Efficacy of Binaural Beat Meditation Technology for Treating Anxiety Symptoms

A Pilot Study

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Abstract: The objective of this study was to examine the efficacy of a novel binaural beat meditation technology for the treatment of anxiety symptoms in both psychiatric outpatients and nonpatients. Twenty psychiatric outpatients with anxiety disorder and eight individuals (nonpatients) in the healing professions were given the opportunity to use this meditation technology over the course of 2 weeks to 2 months. The State-Trait Anxiety Inventory scores were measured in all participants over the course of the study. Of the 20 outpatients who took part in the study, nine used the meditations as planned, whereas 11 did not for various reasons (could not download, forgot, did not have time, etc.), resulting in the formation of three treatment groups: psychiatry + meditation ($n = 8$), psychiatry only ($n = 10$), and meditation only ($n = 8$). The psychiatry + meditation group showed a 13.5-point (26.5%) decrease in State-Anxiety ($t = 5.28$, $p = 0.001$), a 14.1-point (24.7%) decrease in Trait-Anxiety ($t = -5.12$, $p = 0.001$), and a 27.6-point (25.6%) decrease in Total Anxiety ($t = 7.63$, $p \leq 0.001$). The psychiatry-only group showed a 4.2-point (8.4%) decrease in State-Anxiety ($t = -2.20$, $p = 0.05$) and a 7.0-point (6.9%) decrease in Total Anxiety ($t = -2.61$, $p = 0.02$). The meditation only showed a 3.5-point (9.8%) decrease in Trait-Anxiety ($t = -2.47$, $p = 0.04$). In a multiple regression analysis controlling for sociodemographic factors, medications, and treatment-related variables, the only statistically significant improvement in anxiety was seen in the psychiatry + meditation group for the Total Anxiety score ($p < 0.01$). These findings suggest that use of this meditation technology may exhibit a positive effect on self-reported measures of anxiety in the context of a psychiatry/psychotherapy practice. However, larger-scale randomized, placebo-controlled trials are needed to confirm our findings.

Key Words: Anxiety, psychiatry, meditation, binaural beats

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Anxiety disorders are the most common mental health problem in the United States, affecting approximately 18% of the population (40 million adults) and costing more than $42 billion a year (Greenberg et al., 1999; Kessler et al., 2012). Anxiety is considered a negative mood disturbance that results from failure to predict, control, and obtain desired goals (Barlow, 2000) and is associated with chronic pain, impaired physical function, and difficulty with activities of daily life (Sawchuk and Olatunji, 2011). Anxiety further impairs health by motivating increased use of tobacco and alcohol (Esmaeelzadeh et al., 2018), predisposing the individual to chronic diseases such as coronary heart disease (Tully et al., 2014) and increasing the risk of suicide (De La Vega et al., 2018).

In conventional medicine, treatment for anxiety includes psychopharmacology and psychosocial interventions such as psychotherapy, exercise, and meditation. Patients using psychopharmacology can fail to achieve remission due to the high risk of polypharmacy, adverse events, and treatment discontinuation (Bazzan et al., 2014). The limitation of the pharmacologic treatments for this chronic, debilitating condition makes the development of nonpharmacologic interventions for anxiety of great public health importance.

Meditation is a commonly used nonpharmacologic treatment for anxiety (Kabat-Zinn et al., 1992), although results of its efficacy have been mixed (Krisanaprakornkit et al., 2006; Khusid and Vythilingam, 2016). Based on a 2012 survey in a large sample of anxiety patients in US primary care settings, 43% endorsed complementary therapy use, the most common being meditation (Bystritsky et al., 2012). Meditation takes many forms and is defined by neuroscientists as a combination of emotional and attentional training regimes developed to cultivate well-being and improve emotional regulation (Lutz et al., 2008). Meditation frequently involves cultivating a state of focused attention, such as by concentrating on the present moment or on one of the following: a sound, a voice, one's breath, one's sensory experience, or a mantra one repeats silently to oneself. Ample research has shown that meditation can reduce anxiety in the short-term (Nidich et al., 2009) and in the long-term (Sheppard et al., 1997), affecting both State-Anxiety (how somebody feels in the here and now) (Raskin et al., 1980; Sheppard et al., 1997; So and Orme-Johnson, 2001) and Trait-Anxiety (one's overall proneness to experience anxiety) (Chen et al., 2012; Eppley et al., 1989; Sedlmeier et al., 2012). Research comparing the relative efficacy of different meditation techniques (*i.e.*, mindfulness, transcendental meditation, loving-kindness meditation, binaural beat meditation, and progressive relaxation) has yielded inconclusive results (Eppley et al., 1989; Sedlmeier et al., 2012).

