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The effectiveness of microcurrent neurofeedback on depression, anxiety, post-traumatic stress disorder, and quality of life

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ABSTRACT

Background: The world faces a mental health crisis with elevated rates of depression, anxiety, and post-traumatic stress, leaving a profound impact on daily quality of life (QOL). Current treatments show varying degrees of efficacy and carry burdensome challenges. Evidence exists for use of an innovative neurotechnology to reduce symptoms of depression, anxiety, and post-traumatic stress disorder (PTSD), but the science is lacking for use in the general population.

Purposes: The purpose of this pilot study was to explore the effects of microcurrent neurofeedback on depression, anxiety, PTSD symptoms, and QOL in adults.

Methodology: This was a one-group, exploratory pilot study that tested outcomes of depression, anxiety, PTSD risk, suicide risk, and QOL in 20 adults using convenience sampling. IASIS microcurrent neurofeedback (I-MCN) was the intervention that was delivered twice a week for 10 weeks; data collection was baseline, 5 weeks, and 10 weeks.

Results: Depression, anxiety, PTSD risk, and QOL improved significantly by the 10th and 20th session; suicidal risk showed nonsignificant reduction. Use of a more feasible interventional procedure established a foundation for use in clinical settings for the population.

Conclusions: Using a more simpler procedure than what was used in a previous study reflected positive outcomes earlier and sustained over 10 weeks. This safe and effective technology carries rare but easily overcome adverse effects and could be an alternative to existing treatments or treatment-resistant conditions.

Implications: Advanced practice nurses can apply the evidence to reduce symptoms of depression, anxiety, and PTSD. Randomized controlled trials and testing on diverse populations are needed.

Keywords: Mental health; neurofeedback; neurotechnology; quality of life.

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Introduction

Depression, anxiety, and post-traumatic stress have a profound impact on daily quality of life (QOL). Global estimates of persons with depression topped 280 million (World Health Organization [WHO], 2021) with an estimated 21 million adults in 2020 being affected by depression in the United States (National Institute of Mental Health [NIMH], 2022a,b). Not only does the prevalence of depression have profound effects on individuals across age and gender demographics, it has been identified as the primary contributor to disability worldwide, leads to approximately 700,000 suicides globally per year (WHO, 2021), and has an annual economic burden of $201.5 billion because of loss of workplace productivity, direct costs, and suicide (Greenberg et al., 2021).

Anxiety is also a leading common mental health disorder affecting 40 million persons in the United States a year, and persons with anxiety are six times more likely to

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be hospitalized with a psychiatric disorder than those without anxiety disorders (Anxiety & Depression Association of America, 2021). Prepandemic rates for adult anxiety disorders in 2019 were 11% as compared to January 2021 rates at 41.1% (Elflein, 2021). This is further compounded by post-traumatic stress disorder (PTSD), an anxiety disorder than can result from previous trauma or adverse experiences. About 70% of adults have endured significant traumatic experiences in their lifetime. In one-fifth of these cases, PTSD will occur (Sidran Institute, 2016).

Background

Contributing factors

Multiple biopsychosocial and spiritual factors are known to contribute to depression, anxiety, and PTSD in adults. Depression and/or anxiety included the following predictors or associative factors: use of internet and smartphone addictions (Ismail et al., 2020); sleep deprivation, worse general health, lower lifestyle health beliefs and behaviors, high stress, and lower perceived control (Hoying et al., 2020); chronic disease (dysthyroidism, benign prostatic hypertrophy, and hypertension), lack of acknowledging feelings for coping, long hospital stay, female gender, and higher education (Fattouh et al., 2019); work-related traumatic events (van Steijn et al., 2019); intimate partner violence (Chandan et al., 2020); dietary intake, specifically fruits and vegetables (Saghafian et al., 2018); and religious and spiritual well-being (Davis et al., 2017). A systematic review of major depression disorder predictors after traumatic brain injury included history of depression, female gender, early post-traumatic brain injury psychiatric symptoms, and lower brain volume, and for PTSD, predictors included post-trauma amnesia, memory of the trauma event, and early onset of post-trauma symptoms (Cnossen et al., 2017).

