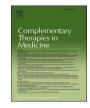


Contents lists available at ScienceDirect

Complementary Therapies in Medicine

journal homepage: www.elsevier.com/locate/ctim



Sound healing reduces generalized anxiety during the pandemic: A feasibility study

Shamini Jain^{a,*}, Eileen McKusick^b, Lorna Ciccone^a, Meredith Sprengel^c, Cheryl Ritenbaugh^{a,d}

^a Consciousness and Healing Initiative, 6919 La Jolla Blvd, La Jolla, CA 92037, USA

^b Biofield Tuning Institute, 382 Hercules Dr, Suite 2C, Colchester, VT 05446, USA

^c Netherlands Organization for Applied Scientific Research (TNO), 22 Rue d'Arlon, B-1050 Brussels, Belgium

^d Department of Family and Community Medicine, University of Arizona, 655 N. Alvernon Way #228, Tucson, AZ 85711, USA

ARTICLE INFO ABSTRACT Keywords: Objectives: This study examined the feasibility and effectiveness of a virtually-delivered, biofield-based sound Feasibility healing treatment to reduce anxiety for individuals meeting criteria for Generalized Anxiety Disorder. Biofield Design: This one-group, mixed-method feasibility study was conducted virtually via Zoom during the SARS-CoV-2 Sound healing Pandemic. Fifteen participants with moderate to high levels of anxiety as determined by the Generalized Anxiety Anxiety Disorder-7 (\geq 10), were enrolled. Distance healing Intervention: Five certified Biofield Tuning Practitioners performed the interventions. Participants were given Healing three weekly, hour-long sound healing treatments virtually, over a month's period. Virtual Outcome Measures: Attrition rates and reports on feasibility of intervention delivery and outcomes assessment Tuning forks behavioral intervention were obtained by participants. Data on anxiety, positive and negative affect, spiritual experience, perceived mental health stress, and guality of life were obtained via validated surveys and analyzed via repeated-measures analysis of variance with intention-to-treat. Linguistic inquiry and word count was utilized to assess changes in affective processing as reflected in participants' spoken words over the course of the intervention. Qualitative interviews were conducted to further determine tolerability and experiences with receiving BT that may not have been captured by survey and language data. Results: Attrition rates were 13.3%, with two participants dropping out of the study after one session. The remaining participants reported acceptability of the data collection process and intervention delivery. Intention to treat analyses revealed statistically significant reductions in anxiety (State-Trait Anxiety Inventory), negative affect (Positive and Negative Affect Scale), and perceived stress (Perceived Stress Scale) (p < .001 in all cases). Linguistic and word count analysis revealed a significant linear decrease (p = .01) of participants' use of negative affect words over the course of the intervention. Qualitative data results are reported in another paper. Conclusions: Results indicate that BT delivered virtually is feasible and amenable to study, and that the impact of BT may be substantial in reducing anxiety and improving mental health. This is the first study of its kind to report clinically significant reductions in anxiety levels in response to a virtually-delivered, biofield-based sound therapy. Data will be used to power a randomized controlled trial to more deeply examine the effects of BT on whole-person healing for those suffering from anxiety.

1. Introduction

As mental health disorders continue to rise during uncertain times, there is a need for swift and effective treatments which may be delivered virtually, particularly for those who are unwilling or unable to seek treatment in-person. The SARS-CoV-2 pandemic in 2020, which included strict stay-at-home orders globally, heightened awareness of the need for mental health interventions that allow for treatments to be delivered virtually.

Anxiety is the most commonly diagnosed mental illness in the USA, with over 19% of US adults having a diagnosable anxiety disorder.¹ During the 2020 pandemic, anxiety levels continued to rise as people were often unable to rely on usual social support or obtain in-person medical treatments to ameliorate anxiety.² Anxiety during the

https://doi.org/10.1016/j.ctim.2023.102947

Received 27 June 2022; Received in revised form 15 March 2023; Accepted 30 March 2023 Available online 5 April 2023 0965-2299/Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

^{*} Corresponding author. E-mail address: shamini@chi.is (S. Jain).

pandemic continued to rise to levels estimated at 31.9%, with the percentage of those reporting an unmet mental health care need rising from 9.2% to $11.4\%.^{3,4}$

Complementary and integrative medicine (CIM) has gained favor among those seeking relief from challenges with emotional and physical health.⁵ Recent survey research suggests that CIM is used more than conventional therapies by people with self-defined anxiety attacks and severe depression, with 56.7% of those with anxiety attacks reporting using complementary therapies to treat their anxiety during the past 12 months.⁶

Within CIM, biofield-based therapeutic approaches, including those using sound, light and subtle energy healing, have been gaining in popularity. Biofields have been defined as fields of energy and information that foster the homeodynamic regulation of a living organism.⁷ Biofield therapies are further defined in this paper as complementary health approaches that use biofield modulation, whether described as subtle or measurable, to stimulate a healing response.