Binaural beats technology, sold internationally for personal development and health improvement, is based on the perceptual phenomenon that occurs when presenting separately to each ear two tones that slightly differ in their frequency. For example, a two-tone exposure of 400 and 410 Hz to each ear separately will be perceived as a single tone with a frequency of 405 Hz that varies in amplitude with a frequency of 10 Hz. The information presented to each ear is processed and combined in a way that is perceived as a single unified percept by a phenomenon known as binaural integration (Oster, 1973; Lentz et al., 2014). There is growing support for the claim that binaural auditory beats positively affect levels of anxiety (Chaieb et al., 2015; Padmanabhan et al., 2005; Weiland et al., 2011) and well-being (Lane et al., 1998; Le Scouarnec et al., 2001; Wahbeh et al., 2007). Although not as extensively studied, monaural beat stimulation, or applying the same amplitude-modulated signal to both ears simultaneously, has been shown to significantly reduce State-Anxiety (Chaieb et al., 2017).

NeuralHelix is a novel meditation technology that involves the sequential convergence of binaural beats and monaural beats, harmonically blended with special carrier tones to optimize relaxation and foster brain entrainment (Sacred Acoustics, 2018). We hypothesized that psychiatric outpatients using NeuralHelix meditations in conjunction with their psychiatric "treatment as usual" (psychiatry + meditation) would experience greater reductions in their self-reported anxiety than patients not using these meditations (psychiatry only) and nonpatients using these meditations (meditation only).

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METHODS

Participants

Thirty-eight subjects, consisting of 25 outpatients from a psychiatry private practice in New York City and 13 nonpatients who worked in the healing professions, were invited to participate in a study examining the effects of the NeuralHelix meditation technology on anxiety levels. The study was completed between March 2018 and August 2018. All the psychiatry outpatients met the *DSM-5* criteria for generalized anxiety disorder as diagnosed by the treating psychiatrist and scored on the State-Trait Anxiety Inventory (STAI) (Spielberger, 2015). All but one psychiatry outpatient scored over 80 points on the STAI-Total, indicating the presence of significant anxiety. Five of the invited psychiatry patients and five of the nonpatients declined participation due to lack of time, lack of interest, or already having a standard meditation practice that they were not interested to change or augment.

The remaining 28 study participants (20 patients and 8 nonpatients) were then followed over the course of 2 weeks to 2 months, depending on their frequency of psychiatric visits and the duration of time between their agreeing to participate in the study and being able to use the NeuralHelix meditations regularly for a dedicated 2-week period. Every person who used the NeuralHelix meditations did so for at least a 2-week period of daily use. Of the 20 psychiatry patients, nine used the meditations as planned, whereas 11 did not for various reasons (could not download, forgot, did not have time, were no longer interested). Both users and nonusers of the NeuralHelix meditations were followed for the duration of the study. Exclusion criteria included medication and/or dosage adjustment during the course of the study, which led to the omission of two psychiatry patients (one who used the meditations and one who did not) from the final analysis. The final analysis included three treatment groups: eight psychiatric patients who used the meditation (designated as the psychiatry + meditation group), 10 psychiatric patients who did not use the meditation (designated as the psychiatry-only group), and eight nonpatients who used the meditation (designated as the meditation-only group). Although none of the participants who used the meditation technology had adverse reactions to the meditations that led them to terminate their use, one patient reported an anxiety-producing nightmare after doing one of the meditations. The nightmare was discussed with her psychiatrist and did not lead her to discontinue use of NeuralHelix.

