Original Article

Decreased anxiety through haptic technology patch usage: A case-control comparison

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Abstract

Background: Chronic anxiety affects one-third of US adults and has increased by 6% from 2023 to 2024. Medical management is typically psychopharmacology utilizing antidepressants and/or anxiolytics and psychotherapy, but these are not always successful as treatments. Nonadherence or noncompliance to prescribed drugs for mental health disorders is common, and benzodiazepines as an anxiolytic class are also recognized as especially subject to misuse. **Settings and Design:** This single blinded, case-control study tested the use of a potential alternative or adjunctive treatment for anxiety of a Haptic Vibrotactile Technology patch. **Methods and Materials:** There were 102 adults enrolled in the study. 65 were assigned to the treatment group (TG) and 37 to the control group (CG). The TG gender ratio was 49 females/16 males; the CG gender ratio was 23 females/14 males. Two types of validated surveys were utilized, the Perceived Stress Scale (PSS) and the Short Form-20 (SF-20), and these two scaled surveys were administered at the three study intervals of Baseline, Day 7, and Day 14. **Statistical Analysis Used:** The numerically coded quantitative data collected were analyzed using SPSS software. Data were analyzed using paired t-tests and a two-tailed alpha level of 0.05 was used for all statistical comparisons. **Results:** At Day 14, there was a 31.3% difference between TG and CG for the PSS, showing marked positive effect for the TG patients as compared to the CG patients. The mean PSS score for TG patients decreased by 33%, showing a significant reduction in emotional/mental stress. For the SF-20, a positive change in the TG was shown, with a 23.8% increase in the percent score for the survey's Mental Health domain and a notable increase for the Health Perception domain. At Day 14, >90% of the TG reported satisfaction with the patch; 90% indicated that they would recommend it. In contrast, there was little change in all PSS and SF-20 scores from baseline to Day 14 for the CG; 97.3% of the CG were not at all satisfied with the patch (which was a placebo), and only 3% reported they would recommend it. **Conclusions:** The overall findings of this clinical trial revealed that the studied patch (PEACE Patch with vibrotactile trigger technology [VTT]; Super Patch Company, Srysty Holding Co, Toronto, Canada) was effective in reducing anxiety symptoms. Gaining a better understanding of how the brain interacts with external stimuli, such as through VTT, may lead to the development of more viable, safe, and effective "drug-free" treatment options, which can provide adults living with chronic anxiety more potential options for relieving their symptoms and acquiring a better overall quality of life. The VTT patch utilized in this study appears to be effective in reducing anxiety symptoms and so may present an alternative or adjunct treatment modality for chronic anxiety. Further research is needed to determine if the results found in our study differ depending upon the specific adult age demographic studied, such as effectiveness in the younger, middle-aged, and senior-aged adult population, rather than across the entire adult age group spectrum, and also in adults with poststroke or post-traumatic brain injury or living with various neurodegenerative disorders.

Keywords: Anxiety, haptic technology, haptic vibrotactile trigger technology, perceived stress scale, SF-20, stress, VTT

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Received: 05-12-2024 **Revised:** 27-01-2025
Accepted: 28-05-2025 **Published:** 24-09-2025

Access this article online

Quick Response Code:

Website: http://journals.lww.com/JFMPC

DOI: 10.4103/jfmpc.jfmpc_1981_24

Introduction

Chronic anxiety is linked to decreased overall health status and quality of life.[1] In the US population, chronic anxiety affects 32.3% of adults.[2] This adult percentage increased by

How to cite this article: Fason J, Gudin J, Hurwitz P. Decreased anxiety through haptic technology patch usage: A case-control comparison. J Family Med Prim Care 2025;14:3529-37.

6% from 2023 to 2024.[3] A persistent abnormally increased release of stress hormones is associated with diverse chronic health conditions (e.g., heart disease and impaired immune function), and the innate "fight or flight" response generated by anxiety promotes increased stress hormone release.[4] Substance abuse is common among U.S. adults dealing with chronic anxiety, impacting wellness and "quality of life" perceptions, social isolation, and potential homelessness.[5-9] Additionally, chronically anxious older-aged adults are at a 57% higher risk of developing dementia,[10] which is extremely costly to the US healthcare system[11] as is substance abuse.[12] Therefore, lessening chronic anxiety in chronically anxious adults in the US is important from both a public health and healthcare system cost standpoint.