Biofield Tuning (BT) is a non-invasive sound therapy practice that uses weighted and unweighted tuning forks on and around the body for the purpose of detecting and releasing areas of tension.⁸ A tuning fork is held in one hand of the practitioner and a hockey puck in the other (for striking purposes). Perturbations, tonal changes and turbulence are measured within the recipient's biofield via sonic feedback from the tuning fork.⁹ When such a change is detected, the practitioner pauses to allow the tuning fork to recalibrate the biofield in each affected area. This sound healing approach, both in person and at a distance, assesses the biofield methodically and uses the information gleaned from the tuning fork, along with dialogue from the recipient, to help restore balance to their biofield, and has been anecdotally reported to clear issues related to psychosocial distress.^{8,9}

Conducted from December 2020 to February 2021 in the United States, the objective of this study was to determine the feasibility of studying a brief, virtually-delivered sound based intervention for those suffering from anxiety, when many were experiencing isolation due to the pandemic. Our primary goal was to study if adults with significant levels of anxiety, who are receiving BT, could feasibly be studied virtually. Our hypothesis was that BT delivered via videoconference on adults with anxiety could be safely delivered and feasibly studied virtually. We further hypothesized that initial data would show evidence of BT reducing anxiety in the study population.

To our knowledge, there have been no studies on biofield-based sound healing approaches delivered virtually for reducing anxiety. One study examined the effects of tibetan bowls on mood and showed promise for reductions in tension, anger and depression¹⁰; however, this approach is different from BT in that the population did not suffer from clinical levels of anxiety, and the therapy was delivered in-person. Regarding distant biofield based interventions on health outcomes, research on the clinical impact of non-contact, non-sound-based biofield healing practices do exist with mixed results.^{11,12} Regarding the specific use of distant biofield approaches for anxiety, one study reported the efficacy of distant Reiki for reducing anxiety and pain in oncology patients; however, the measurements were based only on visual analog scales and the statistical approach may not have been ideal.¹³ In-person biofield approaches for anxiety reduction using therapies including Spiritist "passe," Reiki, and Healing Touch suggest promise.¹⁴ Regarding the study of BT specifically, our group previously published a study reporting a lack of evidence for inter-rater agreement amongst BT practitioners.⁹ To date, clinically oriented studies with BT have not been explored, despite promising anecdotal reports.⁸

2. Methods

2.1. Clinical practice of BT in a virtual setting

In this study, we examined the virtually-assisted delivery of BT as practiced during the 2020 pandemic. BT practitioners connected with

participants via a HIPAA-compliant online teleconference system. Once contact had been established, the participant and practitioner turned their video off. The participant was instructed to recline comfortably to receive the BT treatment. The practitioner then imagined the hologram of the participant on the table for the remainder of the session and tuned into the field of the recipient. A standard BT protocol was then applied for treatment (APPENDIX A). The three core elements of a BT session are the opening sequence (grounding the participant), the adjustment (combing the biofield to identify and resolve perturbations), and the closing sequence (integrating the adjustment into the whole system). Five trained and certified BT practitioners engaged in this study, with each practitioner providing treatments to three participants. The standardized training program for BT practitioners consists of two separate modules over sixty-four hours of training. Certification is granted following completion of six practicum evaluations and thirty completed sessions outside of the training program.

2.2. Participants and setting

Participants were recruited via website announcement, emails, and social media postings from the sponsoring research organization, the Consciousness and Healing Initiative. Interested participants contacted the study coordinator who arranged a telephone screening. Eligibility criteria included: (a) to be adults (>18); (b) to meet the criteria of moderate to high levels of generalized anxiety disorder (GAD) (>10) using the Generalized Anxiety Disorder-7 (GAD-7), a seven-item anxiety scale¹⁸; (c) no previous experience of a one-on-one session of BT; (d) had regular access to and experience using a computer; and (e) were comfortable using HIPAA-compliant Zoom teleconference software for the BT sessions. Participants were screened by the study coordinator using the GAD-7 to determine eligibility. Participants were ineligible for the study if they: (a) had an active diagnosis or history of suicidality, Post-Traumatic Stress Disorder (PTSD), schizophrenia, or/and psychotic disorders; (b) were pregnant or nursing; (c) have an electronically implanted device (excluding cochlear implants); (d) were currently seeking treatment for an active cancer; (e) had an untreated serious illness (e.g. heart disease, diabetes, etc.); or (f) were currently taking daily antidepressants. For this one-group feasibility study, a sample size of 15 was considered sufficient for determining feasibility of intervention delivery, assessing study retention, and providing initial data on effect size. This sample size was determined based on the recommendations of Julious (2005).¹⁹ A sampling bias must be considered, since study promotion occurred through organizations known for their work in biofield therapy research and practice. However, it is noteworthy that 40% of study participants reported never having previously used a biofield-based therapy, and all participants had to be naive to the use of BT.

2.3. Research study flow and outcomes assessment

All eligible participants completed a written consent form in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The study was approved by the Institutional Review Board of the National Foundation for Energy Healing in Marzana, AZ. Participants who met the study criteria were assigned a BT practitioner and provided baseline measurements via self-report questionnaires and audio recording before receiving the intervention. Each participant received three, one-hour sessions of BT over three weeks (one BT session/week) by the same BT practitioner. Sessions were 60-minutes long and delivered virtually by one of five practitioners. Participants provided self-report data at various time points throughout the study. Participants also provided audio recordings in response to a "How was your Day" prompt for further analysis (see APPENDIX B for more information). Interventions were conducted virtually over HIPAAcompliant Zoom. Data was obtained through HIPAA-compliant digital surveys and online databases. There was no physical contact between

S. Jain et al.

the practitioner and participant.

Table 1 depicts timepoints for all types of data collection.