Current treatments: pharmacological and nonpharmacological

Psychopharmacologic treatments for depression have shown to be effective for moderate to severe depression but not for mild, and major drug groups include tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs), and selective noradrenaline reuptake inhibitors (SNRIs; Informed Health.org, 2020). Antianxiety medications also include the SSRIs and SNRIs along with benzodiazepines. Although shown to be efficacious, side effects of selected drugs have been shown to contribute to adverse effects, withdrawal symptoms, intolerability, and nonadherence (Dell'Osso et al., 2020; Marasine et al., 2020). Benzodiazepines have been shown to be addictive and difficult to discontinue (Gomez & Hofmann, 2020). Recent guidelines from the American Psychological Association (APA) recommend nonpharmacological treatments for depression include psychotherapy in the forms of behavioral therapy, cognitive therapy, cognitive-behavioral therapy (CBT), mindfulness-based cognitive therapy (Weir, 2019), and social support and exercise (APA, 2022). A review of evidence-based guidelines showed that PTSD (Watkins et al., 2018) is best addressed with CBT, cognitive processing therapy, prolonged exposure, eye movement desensitization therapy, narrative exposure therapy, cognitive therapy, and brief eclectic psychotherapy. However, evidence in this review showed significant concerns of dropout rates for those being treated for PTSD.

Current treatments: neurotechnology

Traditional neurofeedback is a system that trains people to increase or decrease different types of brain wave activity through operant and occasionally classical conditioning. Traditional forms of neurofeedback for treatment of depression in adults have suggested potential effectiveness or have been inconclusive (Kaur et al., 2019). Transcranial magnetic stimulation (TMS) is a noninvasive neurophysiological stimulation of the nervous system that uses "application of rapidly changing magnetic fields to the superficial layers of the cerebral cortex" (Chail et al., 2018, p. 142). Use of TMS for the treatment of depression for those with severe depression and those who had medication-resistant depression has shown promise (Liston et al., 2014), with some studies reporting efficacy in 50% of the population with major depression (Perera et al., 2016). However, current treatment sessions are typically five days a week for several weeks, representing a significant time burden; recommendations have been made to reduce treatment sessions in terms of frequency and duration (Reddy & Vijay, 2017).

Noninvasive direct current brain stimulation studies have shown promise for treating depression (Bennabi & Haffen, 2018). Three forms of noninvasive, low-intensity, pulse-based, transcranial electrical stimulation (LIP-tES) are known to exist: low-energy neurofeedback system (LENS), Flexyx neurotherapy system (FNS), and most recently, IASIS LIP-tES (Huang et al., 2017). Low-energy neurofeedback system has evolved since the 1990s and has undergone numerous names as its functions became better understood (Larsen, 2006). Flexyx neurotherapy system at one time was a name assigned to LENS but seemed to be an independent therapy treatment (Nelson & Esty, 2012). Although similarities exist with the hardware of LENS, FNS, and IASIS LIP-tES, the latter is a newer system and incorporates a different software and protocol (Huang et al., 2017) and could be considered more innovative and advanced than its predecessors for addressing similar conditions that affect QOL.

IASIS LIP-tES, also known as IASIS microcurrent neurofeedback (I-MCN), is a noninvasive neurophysiological stimulation of the cerebral cortex, but instead of using magnetic fields as is seen in TMS, varying pulsations of microelectrical currents are applied, are so small that they

are not perceptible to the individual, and are estimated to be three picowatts or three trillionths of one watt. Significant improvements were shown in postconcussive symptom measures that included depression and components of anxiety categories in five persons with traumatic brain injury using I-MCN (Huang et al., 2017).