The usual psychopharmacology approach to treating chronic anxiety is the prescribing of antidepressants and/or anti-anxiety medications, with selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors as the most commonly prescribed antidepressants.[13] Benzodiazepines are the class of anti-anxiety medications most often prescribed – and especially in cases where antidepressants have not been effective – but these have long been associated with a high misuse liability.[14] In 33% of suicide attempts, benzodiazepines were the chosen method,[14] and benzodiazepines are also linked to 21% of alcohol overdose deaths annually[15] and around 14% of overdose deaths each year due to opioid abuse.[16] However, prescription drugs used to treat chronic anxiety are contraindicated for some people due to side effects and/or interactions with other prescribed medications, as well as potential liver damage in some people.[17]

Psychotherapy is a standard treatment for chronic depression and anxiety and is often utilized in combination with psychopharmacological treatment.[18] However – despite enactment of the Affordable Care Act – insurance coverage and co-pay cost remain a barrier to accessing psychotherapy for many US adults who need it.[19] Moreover, less than one-third of the US population lives in an area where there are enough mental health professionals to meet the need in that US location for psychotherapy.[20] Even when available, psychotherapy is not always effective in reducing anxiety symptoms. Therefore, adults living with chronic anxiety need effective alternatives to solely psychotherapy (or combined pharmacological management and psychotherapy) to combat their anxiety symptoms.

Comorbidities have also been identified in adults who have been diagnosed with clinical depression as almost 70% also meet the criteria for an anxiety disorder. Similarly, those diagnosed with an anxiety disorder, more than 60% also have clinical depression.[21] Adults experiencing both conditions concurrently are more likely to show resistance to first-line therapeutic approaches compared to those diagnosed with either anxiety or depression.[21]

Chronic depression/anxiety in stroke and traumatic brain injury survivors

Stroke and traumatic brain injury (TBI) survivors often experience resulting chronic depression and/or anxiety.[22] Indeed, chronic depression occurs in at least one-third of all stroke survivors[23] and chronic anxiety occurs in at least one-quarter of stroke survivors.[22] Besides negative impacts on cognition, and both mood and neurotransmitter secretions affecting mood, injury to the somatic sensory cortex can impair tactile perception and other brain function roles[24] such as body temperature regulation.[25]

Participating in daily stroke/TBI rehab exercises is vital to regaining lost abilities, but the motivation in stroke/TBI survivors living with chronic depression/anxiety to participate fully is often lowered as its result.[26] Since stroke/TBI survivor participation in the prescribed rehab exercises also boosts brain healing due to neuroplasticity,[27] that participation in rehab exercising can be essential for attaining a full recovery poststroke or TBI. Therefore, stroke and TBI survivors may benefit from somatosensory relearning as a potential cognitive rehabilitation component.[28,29]

Understanding haptic technology

Haptic technology, and related haptic-controlled systems and devices, facilitates feedback responses to tactile sensations which may be introduced through vibration, motion, or touch.[30] This communication relies on the known neural networks of the central nervous system (CNS) and peripheral nervous system, which process response to tactile sensations and other sensory information.[31] Haptic technology has also been integrated into neurorehabilitation programs for those with cognitive impairments and/or injury, including those who have been affected by stroke or TBI.[28]

In clinical practice, haptic technology has been incorporated into robotic surgical and rehabilitation devices, as well as robotic prosthetics.[32] Haptics have been divided into brain–computer interface (BCI) and neurofeedback (NF) systems.[33] While BCI dominates the medical haptic landscape, NF has traditionally been used to enhance human internal control. For instance, haptic-enabled footwear has been designed for TBI rehabilitation patients to improve balance through NF.[34] Similarly, haptic-controlled pressure sleeves create varying tactile sensations to stimulate enhanced sensory perception, as evidenced by improved electroencephalogram (EEG) results.[35]

