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Integrating a Portable Biofeedback Device into Clinical Practice for Patients with Anxiety Disorders: Results of a Pilot Study

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Abstract This study examined the effectiveness of a portable Respiratory Sinus Arrhythmia (RSA) biofeedback device as an adjunct to CBT in persons with anxiety disorders and other disorders associated with autonomic dysfunction attending outpatient treatment. Participants were 24 individuals attending outpatient cognitive behavioral treatment for a range of anxiety disorders. Participants were assessed over a 3 week period. Outcomes included measures of anxiety (STAI-Y), sleep disturbances (PSQI), anger (STAEI), and subjective questions about the effectiveness of the device as a treatment adjunct. Significant reductions were found for anxiety and anger and for certain sleep variables (e.g. sleep latency). There was a significant dos–effect in that those who were more compliant had significantly greater reductions in most domains including sleep, anger and trait anxiety. Overall, participants found the device more helpful than other relaxation techniques such as mediation, yoga and unassisted breathing techniques but less helpful than exercise. The most frequently endorsed side effects were dizziness (15%) and sleepiness (55%). These preliminary results suggest that portable RSA biofeedback appears to be a promising treatment adjunct for disorders of autonomic arousal and is easily integrated into treatment. Results support the need for further investigation with more rigorous experimental designs.

This study was conducted at the Behavioral Associates and The CBT Institute in New York, NY from 6/06 through 8/06.

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Background

There is now ample evidence that many psychiatric and medical disorders are characterized physiologically by autonomic imbalance (Berntson and Cacioppo 2004; Mussgay and Ruddel 2004; Thayer et al. 1996; Watkins et al. 1999). This imbalance of the body's fight or flight response typically presents as arousal/rigidity in the sympathetic nervous system (SNS; stress response) and decreased activity in the parasympathetic nervous system (PSNS; relaxation response) (Berntson and Cacioppo 2004). For the most part, the introduction of a stressor will increase activity in the SNS or the ratio between the two systems, while the introduction of methods that induce relaxation will increase PSNS activity, though this relationship is not linear and exceptions do occur. The simplest and most direct non-invasive route to measure real-time autonomic activity is using heart rate variability (HRV)/respiratory sinus arrhythmia (RSA) (Eckberg 1983; Fouad et al. 1984; Katona et al. 1975; Porges 2007). Short and long-term stress reactions and disorders associated with increased sympathetic activity typically involve a decrease in HRV/RSA. The literature corroborates the relationship between low HRV/RSA and numerous psychiatric and medical conditions such as Anxiety Disorders, Depression, Diabetes, Asthma, Insomnia and HRV is one of the strongest predictors of cardiac morbidity and mortality—both of which are higher in patients with anxiety disorders and sleep difficulties (Berntson and Cacioppo 2004; Bonnet and Arand 1998; Lehrer 2007; Porges 2007; Thayer et al. 1996; Watkins et al. 1999; Yeragani et al. 1995).

Additionally, laboratory studies designed to induce stress reactions have confirmed the association between stress, lowered HRV and increased sympathetic activity (Berntson and Cacioppo 2004; Friedman et al. 1996; Delaney and Brodie 2000; Hughes and Stoney 2000).

An effective strategy known to reliably reduce the stress response and increase HRV is slow diaphragmatic breathing (Schipke et al. 1999; Strauss-Blasche et al. 2000; Tripathi 2004). It is no coincidence that the overwhelming majority of relaxation techniques (e.g. yoga, meditation, etc.) include breathing retraining as a central component (Greenberg 2004). Various forms of breathing retraining have been found to be effective treatments and/or treatment adjuncts for anxiety disorders and other disorders of autonomic dysregulation (Freid and Grimaldi 1993; Lehrer and Woolfolk 2007; Sultanoff and Zalauett 2000).

While paced deep rhythmic breathing is an effective relaxation technique in its own right, there are several limitations to its successful implementation. Primarily, without proper physiological assessments there is no way to ensure that one is performing the activity correctly. Is one exhaling for too long? Is one's respiration rate individualized to one's current state? Is limbic activity interfering with proper autonomic balance? Biofeedback techniques that directly measure autonomic functioning have been found to combat this difficulty because they provide direct feedback, completing a loop that nature did not build in. The completion of this loop provides an opportunity to learn through self correction and eventually alteration of physiological state, in real time (Schwartz 1987).