Current treatments involve medications with inconsistent effectiveness and various types of neurofeedback and transcranial stimulation that show promise but also come with disadvantages of frequent session requirements, long duration, requirements of extensive pretreatment preparation, and inconsistent long-term success. Exploring how more recent and innovative treatments can address these challenges may contribute to more people experiencing an optimal QOL. Thus far, only one published study exists regarding the effectiveness of I-MCN to treat anxiety and depression and that study focused on persons with traumatic brain injury (Huang et al., 2017). Anecdotal evidence has shown significant improvement using I-MCN in persons who have symptoms associated with depression, anxiety, and PTSD in the adult population, but no research has been conducted using this innovative and newer technology on adults with depression, anxiety, and/or PTSD. We present a pilot study to examine how clinical symptoms of depression, anxiety, PTSD, and QOL changed after receiving one form of pulse-based, low-intensity MCN.

Methods

Human participants' approval for this study was obtained through The University of Texas at Tyler Institutional Review Board under full board review. All participants signed an informed consent form and provided a copy that had the researcher's contact information.

Research participants

Participants were recruited through convenience sampling using networking, snowball sampling, flyers, and social media. Inclusion criteria were 18 years and older and persons meeting minimal screening scores for anxiety, depression, and/or PTSD. A history of seizure disorder was the sole exclusion criterion. Potential participants were asked to contact the researchers by phone or email, at which time study protocols were explained and participants were screened and scheduled for their initial visit. Medications that participants were taking were not a factor in the study, and they were not required to be under the care of a mental health professional. Participants were instructed to not change any current medications without consulting with their health care provider.

Procedures

Instruments. Five study instruments were used in addition to a demographic tool and a researcher-generated Observation Report that was used to determine participant responses to individual sessions and to influence procedural decision making with subsequent interventional sessions. These instruments included the Beck Depression Inventory II (Beck et al., 1996), Beck Anxiety Inventory (Beck et al., 1988), the Post-traumatic Stress and Suicide Screener (PSS; Briere, 2013), and the QOL Inventory (QOLI; Frisch, 1994). All instruments were electronic. Participants were given the choice to complete them either in their own setting or in the research office if they encountered difficulties completing the tool independently.

The demographic tool collected age, gender, race, ethnicity, occupation, morbidities, and medications. The Beck Depression Inventory II (Beck et al., 1996) is a 21-item, Likert scale tool that measured four domains of depression. Scores range from 0 to 63 with 0–13 being minimal depression, 14–19 mild depression, 20–28 moderate depression, and 29–63 severe depression. It is widely used, has high internal consistency, content, and structural validity, and demonstrated ability to discriminate between depressed and nondepressed participants (Wang & Gorenstein, 2013). Beck Anxiety Inventory is a 21-item tool that has demonstrated internal consistency (alpha of 0.92) and concurrent validity (Beck et al., 1988). It assesses three levels of scoring: 0–21 low anxiety, 22–35 moderate anxiety, and 36 and above are considered potentially concerning levels of anxiety. The PSS (Briere, 2013) served two purposes in this study. The degree of risk of PTSD was measured, as a study outcome, but also the researchers felt it was important to determine whether a participant was at high risk of suicidal behaviors, so that appropriate interventions could be initiated. This instrument is a 14-item scale that has two screening questions and 12 Likert scale items that assesses risk of PTSD and suicide. It is designed for persons 18 years and older and is derived from the Detailed Assessment of Posttraumatic Stress (DAPS; Briere, 2001). The 8-item PTSD risk scale reflects all PTSD clusters in the DSM-IV-TR and what Briere referred to at the time the PSS manual was written, the "proposed" DSM-5 (Briere, 2013). The first eight items ask about traumatic events in terms of memories, symptoms, and impact on life and predict PTSD status. The other four items predict suicide risk through assessing suicidal ideation, plans, and behaviors (Briere, 2013). The PSS is to be used strictly to identify those at risk of PTSD or suicide and is not diagnostic. The first eight items have a score of 8–40; a score of 15 or greater for a trauma that occurred a month or more ago indicated high risk of PTSD. The suicide subscale items have a range of 4–20; a score of five or greater is considered high risk of suicidal behaviors. Cronbach's alpha was shown to be 0.87 for the PTSD subscale and 0.91 for the suicide risk subscale (Briere, 2013). The QOLI measures 16 areas of life that reflect well-being and satisfaction with life (Frisch et al., 1992). Its 32-item, Likert scale

