiety reduction.

The strengths of this study include its randomized controlled design and generalizability to primary care populations: we included almost everyone who presented with symptoms of anxiety, regardless of whether they met particular diagnostic criteria, used substances, or had recent major life changes. In addition, the protocol utilized multiple 2- to 10-minute interventions performed by a non-behaviorist that would be easy for primary care clinicians to incorporate into office visits.

Nonetheless, there are limitations worth noting. First, the design was unblinded. Though we took care to minimize expectations and maximize consistency, it is possible that there were unmeasured effects of investigator bias. Follow-up surveys and interviews were standardized and scripted; however, investigator MMH performed these directly and did have awareness of treatment group assignment; follow-up measures in future studies should be performed by a third party. If participants are to be blinded from treatment condition, an alternative to false feedback should be used, as this has been shown to increase anxiety and induce panic in susceptible populations.[43] Blinding of the investigator can be accomplished by using audio recordings instead of an in-person facilitator, and providing visual heart rate feedback, as an exercise HRM is generally used. In our study, we used verbal feedback

based on evidence that this reduces fear,[45] and that feedback without context might trigger anxiety for lay participants. Study design with visual, absolute heart rate feedback will require sufficient psychoeducation incorporated into the script. Audio recordings have been shown to facilitate the use of mind-body techniques to lower blood pressure,[44] for example, and thus we expect that this strategy could help minimize the confounds of interpersonal interactions with participants.

Second, our study was not designed to address the role of potential interacting variables (ie, use of specific classes of concurrent medications, history of panic attacks) and thus may not have had sufficient statistical power to detect an effect from these variables. Though our inclusiveness increases external validity, we did not measure the presence of substance abuse, PTSD, and other variables suggested by previous studies to limit response to biofeedback.[46,47] Further research should examine the role of these variables.

Future Directions

We recommend that this study be repeated at multiple sites with efforts to minimize the effects of potential confounds, including therapeutic relationship with the investigator, and to maximize the extent of impact (for example, by incorporating home practice into the protocol). Administering end-of-study measures immediately after the final treatment session will also help to detect maximum effect of the intervention, with re-measurement at longer intervals to detect the duration of benefit as well.

More importantly, future work should identify a mechanism for HRMs' efficacy. By designing appropriate control group(s), the specific contribution of the HRM can be isolated. For example, is it knowing one's absolute heart rate versus the change in heart rate? Is it the process of linking a specific mind-body technique with a change in heart rate? Is it acknowledging personal control over one's heart rate? Is it also possible that the act of being monitored by a gadget is anxiolytic on its own? It would also be interesting to explore potential mediators other than self-efficacy, such as locus of control, cognitive distortions, or coping styles[48] to help explain the effect of HRM use on anxiety.

Although there is still more work to be done, this small pilot study did demonstrate that exercise heart rate monitors, used in conjunction with simple mind-body techniques, improved anxiety and self-efficacy in anxiety patients in a rural primary care setting. Of note, our intervention was effectively performed by non-behaviorists. This series of 15–20 minute exercises would be easy for primary care clinicians, including at the residency level of training, to learn and incorporate into individual or small-group visits. Future studies with larger samples may provide greater support for use of HRMs in clinical practice both as a self-management tool for patients and as an in-office tool for clinicians.

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