Recent research has reported positive outcomes with haptic vibrotactile trigger technology (VTT) for conditions such as insomnia, psychiatric disorders, balance problems, and chronic pain.[36-39] In addition, haptic applications that combine head-mounted displays to create virtual reality (VR) environments have also shown promise for individuals diagnosed with post-traumatic stress disorder, specific phobias, and generalized anxiety disorder.[40-42] Meanwhile – during radiation treatments for cancer – haptic technology has also

been used to simulate human empathetic touch as a mode to relieve patient anxiety.[43]

Interim results from the Stress Reduction After Use of a Haptic Vibrotactile Trigger Technology Patch: Analysis and Assessment (STRAVA) study, a minimal-risk, blinded, controlled, observational, and IRB-approved trial, were published in 2024, focusing exclusively on results from a treatment group (TG) of 65 individuals.[44] This study evaluated an over-the-counter, noninvasive, drug-free patch (PEACE Patch; Super Patch Company, Srysty Holding Co, Toronto, Canada) designed to support stress and anxiety through haptic-VTT. The TG used the VTT-enabled patch, while the control group (CG) received a sham patch without VTT. All participants were adults diagnosed with stress and anxiety symptoms.

The data analysis findings presented here are for all the studied groups of this pilot STRAVA study, which was a case-control study within a federally approved clinical trial. These two groups were the TG and CG.

Materials and Methods

Study design

This prospective, single-blinded case-control study aimed to evaluate patients' experiences, perceptions, and responses to a haptic VTT embedded patch (PEACE Patch; Super Patch Company, Srysty Holding Co., Toronto, Canada). The TG received the VTT-enabled patch from their clinician, while the CG was given an inactive patch for comparison. All data collection for this study was completed by August 30, 2024.

Study participant sample

For this analysis, a total of 65 patients (49 females, 16 males) at 3 US investigator sites were enrolled in the treatment ($n = 65$) group of the study and completed the baseline, Day 7, and Day 14 surveys. A CG of counterparts ($n = 37$; 23 females, 14 males) also completed the baseline, Day 7, and Day 14 surveys. The minimum age at baseline for the TG and CG was 18.3 and 31.3, respectively; the maximum age at baseline for the TG and CG was 75.1 and 77.6, respectively. Demographic results were relatively similar for gender and age at the baseline survey. The mean age at baseline was 46.8 years (TG) and 60.7 years (CG).

Study participants completed surveys that included validated scales for measuring stress and anxiety symptoms, such as the Perceived Stress Scale (PSS) and the Medical Outcomes Study Short Form-20 (SF-20). Feedback regarding patient satisfaction, quality of life, and the return to normal activities were also captured.

The TG included subjects who met the eligibility criteria and received the active patch, while those given a visually identical patch without the embedded VTT were assigned to the CG. Inclusion criteria for participation in the study were: (1) ages 18–85 years, (2) ability to provide written informed consent, (3) receipt of either the active VTT-embedded patch or the placebo patch, and (4) a diagnosis of emotional/mental stress or anxiety-related symptoms.

Exclusion criteria included a history of drug or alcohol abuse; the presence of an implantable pacemaker, defibrillator, or other electrical devices; and pregnancy. For the CG, subjects received a patch without VTT technology. All study subjects were blinded to which patch they received. Each patch was identified by a number on its external packaging, and these numbers were tracked by the compliance team of the contract research organization.

Each participant was assigned a unique identification number (IN), and a confidential file containing signed informed consent forms and participant INs was securely stored, accessible only to the principal investigator and authorized personnel. Survey responses were anonymized, with no identifying patient information. Participants could withdraw from the study at any time without affecting their medical care. All treatment decisions were made by clinicians at their discretion. Participants provided written informed consent voluntarily and received the patches free of charge, without compensation, for their involvement in the study.

The study protocol was approved by the ADVARRA Institutional Review Board and was conducted in full compliance with the Health Insurance Portability and Accountability Act of 1996, the Declaration of Helsinki, and the International Council for Harmonisation/Good Clinical Practice principles.