2.4. Outcomes assessment

While the primary aim of this study was to determine the feasibility of delivering a virtually delivered, biofield-based sound healing intervention, we aimed to collect initial data exploring the impact of the intervention. Because BT is a whole-person intervention that purports to not only mitigate symptoms but affect recipients' sense of energy as well as interpersonal and spiritual connections, we took a broad approach in our initial assessment (self-report, language analysis and qualitative interview) further outlined below.

2.5. Self-report outcomes

2.5.1. State-Trait Anxiety Inventory (STAI)

The self-report measure of primary interest was anxiety. We used the STAI, a 40-question self-report measure used in both research studies and clinical settings. The STAI includes two subscales with good reported validity: a state anxiety subscale (STAI-S) (20 questions), which assesses the severity of current anxiety symptoms and a trait subscale (STAI-T) (20 questions), which measures an individual's general proclivity to be anxious. The STAI is one of the most widely researched and used anxiety questionnaires that has good validity (internal consistency coefficients ranging from.86 to.95) and reliability (test-retest reliability coefficients range from.65 to.75).^{20,21}

2.5.2. Positive and Negative Affect scale (PANAS)

Positive and Negative Affect was measured using PANAS, a 20-question, self-reported measure that consists of two 10-item scales to measure both positive and negative affect. PANAS is a well-researched measure with good validity (internal consistency coefficient.89 for positive affect and.85 negative affect) and reliability (test-retest reliability coefficients ranging from.86 -0.90 for positive affect and.84–0.87 negative affect).^{22,23}

2.5.3. Perceived Stress Scale (PSS)

Stress was measured using PSS, a 10-item, self-reported Likert scale that offers a nonspecific measure of appraised stress. Specifically, PSS measures the extent to which an individual considers nonspecific events in life as stressful, unpredictable, and uncontrollable. PSS-10 is a standardized measure with good validity (internal consistency coefficients ranging from.78–0.91) and reliability (test-retest reliability coefficients ranging from.72–0.88).²⁴

Table 1					
Timepoints of Data C	Collection f	for the	3-Week	Feasibility	Study.

	Baseline	Week 1	Week 2	Week 3	
Demographics & CAM use	х				
STAI	х	x	x	x	
PANAS	х	x	x	x	
PSS	х	x	x	x	
WHOQOL-BREF	х			x	
NETI	х			x	
SAC				х	
Audio Recordings	xx	xx	xx	xx	
Qualitative Interview				x	

Abbreviations: CAM, Complementary and Alternative Medicine; STAI, State-Trait Anxiety Inventory; PANAS, Positive and Negative Affect Schedule; PSS, Perceived Stress Scale; WHOQOL-BREF, World Health Organization Quality of Life-BREF; NETI, Nonduel Embodiment Thematic Inventory; SAC, Self-Assessment of Change

^a Biweekly recordings

2.5.4. Nondual Embodiment Thematic Inventory (NETI)

To measure potential changes in spiritual experiences, we used NETI, a 20 question, self-reported measure that evaluates aspects of spiritual awakening and the nondual experience. This scale is designed to distinguish between people who have transpersonal ideas from those who embody at the deepest levels the transpersonal. This scale has demonstrated good validity (0.913).²⁵

2.5.5. Self-Assessment of Change (SAC)

SAC is a 16-domain, self-reported measure used to identify the extent of perceived changes following a therapeutic intervention. It is designed to gather information on "other" outcomes of interest that may not be captured by primary and secondary outcome measures. SAC was developed using extensive available qualitative data, and refined with cognitive interviews.^{26,27}

2.5.6. Naturalistic linguistic inquiry

In order to understand whether participants' natural language changed to reflect shifts in affective language consistent with views of self and relationships, a naturalistic linguistic inquiry and word count (LIWC) was also included in this study.^{28,29} To extract objective psychological information from the verbatim transcripts of the participants' bi-weekly reports, we used LIWC2015, Linguistic Inquiry and Word Count software.³⁰ LIWC is currently one of the most widely used and most extensively validated word-count-based, closed-vocabulary text analysis programs.^{28,31,32} Further details on LIWC analysis may be found in APPENDIX A.

3. Results

3.1. Feasibility, attrition and adverse events

Two participants (13.3%) dropped out of the study after one week; both received one BT session and provided the first week data before removing themselves from the study. These participants were queried for potential adverse events or other reasons for dropout. Neither reported adverse events, but cited scheduling issues. The remaining participants engaged in all intervention sessions and provided data at all timepoints. Overall, participants reported they found the duration of the study acceptable, and the assessments and recordings were easy to complete. They also felt that the HIPAA-compliant, online data collection platform was convenient and easy to use, since they could use their computer, phone, or tablet to complete the questionnaires.

All remaining participants were queried for potential adverse events throughout the study. Five participants reported that 24–72 h after the BT sessions, they experienced "detox" symptoms including headaches, agitation, sleep disruption, aches and pains, cold-sweats, and nausea. Participants who experienced one or more of these symptoms reported that they did not last more than a few days, that they were most intense following the first session, and decreased intensity after the second and third sessions. Of note, all participants who reported any number of these symptoms had received other biofield therapies in the past.

3.2. Demographics

Table 2 describes the demographics of the 15 study participants, including ethnicity, age, gender, and education. Of note, participants completed a survey at baseline about their use of Complementary and Alternative Medicine (CAM) modalities as defined by Johns Hopkins School of Medicine (a total of 17 modalities were included): six (40%) of the participants reported never having used a biofield or energy healing therapy, four (26.7%) reported having used a biofield therapy less than 5 times, and five (33.3%) reported regularly using biofield therapies.