ranges from three to six rankings. Reliability was shown to be 0.85 (McAlinden & Oei, 2006), and convergent and discriminant validity has been demonstrated (Frisch, 1994). The Observation Report was a 24-item phone application that assessed energy, sleep, emotions, and physical reactivity using a Likert scale of 1–10, as well as a qualitative query to insert any other relevant comments. The Observation Report was used to determine whether participants were reacting adversely to the intervention and/or experiencing other effects to the intervention. These measurements were not considered a study outcome and served mainly to inform researchers how participants were responding to individual intervention sessions, so that subsequent intervention procedures could be modified if indicated.

The intervention. IASIS microcurrent neurofeedback is a passive neurofeedback therapy that requires no effort on the part of the participant during a session. The technology is IASIS 5.0 designed by J&J Engineering according to specifications provided by the Mind-Brain Training Institute (Huang et al., 2017). Additional information on the technological aspects can be found in Huang et al. (2017). The I-MCN device uses five electrodes, four of which deliver the transcranial electrical stimulation (A+, A−, B+, and B−) with respect to the common neck ground lead (the fifth electrode). During each session, two of the leads (A− and B−) were attached to the left and right mastoid. The remaining two leads, also known as site pairs, were attached to various locations on the scalp depending on the procedure for that particular session. Site pair placement was consistent with standards set by the International 10–20 electrode placement system. The founder of I-MCN was a former LENS-certified provider and was mentored using the International 10–20 electrode placement system as a standard of care, and this transferred over as a standard of care for I-MCN. Furthermore, using the International 10–20 electrode placement system is a standard of care used in traditional neurofeedback (Marzbani et al., 2016). All four electrodes emit weak current pulses to the brain (feedback process). I-MCN equipment includes five preprogramed protocols that include Genesis, Balanced Energy, Activation, Activation Plus, and Neuroblast. All participants began on the lowest protocol level (Genesis) and five site pairs (F3/F4, C3/C4, Fz/Pz, F7/F8, and Fpz/Oz) with four exposures on each site pair. Site pair numbers and locations were chosen based on the standard of care that was taught in the I-MCN training classes and that standard reflected typical I-MCN practice in clinical settings. It should be noted that site pair numbers and locations differed from the Huang et al. (2017) study in which 10 site pairs were used when this standard of care did not exist. The I-MCN procedure was flexible depending on the presence or absence of negative reactivity and positive responses. Negative reactivity is a term used when a person is more sensitive to I-MCN and experiences within 24 hr of mild to moderate symptoms of sensitivity, such as a headache that will not go away, extreme fatigue, nausea, spaciness, and/or feeling of being wired or hyperenergetic. If negative reactivity occurred then a reduced or recovery protocol was instituted if significant distress was experienced, but if the reactivity was mild to moderate and easily tolerated by the participant (participants were given a choice about coming to office for recovery procedure or waiting until the next session), the procedure was changed by reducing the exposures (duration of each site pair microcurrent delivery, each exposure being an average of 22–25 seconds) and/or site pairs and/or protocol level. Positive responses referred to improvement in symptoms, such as sleep, appetite, mood, and other emotions. If positive effects were noted, the participant remained at the same I-MCN level with the same site pairs as the previous session. Decisions regarding procedures for site pairs, exposures, and protocol levels were made based on a sequential system. For example, exposures were first changed, then site pairs, and then protocol level (Genesis through Neuroblast protocols). If there was neither a positive nor negative response, the I-MCN procedure was advanced to the next level beginning with numbers of exposures, then addition of site pairs, and then protocol level. A physician and I-MCN expert practitioner not associated with the study were available for consultation at all times during the study. Study participants received no money or other incentives for participating, but at the end of the study, participants who completed all sessions and assessments were offered a minimum of 65% discount on future MCN sessions outside of the study setting.