Description of the topical intervention:

The active patches feature an adhesive backing on one side and contain no drugs or energy sources. These noninvasive, 2 × 2-inch, nonpharmacological patches are embedded with proprietary sensory pattern imprints that form the haptic VTT. Participants were instructed to wear a patch on their forearm daily, with the placement being identical for both the active and

Photo 1: PEACE Patch with vibrotactile trigger technology [VTT]; Super Patch Company, Srysty Holding Co, Toronto, Canada

nonactive TGs. Although the nonactive patch resembled the active version, it did not contain the VTT technology [Photo 1].

Study procedures and assessments:

After consenting, all participants were asked to complete the PSS and the Medical Outcomes Study SF-20 surveys at enrollment (Day 0) and on Days 7 and 14. Surveys included questions to assess emotional and mental stress, anxiety symptoms, and their impact on daily life and quality of life.

The PSS is a tool used to understand how various situations affect feelings of stress and anxiety. It measures how respondents perceive the unpredictability, uncontrollability, and overload of their daily lives and includes questions about their current levels of stress. The PSS is the most commonly used scale for assessing individual stress perceptions.

The SF-20 is a 20-item questionnaire used to assess quality of life in patients with specific health conditions. It has been extensively validated and is considered reliable for measuring health-related outcomes.

Study subjects were also asked to indicate their satisfaction with the patch and preference between using the patch or their existing medications or treatment method for stress and anxiety relief. Any side effects experienced from the patch were also captured.

Study endpoints

The primary endpoints were changes in patient responses to the PSS and SF-20 scores in both the treatment and control groups. Additional endpoints included differences in preference for the patch versus prescription and over-the-counter medications, as well as differences in other treatments used by participants. Patient satisfaction with the patch treatment and any side effects reported during the clinical trial were also evaluated.

Data analysis and statistical methods

Descriptive statistics were used for all variables, including frequencies and percentages for categorical variables, and means with standard deviation for continuous variables. The maximum sample size available was used for each analysis. Changes in PSS and SF-20 scores from baseline to Day 7, and from Day 7 to Day 14, were analyzed using paired t-tests to identify any statistically significant differences within the treatment and control groups. Descriptive statistics were used to report patient satisfaction and side effects within both the treatment (TG) and control (CG) groups. A two-tailed alpha level of 0.05 was used for all statistical comparisons. All data analyses were conducted using SPSS (IBM SPSS Statistics for Windows (Version 27.0). Computer software, Armonk, NY: IBM Corp; 2020).

Results

The results of our analyses included only those research subjects that completed the entire 14 days of the study, and analysis/results are omitted for any research subject that did not complete the full 14 days. There were three subjects in the treatment ARM that did not complete the full 14-day study period.