Table 2

Baseline characteristics of 15 Study Participants.

Race/Ethnicity,	No. (%)
Caucasian	10 (66.6)
Hispanic	1 (6.7)
American Indian or Alaska Native, White	1 (6.7)
Asian	1 (6.7)
Prefer not to say	2 (13.3)
Not identified as white	5 (33.3)
Gender,	No. (%)
Female	13 (86.7)
Male	2 (13.3)
Age	No. (%)
18–24	1 (6.7)
25–34	3 (20)
35–44	4 (26.7)
45–54	4 (26.7)
55–64	2 (13.3)
65–74	1 (6.7)
Education	No (%)
High school	2 (13.3)
Associate's degree	4 (26.7)
Bachelor's degree	8 (53.3)
Master's degree	1 (6.7)

3.3. Self-reported questionnaire data

All questionnaire data were analyzed by repeated measures analysis of variance (RMANOVA, SPSS 28.0.1) with intention to treat (ITT) analyses (last score carried forward approach). Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated for the primary variable STAI-State ($\chi 2$ (5) = 24.6, p < .001) as well as for other self-report data (which is often the case for repeated measures data with smaller sample sizes). We thus employed Greenhouse-Geisser (GG) corrections in the analyses. In addition, given the multiple tests for statistical significance combined with a smaller sample size which often reflects wider variability of scores, we conservatively applied Bonferroni correction (0.05/6 or p < .0083) to our omnibus tests of significance. Mean values along with confidence intervals for each variable are provided in Table 3.

Table 3

Results of 15 Stud	ly Participants f	for Self-Report	Outcomes.
--------------------	-------------------	-----------------	-----------

Scale Name	Week ^a	Mean	SD
STAI-State	0	52.07	10.173
	1	42.40	8.365
	2	38.40	8.458
	3	34.07	10.633
STAI-Trait	0	50.60	11.268
	1	47.20	9.937
	2	43.80	9.923
	3	39.20	10.387
PANAS- Positive	0	30.27	7.516
	1	33.80	7.408
	2	33.60	7.753
	3	35.67	8.235
PANAS-Negative	0	29.53	7.643
	1	26.13	9.425
	2	19.87	5.357
	3	16.87	4.627
PSS	0	23.13	5.914
	1	21.47	5.276
	2	18.40	5.207
	3	16.80	4.475
NETI	0	23.13	5.914
	3	21.47	5.276

Abbreviations: STAI, State-Trait Anxiety Inventory; PANAS, Positive and Negative Affect Schedule; PSS, Perceived Stress Scale; NETI, Nonduel Embodiment Thematic Inventory

^a Week, 0 =Baseline

3.4. Anxiety outcomes: STAI

RMANOVA with GG correction indicated a significant decrease in STAI-State Anxiety scores during the course of the intervention (F (1.4) = 20.21; p < .001), with a significant linear trend (p < .001). Similarly, STAI-Trait Anxiety scores showed a significant decrease during the intervention (F (1.7) = 15.6; p < .001) with a significant linear trend (p < .001). Effect sizes for state anxiety and trait anxiety were large (eta2 partial =0.629 and.528, respectively). Results, depicted in Figs. 1 and 2, indicate that effects for this intervention on reducing anxiety are clinically and statistically significant, with an average 18-point drop for STAI-State and 11-point drop for STAI-Trait scores.²⁴

3.4.1. Perceived stress, positive and negative affect, quality of life and spiritual experience outcomes

RMANCOVA with GG correction indicated significant and notable decreases in PSS-rated perceived stress (F (1.9) = 19.86; p < .001) with a significant linear trend (p < .001; eta2partial =0.673) as well as significant PANAS-rated Negative Affect (F (2.2) = 24.25; p < .001) with a significant linear trend (p < .001; eta2partial =0.673). Results for PANAS-positive affect and NETI-rated spiritual experiences were not significant (p = .1 and.07, respectively).

4. Linguistic analyses

At the level of overall change, a paired-samples t-test for word count showed no difference in the number of words participants recorded during baseline and treatment suggesting that their task engagement and adherence with the assessment protocol did not change (e.g., decrease) over time (WC: $M_{\text{baseline}} = 199.8$ vs. $M_{\text{treatment}} = 237.1$; t = 1.059; p = .311). At the finer temporal level, which was tested with repeated-measures ANOVAs, there was no significant variability in the means (baseline, week 1, week 2, week 3) for the raw word count recorded. This solidifies the results that participants' task engagement and adherence was stable over the four week period overall (*F*[1.74, 20.89] = 1.320, p = .285).

The paired-samples t-tests for the 9 LIWC variables selected for their relevance to potential treatment outcomes revealed a significant effect for Negative Emotion Words or NEW. On average, participants used fewer negative emotion words in their "How was your day?" assessments during treatment relative to baseline ($M_{\text{baseline}} = 2.29$ vs. $M_{\text{treat-ment}} = 1.66$; t = -2.280; p = .042). No evidence of statistically reliable change emerged for the other variables (all other ps > 0.12).