There is an emerging literature on the efficacy of computerized HRV biofeedback to treat a variety of stress related conditions (c.f. Lehrer 2007). HRV biofeedback is designed specifically to reduce autonomic reactivity and attempts to regulate homeostatic mechanisms (Lehrer et al. 2003). There are several methods for conducting HRV biofeedback, including using the Respiratory Sinus Arrhythmia heart rate wave. RSA is natural fluctuation of the heart in real time and is highly influenced by respiration, baroceptors and limbic activity. Training using the RSA wave involves individuals slowing their breathing to a rate that is unique to them so that the amplitude of RSA is maximized. When the proper breathing rate is found, called the individuals "resonant frequency" real time heart-rate and respiration covary in a perfect phase relationship so that users inhale until their heart rate peaks and exhale until it begins to rise again (Vaschillo et al. 2004). When this occurs, the baroceptors are stimulated, strengthening the overall capacity of the body's homeostatic functioning (Lehrer et al. 2003). Gevirtz and Lehrer (2003) cite that RSA biofeedback systems increase vagal activity, promote relaxation, stimulate the baroreflexes and increase the efficiency of cardiac reflexes. In turn, this should increase modulation of autonomically- and emotionally-mediated reflexes throughout the body (Lehrer et al. 2003).

Biofeedback equipment is usually clinic based. Patients are taught biofeedback skills for a few sessions then instructed to generalize them to practice outside the clinic (Greenberg 2004; Schwartz 1987; Yucha and Gilbert 2004). In essence, patients are shown that they can control their physiological states and this is designed to motivate them to practice regular relaxation using the skill acquired while attached to the biofeedback equipment. Ultimately, efficacy of the intervention is determined by the amount of generalization that the patient retains.

Replicating a trend observed in measurement of compliance to therapeutic homework assignments and medication adherence, behavioral research reveals that relaxation therapies also generate low compliance rates (Cox et al. 1988; Lehrer and Woolfolk 2007) and that self-reports, which are typically overstated, are poor indicators of actual compliance (Talyor et al. 1983). Unlike written homework assignments and devices designed to maximize medication adherence, it is difficult to measure adherence to relaxation therapies beyond simple self-report (Murdoch 2000). There is evidence that patients consistently over-report their use of out of session relaxation exercises (c.f. Lehrer and Woolfolk 2007). Since homework adherence across interventions is associated with improved outcomes (Kazantzis and Deane 1999; Kazantzis 2000; Scheel et al. 1999), it is important to develop interventions that increase implementation and maintenance of out of session activities.

The present pilot study examined the effectiveness of a handheld portable biofeedback device designed to decrease autonomic reactivity by teaching patients to increase RSA fluctuations through guided slow breathing and cognitive focus. The device, called the Stress Eraser, is a 510 (k) exempt, class II FDA regulated medical device marketed for stress reduction, relaxation, and relaxation training.

Method

Participants and Procedures

The pilot study took place at two outpatient treatment facilities in New York City specializing in cognitive behavioral therapy. Both sites offer empirically supported treatments, routinely integrate biofeedback and/or other relaxation procedures into treatment, and have the capacity to carry out a pilot study involving informed consent and multiple assessments. Four therapists were selected to deliver the brief intervention (three Ph.D.'s and one M.A.). The treatment period was 3 weeks.

Participant Selection

Participants were included in the pilot study if their age range was between 18 and 65 years and were diagnosed with a disorder associated with sympathetic over-arousal. These included Generalized Anxiety Disorder, Specific Phobia, Social Phobia, OCD, IBS, or Insomnia. Participants were selected based on the diagnoses given by the intake counselor upon treatment entry into the clinic and willingness to take part in the study. Participants were not included/selected if they demonstrated examples of obvious cognitive impairment, current or previous psychosis, insulin dependent diabetes, and/or a prior adverse reaction to relaxation therapies. Since all participants were currently in treatment, therapists were also instructed to only recruit persons who met eligibility criteria. All participants completed informed consent prior to enrollment.