Assessment

The STAI, a widely used, self-report measure of anxiety with excellent internal consistency and test-retest reliability, was used in this study (Spielberger, 2015). The STAI contains two subscales: the STAI-S measures State-Anxiety, the current levels of anxiety in the "here and now"; the STAI-T measures Trait-Anxiety, a relatively stable personality trait reflecting the participant's characteristic tendency to be anxious. Each subscale contains 20 items, rated on a Likert-type, four-point scale. A rating of 4 indicates the presence of a high level of anxiety for the 10 State-Anxiety items and 10 Trait-Anxiety items (*e.g.*, "I feel frightened," "I feel upset"). The remaining questions are reversed, meaning that a high rating indicates the absence of anxiety (*e.g.*, "I feel calm," "I feel relaxed"). After appropriately reversing the scores for the anxiety-absent items, the weighted score for the 20 items is added up to obtain the State-Anxiety score (20 items), Trait-Anxiety score (20 items), and Total Anxiety score (all 40 items). The State-Anxiety Total and the Trait-Anxiety Total scores each vary from a minimum of 20 to a maximum of 80, with a Total score of 40 to 160. For respondents who omitted one or two items on either scale, the prorated full-scale score was obtained by determining the mean weighted score for the scale items to which the individual responded, multiplying this value by 20, and rounding the product to the next higher whole number. No subject omitted more than two items. Scores greater than or equal to 40 on each subscale and greater than or equal to 80 on the Total scale indicate the presence of anxiety (Hofmann et al., 2010).

Each of the above 28 participants completed the STAI survey twice, at baseline and postintervention. For the psychiatry patients, both STAI subscales were administered by the treatment psychiatrist at the end of the 45-minute psychiatry session. For the nonpatients, an e-mail was sent asking them to complete and e-mail back both STAI subscales.

Procedures

The psychiatric outpatients visited their psychiatrist at the same frequency as before the study (between once weekly and once monthly) for individual psychiatry appointments lasting 45 minutes ("treatment as usual"). Sessions included a combination of psychotherapy and psychopharmacology. Psychotherapy treatment was provided by the treating psychiatrist and included a combination of cognitive-behavioral therapy, psychodynamic therapy, and existential therapy. Psychopharmacological treatments included the standard of care in psychiatric treatment in the United States, as elucidated in the Treatment Guidelines of the American Psychiatric Association.

Psychiatric medications for the patients' anxiety and comorbid conditions included selective serotonin re-uptake inhibitors antidepressants (escitalopram, citalopram, sertraline), selective norepinepherine re-uptake inhibitors antidepressants (duloxetine, venlafaxine, desvenlafaxine), other antidepressants (bupropion, mirtazapine), mood stabilizers (lithium, lamotrigine), atypical antipsychotics (olanzapine, quetiapine), benzodiazepines and benzodiazepine-like medications (clonazepam, lorazepam, alprazolam, zolpidem), stimulants (methylphenidate, amphetamine/dextroamphetamine salts), and other medications (propranolol, gabapentin, naltrexone, trazadone, clonidine). The two patients whose medications or medication dosages were changed during the study were excluded from the final analysis.

The NeuralHelix meditation practice was introduced to patients during one of their psychiatry sessions. For nonpatients, NeuralHelix was introduced during a prescheduled telephone call or videoconference. It was described as a series of three 20-minute audio recordings designed to assist the listener in quieting the mind. Participants were instructed that best results would be attained using headphones, but speakers were also acceptable. NeuralHelix contains both binaural beats and monaural beats, making speakers a viable option because monaural beats do not require left-right differentiation. A variety of listening devices could be used, including mobile devices, smartphones, mp3 players, laptop computers, and others. The following guidelines were recommended: setting aside at least one 30-minute period a day, allowing a few minutes before listening to get settled and a few minutes after to record any significant notes or remarks on their experience; sitting comfortably or lying down during the meditation; eliminating distractions to the degree that was possible; and wearing a blindfold to eliminate ambient light.

Each participant was provided with three meditation tracks of different sound frequencies—delta (3 Hz), theta (6 Hz), and alpha (9 Hz). In addition to the 20-minute tracks, participants were also provided 60-minute tracks of the same frequencies that could be played while performing activities such as study, relaxation, or reading. The three tracks were described as follows to the participants:

Whole Delta—3 Hz tones. Delta brainwaves are associated with deep sleep, unconsciousness, meditative trance, dreamless sleep, and coma. These meditations may aid relaxation and inducing sleep.
Whole Theta—6 Hz tones. Theta brainwaves are most pronounced during meditation, prayer, and spiritual awareness. These meditations may enhance intuition, creativity, fantasies, imagery, and dreams.
Whole Alpha—9 Hz tones. Alpha brainwaves are prominent during wakefulness and dream (rapid eye movement) sleep. They may enhance mental focus, contemplation, calm, and relaxation.