In the ANOVAs for the 9 LIWC variables selected for their relevance to potential treatment outcomes, a statistically significant effect again emerged for NEW. Participants evidenced significant variability in their use of negative emotion words over time (F[3,36] = 2.957; p = .045). The follow-up contrast tests revealed a significant linear effect indicating that the pattern of variability followed a linear decline over the course of the four weeks (NEW: $M_{\text{baseline}} = 2.29$, $M_{\text{week1}} = 1.86$, $M_{\text{week2}} = 1.70$, $M_{\text{week3}} = 1.43$; F[1,12] = 9.208; p = .010).

Thus, LIWC analysis found a statistically significant decrease in the use of negative emotion words over the course of the 3-week intervention and is depicted in Fig. 3. This is consistent with the decreases in anxiety and negative affect found in self-report measures.

5. Discussion

5.1. Feasibility

This one-group, pre-post feasibility study examined the acceptability of delivering a biofield-based sound therapy for those suffering from generalized anxiety during the pandemic. Results indicate an acceptable attrition rate of 13% with 87% of the remaining sample completing all sessions and providing all self-report, audio recording, and qualitative data. For the 13 of 15 subjects who completed the study, all completed

STAI State Anxiety Intervention Changes

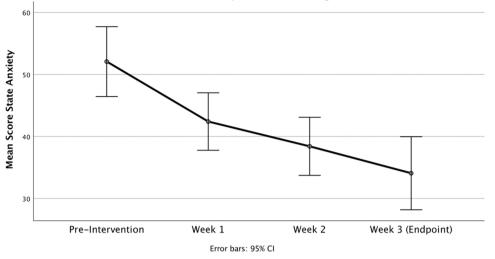


Fig. 1. Intervention changes on Anxiety using the State Anxiety Inventory. Points represent mean values and bars are 95% confidence intervals. There was an 18-point drop in state anxiety.

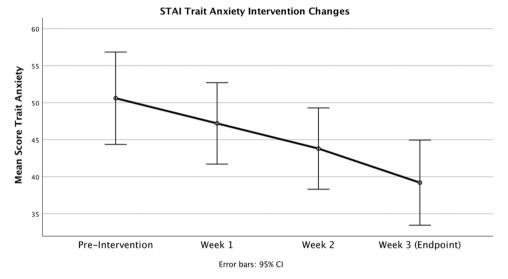


Fig. 2. Intervention changes on Anxiety using the Trait Anxiety Inventory. Points represent mean values and bars are 95% confidence intervals. There was an 11-point drop in trait anxiety.

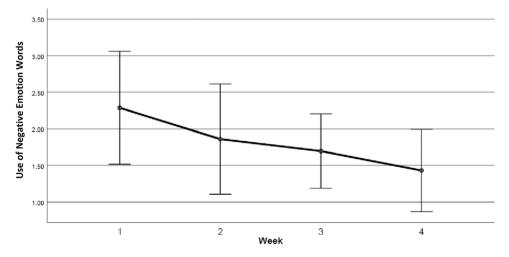


Fig. 3. LIWC analysis found a statistically significant decrease in the use of negative emotion words over the course of the 3-week intervention.

their three planned sessions of BT, and there was no missing data in selfreport, linguistic data, or qualitative interview, indicating success in feasibility of intervention delivery and data collection. All participants reported that they experienced bodily sensations and that the momentto-moment healing experience was maintained using videoconference. Both qualitative and quantitative measures suggest that the BT intervention was effectively delivered virtually.

5.2. Outcome results

Results from both self-report and quantitative linguistic analysis from this study indicate that three sessions of BT delivered at a distance significantly reduced the primary outcome of anxiety and decreased negative affect and perceived stress. These results were corroborated by linguistic analyses which revealed a statistically significant decrease in the use of negative affect words over the course of the intervention. It is noteworthy that the decrease in anxiety was clinically and statistically significant. Participants began the intervention with significant levels of anxiety (GAD-7 > 10 and STAI-state score mean = 52) and dropped to post-intervention STAI scores (mean score = 34) being below generally reported cutoff scores for anxiety (reliable change index = 8, cut-off point = 46).³³ Results from this study are consistent with the reporting of other biofield-based interventions on anxiety levels $^{14-17,34,35}$; however these interventions were delivered in person and did not include a sound component.

5.3. The need for controlled research in BT

While the study was successful in determining feasibility, it is limited in its ability to make firm conclusions on the efficacy of BT for anxiety due to its one-group design. Without a control group, natural history effects on outcomes and other confounding placebo variables, such as expectation, conditioning, and practitioner-client interaction, cannot be accounted for. Further controlled research examining a broader demographic, follow-up data, and active control or comparison groups are needed.

It is notable that several participants, all of whom had prior exposure to other biofield therapies, reported "detox" symptoms at the start of the intervention, but these adverse symptoms resolved and participants continued the study. The two dropouts from the study did not report experiencing any adverse events. We reported the following symptoms: headaches, agitation, sleep disruption, aches and pains, cold-sweats, and nausea. BT practitioners anecdotally report that these "detox" symptoms can be present for 1–3 days in some BT recipients. The practitioners report that detox experiences do not occur for everyone, but if they do happen, it is most often observed in the first one or two sessions. This is consistent with what was reported in our study and would need to be further elucidated in future research.

This study indicates strong feasibility and initial efficacy for a sound healing therapy, delivered virtually, to reduce anxiety, stress, and negative affect for adult US participants suffering from clinical levels of anxiety during a significant time of health and social crisis. Further controlled research on BT and similar modalities for mental health is warranted.