Therapist Training

All therapists were trained on the delivery of the protocol which was designed to simulate a real world intervention. Consequently, therapists were instructed to devote about 15 min for the initial introduction of the Stress Eraser device and 3–5 min for follow-up visits, but were able to use their clinical judgment and preferences in deciding if they wanted to spend more time using the device in session. Moreover, therapists were not given extensive training on the device, but were given reading materials to further replicate a real world clinic situation in which therapists do not have the luxury of extensive individual training.

Intervention

The initial intervention consisted of four parts. (1) Introducing (or reintroducing) the relationship between the sympathetic and parasympathetic nervous systems and their contributions to anxiety/stress and relaxation. (2) Discussing the relationship between deep, rhythmic, paced breathing and engagement of parasympathetic activity. (3) Discussing the rationale for biofeedback. (4) Introducing the Stress Eraser.

The introduction of the Stress Eraser varied depending on the participants' knowledge of biofeedback procedures but generally included an overview of the general device specifications (on–off button, setting the date and time, backlighting, sound, finger sensor, etc.). All therapists were instructed to help participants find their unique breathing inhale–exhale ratio that would maximize their ability to achieve long smooth RSA waves. For each long smooth wave users are awarded a "point". Once a participant received continuous points, they were asked if they understood the procedure. During this period, all participants were also assessed for side effects stemming from the procedure. If a participant reported any side-effect that was more than temporary (e.g. prolonged dizziness), they were excluded from the study—no participants were excluded. Once the participants felt comfortable with their capacity to generate points, they were instructed to follow the 100 point daily program (20 min total throughout the day). Therapists highlighted that the Stress Eraser could be used anywhere (e.g. bed, work, subway, etc.) and that participants could choose when and how they achieved 100 points. All participants were instructed not to use the device prior to operating machinery because preliminary testing revealed that some persons become drowsy after using the device.

Follow-up sessions consisted of a brief check-in regarding adherence to the 100 point program and therapeutic effects. Therapists viewed the history feature on the device to assess whether participants were adhering to the program. For those who were compliant with the program and reported benefits, therapists simply reinforced the use of the device and assessed for side-effects. For those who did not follow the program, therapists inquired as to why and attempted to motivate the person by removing perceived barriers to non-adherence, (e.g. I forget to take it with me). Because subjects were already in treatment, therapists were instructed not to push if clients were using the device less than instructed to avoid strains on therapeutic alliance. The final session included a brief review of the participants' experiences in using the device.

Measures

Once enrolled, participants completed baseline and end of the study (3–4 weeks) assessments. The State-Trait Anxiety Inventory (STAI-Y; Speilberger et al. 1983) is a 40-item self-report instrument used widely in anxiety disorders research (Barlow 1988) composed of two subscales measuring state anxiety (current) and trait anxiety (dispositional) each measured on a four point scale, yielding a total subscale range of 20–80. The scale has shown excellent reliability and validity across populations (Speilberger 1989). Both raw scores and percentile scores were calculated in the current study.

Subjective sleep parameters were evaluated using the Pittsburgh Sleep Quality Index (PSQI; Buysse et al. 1989). The PSQI is separated into seven subscales which measure: (1) sleep quality; (2) sleep latency; (3) sleep duration; (4) habitual sleep efficiency; (5) sleep disturbances; (6) use of sleeping medication; (7) daytime dysfunction. Subscale scoring is based on a 0–3 scale (0 = no difficulty,

3 = severe difficulty). A PSQI total score is calculated as the sum of the seven subscales in which a global sum of 5.5 or greater indicates a "poor" sleeper. The PSQI has been demonstrated to be a reliable and valid measure of sleep disorders, particularly primary insomnia (Backhaus et al. 2002; Buysee et al. 1989).

Trait anger was measured using the four-item trait anger subscale from the State-Trait Anger Expression Inventory (Speilberger 1988). Each item is measured on a four point scale ranging from 1 (Almost Never) to 4 (Almost Always). This subscale is a global measure of anger sensitivity widely respected for its good psychometric properties. One identified shortcoming has been the emergence of floor effects for patients without high trait anger.

Several single item questions were included that assessed frequency and helpfulness of current relaxation exercises. Frequency of exercise was measured using a five point likert scale ranging from rarely to almost every day.