Participants were encouraged to try all three tracks and note which one(s) they liked the best and the reasons why. Each of the three tracks had two versions—one with and one without verbal guidance, whereby a human voice provided instruction on how to assume a relaxed posture and enter the meditative mental space. It was suggested that participants listen to the verbally guided version first. Guidance was provided on how to handle distracting thoughts that arose during the meditation: bringing attention to their breath and becoming a "neutral observer" of the thoughts rather than engaging with or becoming attached to the thought. Participants were counseled that they might experience unexpected emotions during the meditation. Should this occur, participants were encouraged to allow themselves to feel the emotion that has surfaced, allow any reactions such as tears to occur naturally and freely, and then to once again bring their attention to their breath and become a "neutral observer" of the emotion rather than engaging with or becoming attached to the emotion. Participants were also encouraged to select and silently repeat a one-word affirmation reflective of what they would like to achieve in their life (such as success, wellness, calm, peace, fulfilled, clarity, presence, etc.).

RESULTS

Sociodemographic and Treatment Variables

Sociodemographic information for all three treatment groups, along with treatment characteristics for the two groups of psychiatric outpatients, is shown in Table 1. The majority of patients in all groups were female, college-educated, and either employed or in college full-time. Half of the patients in the psychiatry + meditation group were married, as compared with 30% of the psychiatry-only group and 87% of the meditation-only group. The average age of the meditation-only group is higher than the other two groups by 18.2 years, a difference which is statistically significant ($t = 3.67$, $p = 0.003$).

Patients in the psychiatry + meditation group were in treatment for an average of 38.7 months before the beginning of this study ($SD = 35.7$; range, 1–90 months), whereas patients who did not use the meditations (psychiatry only) were in treatment for an average of 21.2 months before the beginning of this study ($SD = 23.4$; range, 0.5–84 months). This difference was not statistically significant ($t = 1.19$, $p = 0.25$).

The average duration of days between baseline and follow-up STAI administration is 35.4 ± 18.5 (range, 14–74 for all groups). All subjects who used the meditations over the course of the study did so for at least a consecutive 2-week period. A greater duration between baseline and follow-up STAI did not correlate with greater STAI improvement. The average number of psychiatry/psychotherapy sessions that each patients had during the study was 3.3 for the psychiatry + medication group ($SD = 2.5$; range, 1–8), as compared with 2.7 for the psychiatry-only group ($SD = 0.94$; range, 0–5). This difference is not statistically significant ($t = 0.59$, $p = 0.56$).

The total number of medications a psychiatry patient was taking during the study ranged from 0 to 5. None of the patients included in the final analysis experienced any medication changes during the course of the study. Four patients were not taking any medication. Five patients were taking one medication. Two patients were taking five medications. The difference in the number and types of medications between the two groups was not statistically significant ($t = 0.02$, $p = 0.97$).

First, we wanted to see whether there was a general improvement in the STAI scores by comparing individual results at baseline and postintervention. When all the data were pooled, the average individual STAI score was 94.3 at baseline and dropped to 81.3 postintervention. The paired *t*-test showed that the difference between the means was

TABLE 1. Sociodemographic Information and Treatment-Related Characteristics in Study Subjects

	Psychiatry + Meditation ($n = 8$)	Psychiatry Only ($n = 10$)	Meditation Only ($n = 8$)
Sociodemographic Characteristics			
Average age	Avg = 39.5 $SD = 12.1$ Range, 29–61	Avg = 31.9 $SD = 9.7$ Range, 18–55	Avg = 53.5 $SD = 11.9$ Range, 34–70
% With college education or greater	100%	80%	100%
% Women	63%	90%	87%
% Married	50%	30%	87%
% Employed or in full-time school	75%	90%	100%
Nature of Psychiatric Treatment			
Months in psychiatric treatment preintervention	Avg = 38.6 $SD = 35.4$ Range, 1–90	Avg = 26.4 $SD = 23.5$ Range, 0.5–84	N/A
Average no. sessions during the study	Avg = 3.3 $SD = 2.5$ Range, 1–8	Avg = 2.7 $SD = 0.9$ Range, 2–5	N/A
Average no. psychiatric medications	Avg = 2.1 $SD = 1.6$ Range, 1–4	Avg = 2.1 $SD = 2.2$ Range, 0–5	N/A
% Taking the Following Medications			
Antidepressants (SSRI, SNRI, Wellbutrin, mirtazapine)	50%	60%	N/A
Antianxiety medications (benzodiazepines, low-dose atypical antipsychotics)	50%	30%	N/A
Mood stabilizers	13%	40%	N/A
Stimulants	63%	20%	N/A

N/A indicates not available; SNRI, selective norepinepherine re-uptake inhibitors; SSRI, selective serotonin re-uptake inhibitors.