CRediT authorship contribution statement

Shamini Jain (corresponding author) Conceptualization, Methodology, Formal Analysis, Data curation, Supervision, Funding acquisition, writing-Original Draft, Review and Editing Meredith Sprengel: Investigation, Writing- Original Draft, Project administration, Eileen McKusick: Conceptualization, Methodology, Investigation, Funding acquisition, Cheryl Ritenbaugh: Methodology, Investigation, Validation, Writing-Original Draft, Lorna Ciccone: Validation, Writing- Review and Editing, Visualization.

Declarations of Competing Interest

Dr. Jain is the Founder and CEO of Consciousness and Healing Initiative, a nonprofit organization who received grant funding via the Biofield Tuning Institute, in order to conduct this feasibility study. Ms. McKusick is the Founder and CEO of BioSona, a for-profit organization that trains Biofield Tuning practitioners, all of whom were practitioners in this research study. Ms. McKusick is also founder of the nonprofit Biofield Tuning Institute, who helped secure grant funding for this study. Dr. Ciccone is a contract employee for the Consciousness and Healing Initiative. Ms. Sprengel was a contract employee for the Consciousness and Healing Initiative at the time the study was conducted. Dr. Ritenbaugh is Professor Emerita of Family and Community Medicine at The University of Arizona, and a Senior Scientist in the Consciousness and Healing Initiative.

Acknowledgements

We would like to thank the Forrest and Frances Lattner Foundation who helped to fund this study. We would like to thank Dr. Matthias Mehl at the University of Arizona who helped guide and conduct the LIWC portion of this study. We would also like to thank the BT practitioners Mary Grunvald, Trish DeRocher, Mary McGillivray, and Jean-Marie Mellichamp who helped to make this study possible.

APPENDIX A. : Additional Information on Linguistic Word Count Analyses

For the purpose of this project, we focused on the following set of LIWC variables: (1) Positive Emotion Words (PEW) as a measure of verbally expressed positive sentiment, (2) Negative Emotion Words (NEW) as a measure of verbally expressed negative sentiment, (3) Anxiety Words, (4) Sadness Words, and (5) Anger Words as subcategories of NEW tapping into the verbal expression of specific emotions (anxiety, sadness, anger ^{36,37};(6) First-Person Singular Pronouns (FPSP; e.g., "T, "me", "my") as a measure of self-focus related to negative emotionality (incl. depression and anxiety ^{38,39}; (7), First-Person Plural Pronouns (FPSP; e.g., "us", "our") as a measure of collective focus related to social inclusion and relationship satisfaction ^{40,41}; (8) Social Process Words (SPW) as a measure of socially-themed thinking (e.g., "talk", "share", "we"²⁶; (9) Cognitive Processes Words (CPS) as a measure of cognitive reflection and processing (e.g., "think", "realize", "understand"). ^{36,41} In addition, we used (10) the raw Word Count (WC) as a control measure of task engagement and adherence to the assessment protocol.

The LIWC results of participants' two weekly "How was your day?" assessments were averaged into a weekly score, yielding values for the preintervention baseline, week 1, week 2, and week 3 of treatment. To test whether, overall, participants' language changed from before to during the intervention, the three treatment data points were averaged into a "during treatment" measure. We then tested whether the 10 LIWC variables differed between baseline and during treatment using paired-sample t-tests (p < .05; two-tailed).

Further, to test for potential temporal (a) dose-response effects that accumulate (i.e. increase) over the course of treatment, (b) rapid onset but short lasting effects that emerge early in treatment but fade towards the end, and (c) delayed "sleeper" effects that emerge towards the end of treatment, we also conducted a series of 10 analyses of variance with time as a 4-level repeated-measures factor (baseline, week 1, week 2, week 3). The omnibus ANOVA tested for overall differences in the means and follow-up polynomial contrasts tested for linear and quadratic trends. One

participant completed only the baseline audio recording task and one other participant dropped out after completing baseline and week 1 recordings. The remaining 13 participants had complete data and were included in all analyses.

APPENDIX A: Standard BT Protocol Sheet

	REFERENCE SHEET STANDARD SESSION
ΟΡΕΝ	IING SEQUENCE
	HOLLOW BONE Center, ground, permission to touch
2	ACTIVATE BODY POINTS K1s, Knees, Hips, Sternum, Lung Points, Crown
	CENTRAL CHANNEL ACTIVATION Adjust Earth Star & Sun Star
(4)	PENDULUM Determine best angle of approach
THE	ADJUSTMENT
5	COMBING Outer edge, moving inward, drop in midline
6	COLUMNING Mixing paint & column at energy center
(7)	PENDULUM Re-assess energy center(s)

CLOS	SING SEQUENCE
8	DETERMINE HANDEDNESS
	Position self on client's dominant side
9	FIGURE 8 & COLUMN
	Figure 8 at Solar Plexus 3x (barrels stacked) Single column up at Solar Plexus (barrels side by side)
10	COCOON
	Use 528Hz or 417Hz
	LEG SWEEP & K1
	Gentle heel pull & hold K1 points
12	WAKE UP BACK ENERGY CENTERS
	Stimulate & column back energy centers Back chi sweep
13	CHECK IN
	Face to face with client Mention post session care

APPENDIX B. : STROBE Checklist

·

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			

(continued on next page)

S. Jain et al.

(continued)

	Item No	Recommendation	Page No
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8 *	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	10
		(d) If applicable, describe analytical methods taking account of sampling strategy	7
		(e) Describe any sensitivity analyses	-
Results			
Participants	13 *	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	-
Descriptive data	14 *	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
Outcome data	15 *	Report numbers of outcome events or summary measures	11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses Discussion	17	Report other analyses done-eg analyses of subgroups and interactions, and sensitivity analyses	7
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

References

 Anxiety disorders. National Alliance on Mental Health Website. December 2017. Accessed May 30, 2021. https://www.nami.org/About-Mental-Illness/Mental-Health-Conditions/Anxiety-Disorders.