Results

Twenty-four participants with a range of anxiety related disorders and comorbid depression were recruited into the study and 20 completed end of study questionnaires. One person did not complete the end of study questionnaire, two dropped out of treatment, and one received a unit that malfunctioned. Among the study completers, gender was split evenly with 50% being female. The average number of points per week was 328.98 ($SD = 231.73$).

Overall, 75% reported the device reduced their stress levels, 80% reported it increased levels of relaxation, 46% reported it enhanced positive emotions, and 60% reported it made them feel serene or at peace. Also compared were participants' ratings of helpfulness for those who regularly practiced other relaxation techniques. The N's for these comparisons varied on whether someone actually engaged in the other activities. In terms of comparisons, 73.3% ($N = 11/15$) reported finding the device more helpful and relaxing than unassisted breathing exercises, 77.8% ($N = 7/9$) more helpful than meditation, and 75% ($N = 3/4$) more helpful than yoga. Although exercise is not typically thought of as relaxation, we also inquired about the helpfulness of the device compared to exercise. Interestingly, only 27.3% (3/11) who exercised regularly found the device more helpful.

In terms of side effects, 55% (11/17) reported it made them drowsy and 15% reported it made them dizzy when they first started using it. One person reported that her sinuses hurt, and another reported that the dizziness made her feel anxious. All subjects were instructed to stop using the device if side-effects persisted. There were no significant differences in compliance between those who reported side-effects and those who did not, $F(18) = .044$, $p = .837$. There were no prolonged side-effects in any participant.

Main outcomes are presented in Tables 1 and 2. Overall findings reveal significant reductions in state and trait anxiety and trait anger from baseline to end of study. Only a portion of participants reported sleep problems, they were included in the analyses if they scored above 5.5 on the PSQI global score. As shown in Table 1, significant reductions were found for total sleep time and a trend existed for the Global Index Score. When examining the subscales of the PSQI, the entire group reported significant improvements in its overall sleep quality, $t(18) = 2.67$, $p < .05$, sleep latency, $t(18) = 2.16$, $p < .05$, and sleep disturbances, $t(19) = 2.65$, $p < .05$, while no overall group significant differences were found with the other PSQI subscales. Additionally, 50% of persons who reported equal to or greater than 30 min to fall asleep reduced their sleep latency time to less than 30 min.

The relationship between the number of points that subjects received on the device and change from baseline to end of study measures was assessed using partial correlations. Results, shown in Table 2, reveal a significant dose–response between compliance (points per week) and trait anxiety, anger, and the PSQI global index score. No

Table 1 Baseline to end of treatment change scores

Domain	BL	EOT	df	t	p
State anxiety	49.00 (15.1)	40.87 (8.7)	19	2.73	.009
Trait anxiety	53.97 (13.2)	46.87 (9.7)	18	4.37	.000
Trait anger temperament	8.05 (3.9)	6.20 (2.1)	19	3.01	.009
PSQI global score*	10.12 (3.23)	8.61 (3.51)	14	1.68	.111
Total sleep time*	336.0 (77.90)	372.68 (68.75)	14	2.36	.033

Note. BL = Baseline; EOT = End of Treatment

* Only those with sleep problems were included in the PSQI and total sleep time analyses

Table 2 Partial correlations between end of study assessment domains and the average number of points per week controlling for baseline scores

Domain	r	p
State anxiety	.41	.103
Trait anxiety	.55	.027
Trait anger temperament subscale	.59	.015
PSQI global score	.53	.030
Total sleep time	.37	.136

Note. df ranged from 12–17 depending on the measure. The entire sample was used for the sleep variables to increase the power

significant dose–effect relationships were found for state anxiety and total sleep time.

Discussion

The results of this pilot study suggest that this portable biofeedback device may be a useful adjunct to behavioral therapies for autonomic arousal and can provide clients with an objective means to increase physiological relaxation. The benefits of having a tangible device with an objective history feature can aide clinicians in ensuring that clients are performing their out of session relaxation exercises and know when they are performing them correctly. Because participants subjectively reported increased relaxation and that it was more helpful than other traditional relaxation techniques suggests that the device may be helpful for those who have difficulty adhering to and/or performing traditional relaxation therapies. The dose–response relationship found in this study highlights the importance of compliance with relaxation homework and the benefits of having a variety of relaxation exercises at a clinician's disposal. Results also appear to replicate earlier studies using HRV biofeedback that found creating autonomic balance through resonant frequency breathing and cognitive focus, leading to increased levels of RSA, is an effective means to induce relaxation.