TABLE 2. State-Anxiety, Trait-Anxiety, and Total STAI Score at Baseline and Postintervention

Treatment Group	Baseline Mean STAI Score (Range)	Postintervention Mean STAI Score (Range)	Difference in STAI Score (95% CI)	*t*, *p*
State-Anxiety				
Psychiatry + meditation	51.25 (33–65)	37.75 (28–47)	−13.5 (−19.5 to −7.5)	$t = -5.28$,*** $p = 0.001$
Psychiatry only	49.9 (40–65)	45 (33–68)	−4.2 (−8.5 to 0.1)	$t = -2.20$,** $p = 0.05$
Meditation only	35.5 (24–56)	33 (23–48)	−2.5 (−9.3 to 4.3)	$t = -0.86$, $p = 0.41$
Trait-Anxiety				
Psychiatry + meditation	56.5 (33–67)	42.37 (23–55)	−14.1 (−20.6 to −7.6)	$t = -5.12$,*** $p = 0.001$
Psychiatry only	52.6 (41–67)	49.8 (37–60)	−2.8 (−6.7 to 1.1)	$t = -1.61$, $p = 0.14$
Meditation only	36.25 (29–49)	32.75 (23–49)	−3.5 (−6.8 to −0.1)	$t = -2.47$,** $p = 0.04$
Total score				
Psychiatry + meditation	107.8 (67–126)	80.1 (52–102)	−27.6 (−36.1 to −19.0)	$t = -7.63$,*** $p < 0.001$
Psychiatry only	101.8 (82–132)	94.8 (76–128)	−7.0 (−13.0 to −0.9)	$t = -2.61$,** $p = 0.02$
Meditation only	71.75 (53–103)	67.75 (48–94)	−6.0 (−15.8 to 3.8)	$t = -1.44$, $p = 0.19$

−13.03 (95% confidence interval [CI], −7.43 to −18.63; $p < 0.001$). In pooling all of the groups, there was no significant difference between improvement in State-Anxiety and improvement in Trait-Anxiety across all study subjects, the average STAI score improvement being −6.53 and −6.50, respectively.

Table 2 shows the comparison of STAI State-Anxiety, Trait-Anxiety, and Total score in our three treatment groups at baseline and postintervention. As was expected, the average baseline anxiety score for the State-Anxiety, Trait-Anxiety, and Total Anxiety was in the high anxiety range (≥40 for each subscale and ≥80 for total STAI) for the psychiatric outpatients and within normal limits for the nonpatients.

While the psychiatry + meditation and psychiatry-only groups showed statistically significant improvement in State-Anxiety ($p = 0.001$ and $p = 0.05$, respectively), the psychiatry + meditation and meditation-only groups showed improvement in Trait-Anxiety ($p = 0.001$ and $p = 0.04$, respectively). Only the psychiatry + meditation and psychiatry-only groups showed statistically significant improvement in Total Anxiety ($p < 0.001$ and $p = 0.02$, respectively).

To confirm the aforementioned findings, we then analyzed each of the three different groups in pairs. The average improvement across the groups is as follows: psychiatry + meditation, 27.6 points; psychiatry-only, 7.0 points; and meditation-only, 6.0 points. In this analysis, the overall difference between groups is statistically significant ($p < 0.01$).

Baseline and Follow-up STAI Scores

Multiple linear regression analysis was used to control for differences between the treatment groups in terms of sociodemographic characteristics and medication variables. For baseline and postintervention Total STAI scores, we found that each increased year of life correlated with a 0.84-point average reduction in anxiety ($\beta_{age} = -0.84$, $t = -3.88$, $p < 0.001$), whereas being female correlated with a 9.76-point average reduction in anxiety ($\beta_{female} = -9.76$, $t = -3.88$, $p < 0.001$).