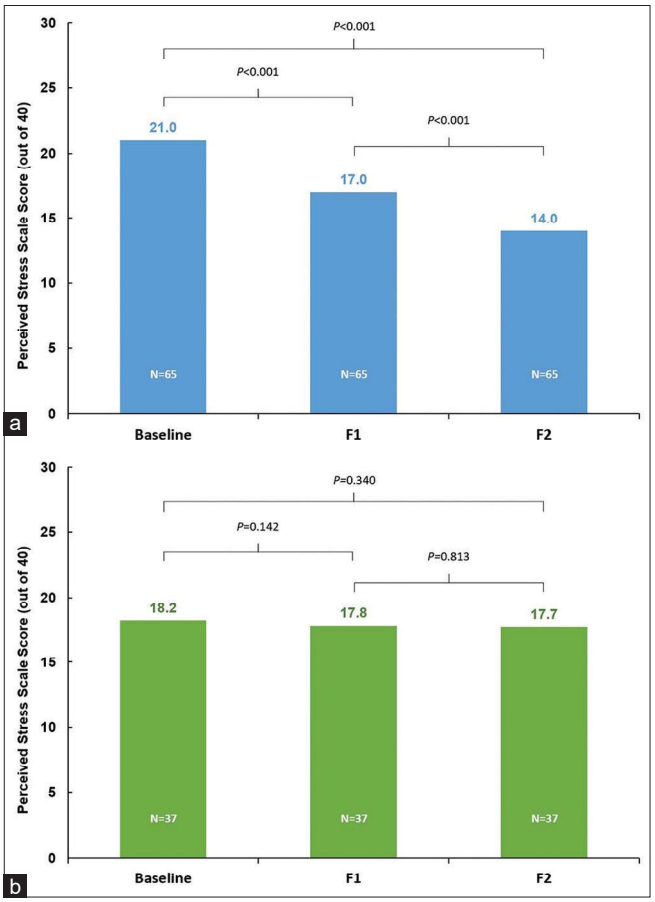

Figure 1: (a) Treatment group mean perceived stress scale score at baseline, F1, and F2. (b) Control group mean perceived stress scale score at baseline, F1, and F2

Perceived Stress Scale Score

The PSS classifies stress levels as high (scores between 27 and 40), moderate (scores between 14 and 26), or low (scores between 0 and 14).[45] For the TG, the mean PSS score decreased by 33% after 14 days (from 21.05 to 13.95 out of 40; $P < 0.001$), indicating a shift from moderate to low stress levels. At baseline, TG participants reported a mean stress level of 21.05, signifying moderate stress. By Day 14, the mean stress level dropped to 13.95, a decrease of 7.0 points on the PSS, reflecting a transition to low perceived stress. The effect size (Cohen's *d*) was 1.14 (large effect) from baseline to Day 7, 0.86 (large effect) from Day 7 to Day 14, and 1.29 (large effect) from baseline to Day 14.

In contrast, the CG showed minimal change from baseline to Day 14. Notably, there was a 22% difference between the TG and CG at Day 14, highlighting a significantly lower perceived stress level in the TG compared to the CG at the study's conclusion [Figure 1a and b].

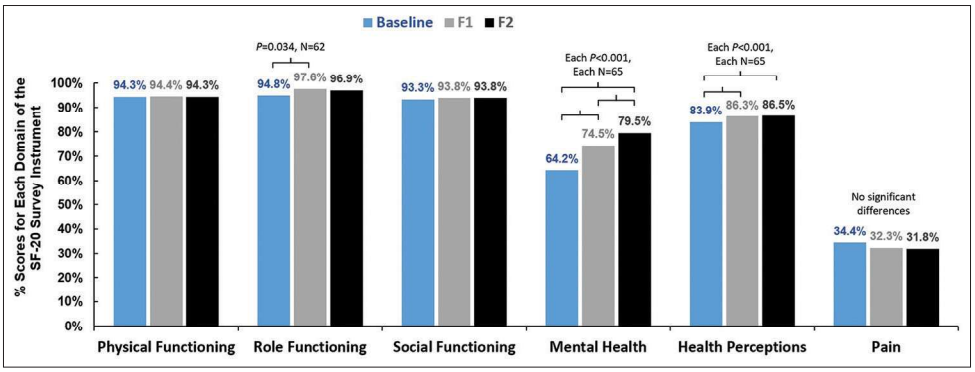

Figure 2: Treatment group percent scores for each of 6 domains of the Short Form-20 survey instrument at baseline, F1, an F2

Medical outcomes study Short Form-20 scores

The SF-20 measures six domains: physical functioning, role functioning, social functioning, mental health, health perceptions, and pain. For all domains except pain, a higher percentage indicates better quality of life. In contrast, for the pain domain, a lower percentage corresponds to less bodily pain. The mental health domain analysis covers four major mental health dimensions: anxiety, depression, loss of behavioral-emotional control, and psychological wellbeing.[46]

As shown in Figure 2, the most notable positive change reported by the TG was a 23.8% relative increase in the percent score for the mental health domain from baseline (64.2%) to the 14-day Follow-up Survey (F2) (79.5%) [Figure 2]. This indicated that research subjects' Mental Health status improved significantly ($P < 0.001$) while using the active patch. Results also showed a positive outcome and statistically significant percentage increase (83.9%–86.5%; $P < 0.001$) from Baseline to F2 in the Health Perception domain, indicating that TG respondents perceived that their health improved over the 14 days of active patch use. There were no significant differences in perceptions of physical functioning, role functioning, or social functioning, and although there was a slight decrease in reported pain levels over 14 days (34.4%–31.8%), the difference was not significant [Figure 2].