Data collection procedures. Eligible participants met on the first day in the research office, which was a quiet, 250-square-foot room with no external distractors. During the first visit, study procedures were carefully explained; once the researcher was satisfied that the participant understood all essential components, the informed consent was signed. Assistance with downloading and completing the Observation Report phone app was then provided. Participants completed baseline assessments through email distribution of instruments and were assigned a pseudonym to protect their identity.

Once baseline assessments were completed, an appointment was scheduled with participants for the initial I-MCN session. The PSS was reviewed within 24 hr of receipt to monitor for high suicide risk; these instances were referred immediately to a Licensed Professional Counselor who contacted the person to assess self-harm. Four people were contacted, and each agreed to comply with a safety plan for the duration of the study.

Data collection outcome measures were at baseline, 10 sessions, and within a week after the final 20th session.

The Observation Report was performed within 24 hr of the first I-MCN session and weekly thereafter.

The I-MCN intervention was performed twice per week for 10 weeks. Most participants were able to space individual sessions equally apart from week to week, and no session was conducted less than 48 hr from the previous session. Each session lasted approximately 30–40 min. Participants were instructed to notify the researcher if any adverse reaction occurred. This was defined as experiencing a distressing degree of one or more of the following five symptoms: fatigue, headache, spaciness, wired or hyperenergetic, and/or nausea. These symptoms could indicate possible overstimulation from the previous session, but no research participant experienced signs of overstimulation.

Data analysis. Descriptive statistics were used for demographics and outcomes. Tests for normality and reliability were confirmed. Paired *t*-tests were used to compare baseline to final study data points, and ANOVA for repeated measures was used to compare data collected at baseline, after 10 sessions, and then at 20 sessions. All tests were conducted using an alpha level of 0.05. The Beck Anxiety and Depression Inventories and the QOLI were scored, and a report was generated by Pearson Assessment. The PSS was scored, and a report was generated by Psychological Assessment Resources.

Results

A total of 33 persons enrolled in the study with 20 of them completing all 20 sessions and instruments at baseline, midpoint (10th session), and completion of 20th session. Attrition was due to participants not completing the online assessments or had difficulties adhering to the data collection schedule of twice per week. Twelve females and eight males participated, with ages ranging from 28 years to 77 years, the mean age being 48 ± 15.9. Twelve were college educated, and the other eight completed high school. Occupations were varied and are shown in **Table 1** along with demographics. All were Caucasian and non-Hispanic.

The focus of this study was to examine how clinical symptoms of depression, anxiety, PTSD, and QOL changed after receiving I-MCN intervention. Symptoms were assessed at baseline, 10 sessions, and 20 sessions. Anxiety and depression showed significant reductions by the 10th session (BAI paired group *t*-test, $t = 4.47$, $p < .001$; Beck Depression Inventory II paired group *t*-test, $t = 6.46$, $p < .001$). Quality of Life Inventory scores had also improved significantly (paired group *t*-test, $t = -2.76$, $p = .013$). Of noteworthy relevance is that verbal reports by participants revealed improvement in depression and anxiety symptoms by the end of the first, second, and/or third weeks, but these data were not captured statistically. These downward trends in anxiety demonstrated that everyone may have not felt the same level of effect, but the negative trend indicates a certain statistical level of effect that should be evaluated within a larger sample.

Table 1. Demographic characteristics of 20 subjects who received the intervention

Variable	*n*
Gender identity	
Females	12
Males	8
Racial identity	
Caucasian	20
Primary reason for seeking treatment	
Anxiety	6
Fatigue	3
Physical pain	2
Cognitive concerns	1
Occupations	
Office receptionist/manager	2
Marketing/sales	3
Health care	3
Business owner	2
Homemaker	2
Detention officer	1
College student	1
Disabled/retired	6