Improvement Analysis

Multiple linear regression of the change between the baseline and follow-up STAI scores, controlled for sociodemographic variables, revealed that the only statistically significant improvement in anxiety is seen in the psychiatry + meditation group. Patients in this group have a predicted 28.9 points greater improvement in their total anxiety as compared with the meditation-only group ($\beta_{psychiatry + meditation\ group} = 28.9$, $t = 5.68$, $p < 0.001$). The 8.12-point differences in improvement between the psychiatry-only and meditation-only group was not statistically significant ($\beta_{psychiatry\text{-}only\ group} = 8.12$, $t = 1.51$, $p = 0.13$). The multiple linear regression analysis, controlling for medications, showed similar results, whereby the psychiatry + meditation group showed a 21.3-point Total STAI score improvement as compared with the psychiatry-only group ($\beta_{psychiatry + meditation\ group} = 21.32$, $t = 3.85$, $p < 0.001$). No medications had a significant effect on the improvement.

Table 3 shows predicted change in STAI scores after controlling for sociodemographic- and treatment-related variables while taking into account group-specific characteristics from Table 1. For each of the subscales (STAI-T and STAI-S), a predicted improvement of 13.9 points is expected in the psychiatry + meditation group; a 3.5-point improvement is expected in the psychiatry-only group; and a 3.0-point improvement is expected in the meditation-only group. For the Total Anxiety score, the improvements for these three treatment groups are 27.8, 7.0, and 6.0, respectively.

DISCUSSION

The purpose of this study was to determine the efficacy of the NeuralHelix meditation technology in reducing anxiety symptoms for both patients and nonpatients. Our results show the greatest decrease in anxiety when the NeuralHelix meditation technology is used in conjunction with psychiatric treatment.

State-Anxiety was significantly reduced in the psychiatry-only group and the psychiatry + meditation group, but not in the meditation-only group. The essential qualities evaluated by the STAI State-Anxiety scale are feelings of apprehension, tension, nervousness, and worry in the present moment. State-Anxiety has been found to be a

TABLE 3. Predicted Changes in STAI Score as a Function of Treatment Group Controlling for Sociodemographic and Treatment Variables

Group	Predicted Change in STAI Score
Subscales (Trait-Anxiety and State-Anxiety)	
Psychiatry + meditation	13.9
Psychiatry only	3.5
Meditation only	3.0
Total score	
Psychiatry + meditation	27.8
Psychiatry only	7.0
Meditation only	6.0

sensitive indicator of changes in transitory anxiety experienced by patients in psychotherapy and other forms of behavioral counseling (Spielberger, 2015). Because the STAI was administered shortly after a patient's psychiatry session, it is not surprising that patients' State-Anxiety showed a significant decrease. Being able to be present and comfortable with a trusted therapist likely helped patients feel at ease and at least temporarily reduced their feelings of anxiety in the here and now.

Trait-Anxiety was significantly reduced in the meditation-only group and the psychiatry + meditation group, but not in the psychiatry-only group. This result is consistent with meta-analyses that show that multiple forms of meditation—transcendental meditation, mindfulness, and progressive relaxation—can reduce Trait-Anxiety (Travis and Arenander, 2006). Trait-Anxiety can be thought of as a stable personality trait describing one's likelihood to experience anxiety. The fact that both meditation groups experienced a significant decrease in Trait-Anxiety suggests that the meditations were working at a deeper level than just the "here and now." With psychotherapy, it is generally believed that Trait-Anxiety changes, or changes to one's personality structure, occur over a long period. The fact that such changes were observed with meditation after only 2 weeks suggests that meditation works through a wholly different mechanism than psychotherapy. That meditation can produce Trait-Anxiety changes in 2 weeks has been confirmed by other studies (Nidich et al., 2009), which also show that the results persist up to 3 years later (Sheppard et al., 1997).

Trait-Anxiety reductions are often correlated with the development of a more internalized locus of control. In this study, meditation participants were taught to improve their relationship to their thoughts and emotions by bringing their attention to their breath and becoming a "neutral observer" of the thoughts and emotions. By having more control over one's thoughts and emotions, one develops greater control over one's own life, and thus a more internalized locus of control. Participants were also encouraged to set an intention that could be translated into a one-word mantra, such as success, calm, presence, integrity, or another word that is meaningful to the participant. Setting intentions is one form of taking greater responsibility for one's life and is therefore another mechanism through which participants could develop a more internalized locus of control. Besides the aforementioned two mechanisms of increasing one's locus of control, binaural beat meditations have been shown to reduce anxiety through neurobiological mechanisms such as altering functional connectivity between regions of the brain (Gao et al., 2014) as well as the connectivity of cortical networks (Beauchene et al., 2017), the effects of which may also reduce Trait-Anxiety.