In contrast, there was little change from baseline to end-date shown in the CG. For Physical functioning, the percent score was 83.2% at baseline and 83.3% at Day 14. Mental Health functioning was 75.9% at baseline and 75.7% at Day 14. Although Social Functioning increased by 2% from baseline to Day 14 and Pain decreased by 1.4%, this may have been due to the placebo effect since the CG participants did not know they had not received the active patch [Figure 3].

Changes in prescription or over-the-counter medication usage

At baseline, 17% of the TG (11/65) indicated that they were taking prescription or OTC medication for their stress or anxiety-related symptoms. After 14 days, there were no significant TG changes in prescription or OTC medication usage. In contrast, for the CG, 5% (2/37) at Baseline indicated they were taking OTC medication for their stress/anxiety-related symptoms, which decreased to 3% on Day 7 but then increased to 8% on Day 14.

Similar to the prescription medication usage by the TG, the CG showed no significant percentage change at the intervals of Baseline (Day 0), Day 7, and Day 14. This is actually unsurprising as psychiatric medications are typically maintained or weaned slowly off in patients that are treated with them.

Changes in use of other treatments

At baseline, 26% of the TG (17/65) reported that they were incorporating other treatments to address their stress and/or anxiety-related symptoms. These included such things as massage, exercise, behavioral therapy, physical therapy, yoga, and meditation. After 14 days, there was a 35% increase in the number of TG participants (17–23) who undertook or began these other forms of treatment, including exercise, massage, yoga, and swimming. Among the CG participants, there were no significant changes to their existing forms of treatment.

Satisfaction with patch and safety

Subjects were queried on specific satisfaction rating aspects regarding use of the patch (scale: 1 = Not at All, 2 = Not Very, 3 = Somewhat, 4 = Very, 5 = Extremely). At Day 14, over 90% of the TG participants reported that they were satisfied with the patch plus approximately 90% indicated that they would recommend it to their family and friends. In contrast, 97.3% of the CG participants responded that they were not at all satisfied with the patch (which was a placebo), and only 3% reported they would recommend it to family and friends.

In terms of safety, all the TG and CG participants reported no side effects or serious adverse events while being treated with the active or inactive 'sham' patch.

Discussion

Findings of this STRAVA study consistently showed that research subjects in the TG that utilized the haptic VTT patch

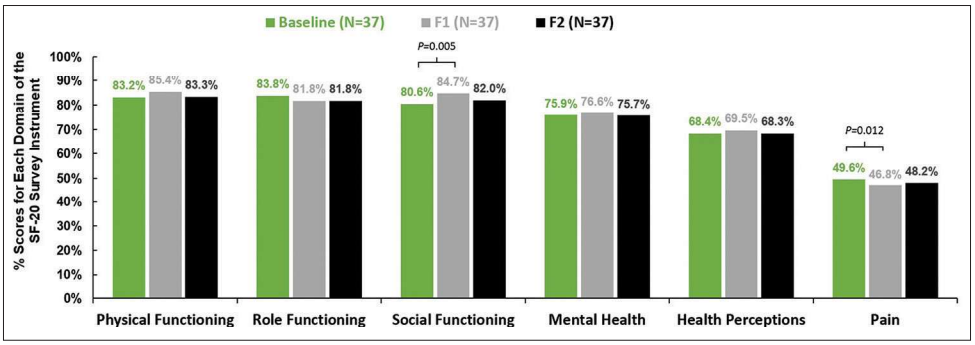

Figure 3: Control group percent scores for each of 6 domains of the Short Form-20 survey instrument at baseline, F1, an F2

demonstrated more positive outcomes in their mental health symptoms than those in the CG with the placebo patch. For the TG data evaluated, results showed overall positive PSS scores, with a decrease in stress level (from moderate to low), and positive outcomes in the SF-20 Mental Health and Health Perception domains. In addition, after 14 days of using the PEACE patch, TG study participants reported an increase and initiation of concurrent and complimentary activities, including massage, exercise, and yoga. Among the CG participants, neutral or negative outcomes were evident from the survey responses.