These preliminary findings support the need for further investigation for several reasons. Improvement in anxiety, anger and sleep is closely linked to frequency of use and success with the device. Because these problems are all associated with autonomic dysfunction (Bertson and Cacioppo 2004) it stands to reason that directly targeting the autonomic nervous system through biofeedback will have some carryover effect in each of these domains. Consequently, it is possible that one of the mechanisms associated with global change is a return to autonomic balance through increased vagal tone.

Anxiety, depression and sleep disorders are all associated with excessive rumination. The autonomic nervous system is influenced by limbic activity, particularly negative affect (Virtanen et al. 2003), even during relaxation (Mashin and Mashina 2000). Aside from the powerful effects of breathing on the autonomic nervous system (Strauss-Blasche et al. 2000), it is possible that users are trained to reduce negative affect through reinforcement from increased HRV as well as because they are focusing on a tangible tool to distract them from negative thoughts. This may also be relevant to the self-reported reductions in anger. There is now evidence that anger is associated with increased cardiovascular disease (Williams et al. 2001).

The immediate feedback may also present a problem for some people causing biofeedback induced anxiety. For example, one participant who was unable to properly manipulate the RSA wave reported increased anxiety. While the majority of participants' were able to manipulate their RSA wave without adverse effects, some people may need additional training prior to using the device. It is likely that the 15% of participants who reported dizziness were not breathing properly causing hyperventilation syndrome. The integration of guided relaxation techniques such as diaphragmatic breathing, pursed lips breathing or computer based assisted biofeedback prior to introducing self-guided biofeedback has been suggested as a means to reduce adverse effects (Lehrer et al. 2000) and may help improve results and compliance.

Participants qualitative experience was generally positive as noted in their ratings of helpfulness compared to other relaxation techniques. The majority of participants noted that simply having a tangible device to perform their relaxation exercises was helpful. Like most other forms of biofeedback, participants reported that the objective feedback on whether they were performing the activity was very helpful whereas others, albeit a much smaller group, reported that it offered nothing new to their current relaxation routines, particularly those who exercised regularly. Because there is a clear relationship between exercise and increased HRV (Sandercock et al. 2005), it is possible that the subjective benefit was reduced in patients who exercise regularly because they already have increased HRV suggesting it is possible that the effects of RSA biofeedback mimic the effects of exercise on parasympathetic activity. This parasympathetic rebound may have also accounted for the 55% of participants who reported drowsiness.

The efficacy of any form of relaxation is ultimately determined by the client's ability and willingness to engage in the technique. Aside from simply preferring one technique over another, clients routinely require external reinforcement to engage in health promoting behaviors. The benefit of having an objective history on the device in which clinicians can track compliance and efficiency should promote compliance or at minimum open an honest dialogue about barriers to implementation. It is well established that when individuals are monitored, compliance increases. Moreover, considering previous reports using objective compliance data which have indicated subjects over reported their actual practice time between 70% and 126% (c.f. Lehrer and Woolfolk 2007), informing clients that the clinician will review their progress should increase the chances that subjects will make an initial effort to try the technique and can open honest communication regarding barriers to successful implementation.

While the results of the present study provide initial support for the adjunctive use of this device, further scientific investigation is required to confirm these subjective self-reports in this single group pilot study. The current

study examined participants receiving weekly psychotherapy using empirically supported treatments so the effects of the psychotherapy and time could have accounted for a significant portion of the change in symptoms. Although the presence of the dose–effect relationship helps support a causal relationship between the device and change scores, those who were more compliant may also have simply been more motivated to change their behaviors or certain personality characteristics may have influenced the improved outcomes in those who practiced more frequently. Because of these limitations, upcoming research should involve active control groups, larger samples and investigators who are experimentally blind to the hypotheses. Without such rigorous methodological control, it is difficult to attribute changes to any one intervention. Future studies would also benefit from hypotheses regarding specific conditions. Despite these limitations, participants and therapists subjectively reported that the device was helpful and could be easily integrated into treatment without straining therapeutic alliance.

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