The observed reduction in anxiety and depression total scores at the 20th session between the pre–I-MCN and post–I-MCN assessments remained statistically significant with large Cohen's *d* (BAI paired group *t*-test, $t = 4.16$, $p = .001$, Cohen's $d > 1.0$; Beck Depression Inventory II paired group *t*-test, $t = 5.97$, $p < .001$, Cohen's $d > 1.0$). QOLI had a significant increase in scores with a medium effect size (paired group *t*-test, $t = -3.46$, $p = .003$, Cohen's $d = 0.78$). Finally, the PTSD subscale of the PSS demonstrated a statistically significant difference after 10 treatments of the IASIS intervention (paired group *t*-test, $t = 2.60$, $p = .023$) and after 20 treatments (paired group *t*-test, $t = 3.31$, $p = .006$, Cohen's $d = 0.84$). For the suicide risk subscale of the PSS, no significant improvements were noted after 10 or 20 treatments (20 weeks: paired group *t*-test, $t = 1.64$, $p = .120$; paired group *t*-test, $t = 0.808$, $p = .431$). The four participants who scored high on suicidal ideation on baseline assessment reported verbally and in writing on the Observation Report reduction in suicidal ideation signs and behaviors, although statistical improvement was not shown on the suicide risk screen scale of the PSS.

Table 2 demonstrates a summary of statistically significant outcome scores, and **Table 3** demonstrates baseline, midpoint, and final outcome scores. Analysis of variance statistics for outcome variables included the following: BAI $F(2, 16) = 10.9$, $p < .001$, multivariate partial eta-squared = 0.58, Beck Depression Inventory II $F(2, 16) = 20.6$, $p < .0001$, multivariate partial eta-squared = 0.72, and QOLI $F(2, 16) = 6.2$, $p < .01$, multivariate partial-eta squared = 0.42.

Discussion

Our exploratory pilot study demonstrated significant improvement in depression, anxiety, and PTSD in the general population following I-MCN. This study begins to address the large gap in the current literature, which has left the potential benefits of I-MCN in treating mental health disorders largely unexplored. This is especially true for disorders that may be considered clinically minor but are distressing enough to interfere with daily QOL. To the best of our knowledge, there has only been one study to date (Huang et al., 2017) that demonstrated the benefits of I-MCN in treating postconcussive symptoms. However, Huang's study population focused on persons with traumatic brain injury, and depression and anxiety were ancillary measures collected as part of the post-concussive symptom measurement. This makes our study the first of its kind, particularly with a general population in which these overlapping comorbidities existed.

Previous studies have focused on the efficacy of various types of neurofeedback for mental health disorders. Populations explored include survivors of traumatic brain injury and intimate partner violence (Brown et al., 2019), those presenting with depressive symptoms (Kaur et al., 2019), and veterans exhibiting PTSD (Fragedakis & Toriello, 2014). Results have been generally positive, but the time and cost commitments of traditional neurofeedback may not be feasible, because traditional feedback typically requires numerous sessions spanning across several months (Marzbani et al, 2016). Such drawbacks are particularly challenging for therapies targeting persons suffering from depression, anxiety, and PTSD because these disorders are in part characterized by amotivation, avoidance, and social anxiety (NIMH, 2022). IASIS micro-current neurofeedback presents an attractive alternative because it takes about 30 minutes or less per session; results are noted after 10 sessions or often, much sooner; it is completely painless; and most people find it to be relaxing.

There is a richer literature to draw on if alternative methods are expanded to include various forms of neuromodulation, although it is notable that such studies are not uniform across clinical populations. For example, there is a dearth of studies that examine the efficacy of either neurofeedback or neuromodulatory alternative methods for the treatment of PTSD. A chart review found that TMS resulted in significant symptom alleviation of comorbid PTSD and major depressive disorder in veterans (Philip et al., 2016). However, TMS confers a number of disadvantages as well, including mild patient discomfort, patient anxiety before and during treatment, facial twitching, and daily sessions for about six weeks with eventual tapering off (Lindner Center of Hope, 2022). Presently, there are insufficient data on how I-MCN would affect adults diagnosed with PTSD.