- 2 Daly M, Robinson E. Anxiety reported by US adults in 2019 and during the 2020 COVID-19 pandemic: Population-based evidence from two nationally representative samples. J Affect Disord. 2021;286:296–300. https://doi.org/10.1016/j. jad.2021.02.054.
- 3 Salari N, Hosseinian-Far A, Jalali R, et al. Prevalence of stress, anxiety, depression among the general population during the COVID-19 pandemic: a systematic review and meta-analysis. *Glob Health.* 2020;16:57. https://doi.org/10.1186/s12992-020-00589-w.
- 4 Vahratian A, Blumberg SJ, Terlizzi EP, Schiller JS. Symptoms of anxiety or depressive disorder and use of mental health care among adults during the COVID-19 pandemic — United States, August 2020–February 2021. MMWR Morb Mortal Wkly Rep. 2021; 70:490–494. https://doi.org/10.15585/mmwr.mm7013e2.
- 5 de Jonge P, Wardenaar KJ, Hoenders HR, et al. Complementary and alternative medicine contacts by persons with mental disorders in 25 countries: results from the World Mental Health Surveys. *Epidemiol Psychiatr Sci.* 2018:552–567.
- 6 Kessler RC, Soukup J, Davis RB, et al. The use of complementary and alternative therapies to treat anxiety and depression in the United States. *Am J Psychiatry*. 2001; 158:289–294. https://doi.org/10.1176/appi.ajp.158.2.289.
- 7 Jain S, Ives J, Jonas W, et al. Biofield science and healing: an emerging frontier in medicine. *Glob Adv Health Med.* 2015;4(Suppl):5–7. https://doi.org/10.7453/ gahmj.2015.106.suppl.
- 8 McKusick ED. Tuning the Human Biofield: Healing with Vibrational Sound Therapy. Simon and Schuster, 2021.
- 9 Hammerschlag R, McKusick ED, Bat N, Muehsam DJ, McNames J, Jain S. Inter-rater agreement of biofield tuning: testing a novel health assessment procedure. J Altern Complement Med. 2020;26:911–917. https://doi-org.liboff.ohsu.edu/10.1089/ acm.2020.0159.
- 10 Goldsby TL, Goldsby ME, McWalters M, Mills PJ. Effects of singing bowl sound meditation on mood, tension, and well-being: an observational study. J Evid-Based

Complement Altern Med. 2017;22(3):401-406. https://doi.org/10.1177/2156587216668109.

- 11 Astin JA, Harkness E, Ernst E. The efficacy of "distant healing": a systematic review of randomized trials. Ann Intern Med. 2000;132(11):903–910. https://doi.org/10.7326/ 0003-4819-132-11-200006060-00009.
- 12 Radin D, Schlitz M, Baur C. Distant healing intention therapies: an overview of the scientific evidence. *Glob Adv Health Med.* 2015;4(1_suppl). https://doi.org/10.7453/ gahmj.2015.012.suppl.
- 13 Demir M, Can G, Kelam A, Aydıner A. Effects of distant Reiki on pain, anxiety and fatigue in oncology patients in turkey: a pilot study. *Asian Pac J Cancer Prev.* 2015;16 (12):4859–4862. https://doi.org/10.7314/apicp.2015.16.12.4859.
- 14 Carneiro ÉM, Tosta AM, Antonelli IBS, et al. Effect of Spiritist "Passe" on preoperative anxiety of surgical patients: a randomized controlled trial, double-blind. J Relig Health. 2020;59(4):1728–1739. https://doi.org/10.1007/s10943-019-00841-7.
- 15 Carneiro É, Barbosa L, Marson J, et al. Effectiveness of Spiritist "passe" (Spiritual healing) for anxiety levels, depression, pain, muscle tension, well-being, and physiological parameters in cardiovascular inpatients: A randomized controlled trial. *Complement Ther Med.* 2016;30, https://doi.org/10.1016/j.ctim.2016.11.008.
- Complement Ther Med. 2016:30. https://doi.org/10.1016/j.ctim.2016.11.008.
 Richeson NE, Spross JA, Lutz K, Peng C. Effects of Reiki on anxiety, depression, pain, and physiological factors in community-dwelling older adults. *Res Gerontol Nurs*. 2010;3(3):187–199. https://doi.org/10.3928/19404921-20100601-01. Epub 2010 Jun 30.
- 17 Mangione L, Swengros D, Anderson JG. Mental health wellness and biofield therapies: an integrative review. *Issues Ment Health Nurs*. 2017;38(11):930–944. https://doi.org/10.1080/01612840.2017.1364808. Epub 2017 Oct 2.
- 18 Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166:1092–1097. https://doi-org.liboff.ohsu.edu/10.1001/archinte.166.10.1092.
- 19 Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharm Stat.* 2005;4:287–291. https://doi.org/10.1002/pst.185.
- 20 Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. Manual for the State-Trait Anxiety Inventory. Palo Alto, CA: Consulting Psychologists Press; 1983.
- 21 Spielberger C.D. State-Trait Anxiety Inventory: Bibliography (2nd ed.). Palo Alto, CA: Consulting Psychologists Press; 1989.