The meditation-only group had significantly lower baseline anxiety than the other two groups, whereas all of the psychiatric outpatients with the exception of one had Total STAI scores of 80 or higher, indicating high anxiety. Studies have shown that initial anxiety level is one of the greatest predictors of the magnitude of anxiety reduction with meditation (Hofmann et al., 2010). Moreover, the average age of the meditation-only group was significantly higher than the other two groups by 18 years, which is important to note because past studies have shown an inverse correlation between age and anxiety (Spielberger, 2015). The aforementioned factors likely contributed to the lower STAI reduction in the meditation-only group relative to the other two treatment groups.

Multiple linear regression analysis controlling for sociodemographic characteristics, treatment variables, and medications attenuated the aforementioned improvements of the psychiatry-only group and the meditation-only group, while maintaining the statistically significant anxiety improvement in the psychiatry + meditation group. Based on this analysis, patients using the NeuralHelix meditations in the context of psychiatric treatment for anxiety can expect a 27.8-point improvement in their total STAI score, as compared with a 7.0-point improvement in patients using only psychiatric services and a 6.0-point improvement in nonpatients using the meditations.

A synergistic effect is observed in the psychiatry + meditation group, whereby the total anxiety improvement is greater than the sum of the other two groups combined. The synergistic effect can exist for multiple reasons. The psychiatry sessions may enable the patients to be more receptive to the meditations by enabling them to share their experience, ask questions, and discuss their concerns about the meditations with the treating psychiatrist. The meditations may bring up difficult or unwanted thoughts and emotions for patients, which the patients can then effectively process in the context of their psychiatry sessions. The meditations can also bring up positive thoughts and feelings on which the patients can draw and expand in their psychiatry session. The meditations may reduce baseline anxiety, thereby enabling patients to focus on different issues (other than their anxiety) in their psychiatry sessions. This did indeed occur for at least one patient in this study, who presented to her psychiatry session after using the meditations for 1 week and said, "I feel so relaxed that I don't even know what to talk about today."

One of the differentiating features of various meditation techniques is their electroencephalographic (EEG) signatures (Travis and Shear, 2010). NeuralHelix uses meditations with three different EEG signatures—alpha, theta, and delta—along with elements of mindfulness and mantra meditations. Mindfulness techniques produce theta (4–8 Hz) EEG waves. Their purpose is to enable people to be more present and cultivate a nonjudgmental attitude toward whatever is occurring in the present moment. By encouraging our subjects to become "neutral observers" of their thoughts and emotions, the NeuralHelix meditations take advantage of the benefits of the mindfulness technique. Mantra meditations, such as the transcendental meditation technique, have been shown to increase alpha EEG coherence and synchrony (Hebert et al., 2005). This form of meditation entails effortlessly repeating a word or sound, which allows the mind to settle to quieter levels of thought until it achieves the silent state of transcendental consciousness. This state is physiologically the opposite of anxiety, characterized by reductions in respiratory rate and the stress hormone cortisol (Jevning et al., 1992). By encouraging subjects to silently repeat a one-word intention during the meditation, NeuralHelix draws on some of the benefits of mantra meditations. Because NeuralHelix involves multiple components (the binaural tones, the monoaural tones, being able to "unplug" from one's daily routine, guidance on how to work with difficult or unwanted thoughts and emotions, and the creation of a one-word intention), future studies can be done to elucidate which of these variables have the greatest impact on anxiety reduction.

There are several limitations to this nonrandomized pilot study. Selection bias may limit the study's generalizability, as this was a convenience sample which included a majority of highly educated and employed females. The meditation-only group included a nonrandom sample of healing practitioners, including therapists, Reiki practitioners, a psychiatrist, and a yoga teacher. With respect to the two different outpatient treatment groups (psychiatry + meditation and psychiatry-only), patients were assigned to the psychiatry-only group if they failed to do the meditations they had originally set out to do. This raises the question of whether the psychiatry-only group included individuals who generally had a more difficult time following through with their stated goals than the psychiatry + meditation group, a confounding factor that could account for some of the variance in anxiety improvement. A control group in which subjects used neither psychiatric services nor meditation was absent from this study. Such a group would have helped us more accurately distinguish the treatment effect from the placebo effect. Larger-scale, placebo-controlled, randomized clinical studies are warranted to further examine the antianxiety effects of this novel meditation technology in an outpatient psychiatric setting and in the general population.

DISCLOSURE

The authors declare no conflict of interest.

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