Multiple studies using direct current transcranial stimulation tDCS have demonstrated significant improvements in major depressive disorder, anxiety disorder, PTSD, poststroke depression, and traumatic brain injury (Aparicio et al., 2019; McClintock et al., 2020; Meena et al., 2021). Most studies were randomized controlled trials; however, many lacked adequate sample sizes and controls. Several reviews of neurofeedback and neuromodulation note that results across multiple studies are inconsistent or inconclusive, and that although most note therapeutic effects, these improvements may take several months and may not be long-lasting (Marzbani et al., 2016; Yokoi et al., 2017). In contrast to other methods that may take much longer, results in our study show that significant improvement was noted after only 10 sessions

Table 2. Measurements of significance for outcomes

Scale	*t*	*p*	Cohen's *d*
Beck Anxiety Inventory	4.47 (10 sessions) 4.16 (20 sessions)	.001 (10 sessions) .001(20 sessions)	1.09 (20 sessions)
Beck Depression Inventory II	6.46 (10 sessions) 5.97 (20 sessions)	<.001(10 sessions) <.001(20 sessions)	1.81 (20 sessions)
Quality of Life Inventory (T-scores)	−2.76 (10 sessions) 3.46 (20 sessions)	.013 (10 sessions) .003 (20 sessions)	0.78 (20 sessions)
PTSD and Suicide Screener—PTSD subscale	2.60 (10 sessions) 3.31 (20 sessions)	.023 (10 sessions) .006 (20 sessions)	0.84 (20 sessions)

Note: PTSD = post-traumatic stress disorder.

Table 3. Questionnaire responses over the course of 20-session I-MCN intervention

Scale	*n*	Baseline	Session 10 (Mean ± SD)	Session 20	Relationship Change	*p*
Beck Anxiety Inventory	18	16.30 ± 9.1	10.39 ± 6.7	7.75 ± 6.4	—	.001
Beck Depression Inventory II	18	26.1 ± 11.7	11.8 ± 6.3	8.4 ± 7.3	—	<.001
Quality of Life Inventory (T-scores)	19	31.5 ± 15.6	40.8 ± 12.7	43.0 ± 13.8	+	.003
PTSD and Suicide Screener—PTSD subscale	14	18.4 ± 9.4	14.2 ± 6.8	11.9 ± 5.6	—	.006
PTSD and Suicide Screener—Suicide risk subscale	17	4.8 ± 11.2	4.1 ± 1.3	4.5 ± 5.9	—	.431

Note: I-MCN = IASIS microcurrent neurofeedback; PTSD = post-traumatic stress disorder.

in those with depression, anxiety and QOL, and PTSD risk. Moreover, observational and verbal reports by participants indicated positive responses often by the second or third session, and about half of the participants noted improvement after the first session. There were no adverse effects reported throughout the study.

Implications and limitations

Findings of this study have meaningful implications for advanced practice nurses who treat clients for depression, anxiety, and/or PTSD in that this newer and cutting edge technology provides evidence for being an effective tool for reducing symptoms of these disorders in the general population. Supporting a holistic approach to care that "encourages the body to heal itself" is at the very core of nursing philosophy and practice. With the lack of sufficient mental health services to meet the needs of patients across the lifespan, an exploration of the effectiveness of I-MCN as a treatment modality or as an adjunct to traditional therapies is appealing. It is well known that medications used in mental health treatment may have concerning side effects, especially in vulnerable populations. Older adults are at high risk of polypharmacy and the exacerbation of chronic illness because of medication side effects. Similarly, children who take antipsychotic medication are at risk of weight gain, sedation, diabetes, high cholesterol, cardiovascular disease, and unexpected death. In very young children, antipsychotics might even cause developmental and other long-term adverse effects (Bushnell et al., 2021; Harrison et al., 2018). Other problematic issues of related medications in the general population that include nonadherence, intolerability, and other issues have been demonstrated (Dell'Osso et al., 2020; Marasine et al., 2020). IASIS microcurrent neurofeedback, on the other hand, has no known side effects, is safe, and can have profound benefits for patients across the lifespan, as noted in this study. Although further research is needed, findings show promise and suggest that I-MCN is an important tool for the advanced practice nurse. Although we recognize the infancy of the science behind I-MCN and therefore its current limited applicability to evidence-based practice, this pilot study demonstrates several advantages over other forms of neurotechnology: (a) It is passive, and the client is free to relax, read, or do whatever is desired; (b) efficacy begins sooner, many times by the end of the first, second, or third session; (c) no pain or discomfort is experienced during a session; (d) occurrences of "overstimulation" whereby a person may experience distressing headache, spaciness, a sense of being hyperenergetic, nausea, or fatigue are rare and can be easily reversed with a five minute procedure; (e) sessions are typically shorter in that preparation, and therapy time takes an average of 20–30 min; and (f) procedures have a multitude of flexible options to facilitate efficacy from one session to the next. Costs to clients receiving I-MCN can be very affordable depending on the practitioner. Many provide care based on a sliding scale, sometimes at no charge, and some require full payment for all, ranging from $100–150.00 per session. Most providers offer packages at discounted rates. Advance practice nurses or other licensed clinician who wants to incorporate I-MCN into their practice must complete I-MCN training and purchase I-MCN equipment. Other options are to either refer the client to an I-MCN practitioner or complete the training and partner with an existing I-MCN practitioner who has the equipment.