S. Jain et al.

- 22 Crawford JR, Henry JD. The positive and negative affect schedule (PANAS): construct validity, measurement properties and normative data in a large nonclinical sample. *Br J Clin Psychol.* 2004;43:245–265. https://doi-org.liboff.ohsu.edu/ 10.1348/0144665031752934.
- 23 Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: The PANAS scales. J Personal Soc Psychol. 1988: 1063–1070.
- 24 Lee EH. Review of the psychometric evidence of the perceived stress scale. *Asian Nurs Res.* 2012;6:121–127. https://doi-org.liboff.ohsu.edu/10.1016/j.anr.2012.08.004.
- 25 Mills PJ, Peterson CT, Pung MA, et al. Change in sense of nondual awareness and spiritual awakening in response to a multidimensional well-being program. J Altern Complement Med. 2018;24:343–351. https://doi-org.liboff.ohsu.edu/10.1089/ acm.2017.0160.
- 26 Ritenbaugh C, Nichter M, Nichter MA, et al. Developing a patient-centered outcome measure for complementary and alternative medicine therapies I: defining content and format. BMC Complement Alter Med. 2011;11:135. https://doi.org/10.1186/ 1472-6882-11-135.
- 27 Thompson JJ, Kelly KL, Ritenbaugh C, Hopkins AL, Sims CM, Coons SJ. Developing a patient-centered outcome measure for complementary and alternative medicine therapies II: Refining content and format through cognitive interviews. *BMC Complement Alter Med.* 2011;11:136. https://doi.org/10.1186/1472-6882-11-136.
- 28 Pennebaker JW, Mehl MR, Niederhoffer KG. Psychological aspects of natural language. use: our words, our selves. Annu Rev Psychol. 2003;54:547–577. https:// doi-org.liboff.ohsu.edu/10.1146/annurev.psych.54.101601.145041.
- 29 Ireland ME, Mehl MR. Natural language use as a marker of personality. In: Holtgraves TM, ed. Oxford library of psychology. The Oxford handbook of language and social psychology. Oxford University Press; 2014:201–218.
- 30 Pennebaker J.W., Booth R., Boyd R., Francis M. Linguistic Inquiry and Word Count: LIWC2015. Austin, TX: Pennebaker Conglomerates (www.LIWC.net). 2015.
- 31 Boyd RL, Schwartz HA. Natural language analysis and the psychology of verbal behavior: the past, present, and future states of the field. *J Lang Soc Psychol.* 2021;40: 21–41. https://doi.org/10.1177/0261927×20967028.

- 32 Tausczik YR, Pennebaker JW. The psychological meaning of words: LIWC and computerized text analysis methods. J Lang Soc Psychol. 2010;29:24–54. https://doi. org/10.1177/0261927×09351676.
- 33 Fisher PL, Durham RC. Recovery rates in generalized anxiety disorder following psychological therapy: an analysis of clinically significant change in the STAI-T across outcome studies since 1990. Psychol Med. 1999:1425–1434. https://doi.org/ 10.1017/s0033291799001336.
- 34 Lee MS, Rim YH, Kang CW. Effects of external qi-therapy on emotions, electroencephalograms, and plasma cortisol (Nov) Int J Neurosci. 2004;114(11): 1493–1502. https://doi.org/10.1080/00207450490509113.
- 35 Bat N. The effects of reiki on heart rate, blood pressure, body temperature, and stress levels: A pilot randomized, double-blinded, and placebo-controlled study. *Complement Ther Clin Pract.* 2021;43, 101328. https://doi.org/10.1016/j. ctcp.2021.101328. Epub 2021 Feb 17.
- 36 Cohn MA, Mehl MR, Pennebaker JW. Linguistic markers of psychological change surrounding september 11, 2001. Psychol Sci. 2004;15:687–693. https://doi.org/ 10.1111/j.0956-7976.2004.00741.x.
- 37 Vine V, Boyd RL, Pennebaker JW. Natural emotion vocabularies as windows on distress and well-being. Nat Commun. 2020 10;11:4525. https://doi.org/10.1038/ s41467-020-18349-0.
- 38 Edwards T, Holtzman NS. A meta-analysis of correlations between depression and first person singular pronoun use. J Res Personal. 2017;68:63–68. https://doi.org/ 10.1016/j.jrp.2017.02.005.
- 39 Tackman AM, Sbarra DA, Carey AL, et al. Depression, negative emotionality, and self-referential language: A multi-lab, multi-measure, and multi-language-task research synthesis. J Personal Soc Psychol. 2019;116:817–834. https://doi.org/ 10.1037/pspp0000187.
- 40 Karan A, Rosenthal R, Robbins ML. Meta-analytic evidence that we-talk predicts relationship and personal functioning in romantic couples. J Soc Pers Relatsh. 2019; 36:2624–2651. https://doi.org/10.1177/0265407518795336.
- 41 Seraj S, Blackburn KG, Pennebaker JW. Language left behind on social media exposes the emotional and cognitive costs of a romantic breakup. PNAS Proc Natl Acad Sci USA. 2021;118:1–7. https://doi.org/10.1073/pnas.2017154118.