Overall, the research subjects in the TG of STRAVA reported a statistically significant decrease in stress and anxiety-related symptoms. They also showed improved mental health scores and improved perceptions about their health and wellbeing. In turn, this contributes to the increasing body of evidence that incorporating VTT into a multimodal treatment strategy promotes successful outcomes in adults suffering from anxiety; such anxiety can be resultant from disabling health disorders as stroke and TBI as well as diverse other causes.

Study limitations

Data gathered from the PSS and SF-20 assessment tools utilized were self-reported study participant responses. Since individuals perceive their mental health symptom level and pain level differently, it is possible that a person with a low level of anxiety and/or pain might self-perceive it to be higher than actually existent. There were no brain scans of the participants at each of the three data collection intervals, and even brain scans are not useful in gauging point-in-time occurrences of mental health distress or pain. Therefore, self-perception – albeit highly subjective – remains the customary manner that degree of anxiety, pain, and other sensory perceptions is identified. The total sample size was small, so it was more difficult to acquire statistical significance. Data from patients who did not complete the follow-up surveys after baseline, as well as from those who indicated that they did not use the patch after the baseline visit, were not included in the culminating data analysis.

Conclusion

Haptic input stimulates higher brain centers that can promote the brain's neuroplasticity. Numerous research investigations are underway to gain a better understanding of how haptics interact with different brain centers, and the potential therapeutic role that haptics may play in the treatment of patients.[31,47-54] Past research has already demonstrated that – when a person is exposed to haptic VTT – there are changes in their EEG patterns.[55,56] Not only have changes in EEG patterns been reported after exposure to VTT but also it is believed that the induced sensory patterns are likely to be in close symmetry.[55] Additionally, a wide array of researchers have added tremendously to the knowledge base of how neural networks are impacted by VTT.[31,47-49,57,58] For example, certain brain areas have been demonstrated as responsive to external stimuli incorporating the VTT; this has consequently shown positive outcomes in regard to a person's balance and physical stability measurements.[59,60]

The connections between cognitive, emotional, and motor skill functioning

In order to understand how cognitive, emotional, and motor skill functional capacities are controlled by the brain through which humans can experience sensations, it is important to consider that specific regions of the brain communicate with networks of neurons in looping pathways as follows: (1) a traditional sensory pathway with neural projections routed through the thalamus, (2) a complex neuron circuitry that follows a path through the brainstem and parts of the limbic system, and (3) a pathway associated with ones that are routed through different Brodmann areas and particularly the somatosensory cortex.[61]

The case for developing more nonpharmacological approaches to treating anxiety

Not all patients respond positively to traditional nonpharmacological approaches. Although they have proven effective in treating patients with anxiety disorders,[62,63] undesirable side effects, tolerability, and less than optimal outcomes warrant the need for the identification and research on alternative treatments for those who do not benefit from these methods. A deeper understanding of how the brain responds to external stimuli, such as through VTT, could pave the way for developing safer and more effective noninvasive "drug-free" options. This could help reduce or eliminate the reliance on conventional therapeutic approaches with their harmful side effects in patients with anxiety disorders.[64,65]

Further research is needed on the use of haptic VTT, and especially on a larger sample of patients. Likewise, further research is needed that focuses on specific adult age groups such as adults aged 50 and older (who are the adult age demographic most at risk of stroke), as well as comparatively with younger adults. Through duplicating our study on a larger study population and/or performing other studies on the use of haptic VTT in adults living with chronic anxiety, broad evidence may support use of VTT technology as either a first-line anxiety treatment or one combined with a behavioral and pharmacological approach. Chronic depression and anxiety are detrimental to health over the lifetime. Due to the Covid pandemic-fostered increase in population-based anxiety across the US, identifying treatments that are nonpharmacologic but effective is imperative to promoting the mental health of the US adult population.

Financial support and sponsorship

Super Patch Company, Srysty Holding Co, Toronto, Canada.

Conflicts of interest

There are no conflicts of interest.

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