Implications for research are numerous and include the need for expanding this current study for larger, more generalizable populations. This pilot showed the instruments used were sound and easy to complete. Future studies should use randomized controls and include more racially and ethnically diverse samples. Furthermore, controlled studies comparing the use of other forms of neurofeedback, transcranial electrical stimulation, and/or TMS would build on the science of

best practices. Interventional studies using I-MCN may benefit from following procedures learned from this study. For example, efficacy was determined using a simpler procedure than the study conducted by Huang et al. (2017) requiring less time and burden on both therapist and client. Furthermore, as with the Huang et al. study, this research leaves many unanswered questions regarding other research-related opportunities for testing the effectiveness of I-MCN for other mental health symptoms and conditions. Researchers should partner with an I-MCN practitioner to assist in the intervention and include sustainability testing.

Although much was learned from this pilot study, several limitations are noted. The sample size was small (n = 20) and was homogenously Caucasian and non-Hispanic. There was some variation in timeliness of sessions when some participants could not come in for regularly scheduled sessions because of life events—notably, this may actually demonstrate the strength and resilience of the treatment, but it bears further study. Blinding in this study was not feasible. One person was trained to recruit and enroll participants, and another person who completed didactic and practicum training for I-MCN was responsible for conducting the I-MCN sessions and forwarding the scored outcome instruments to the statistician for analysis. The Principal Investigator monitored all aspects for compliance to the research plan. Finally, the current study lacks a statistical measure of post–final session effects. Original plans were to collect data at the 15th and 20th week after the final session to explore sustainability, but response rate was too poor for reporting because of coronavirus disease 2019 and other individual participant factors. Most respondents completed the study around March 2020, when coronavirus disease 2019 became a major issue in Texas. More aggressive follow-up was deemed unwise because researchers did not want to put additional pressures on participants because of the nature of coronavirus disease 2019 effects on daily life. In addition, the university's Institutional Review Board put a hold on all research during most of the coronavirus disease 2019 pandemic, and collecting data several months after the last I-MCN session would not have been meaningful. Finally, the possibility that threats of self-reported bias and placebo effects cannot be ruled out in this study. Participants were instructed to respond honestly to survey items and explanations as to why this was important were provided. No specific strategies were implemented to control for placebo effects, and this is to be considered in light of the findings.

Despite these limitations, the current study builds substantially on the only other study examining the effect of I-MCN on mental health outcomes. Huang et al (2017) used imaging to show pre–I-MCN and post–I-MCN changes in brain activity, and although we did not have comparable imaging, our study has its own strengths. Sampling was derived from the general population (including those with mild symptoms), and we used outcome-specific and psychometrically sound tools, a less complex procedure that included an average of five instead of 10 site pairs, and an individualized and flexible, participant response-specific procedure. Taken together, findings from this study and those of Huang et al (2017) should serve as a springboard for future research and innovations in clinical practice for the treatment of traumatic brain injury-related symptoms and for depression, anxiety, and PTSD.

Conclusions

IASIS microcurrent neurofeedback is a relatively new technology that has been used only in the past decade. Anecdotally, it has shown great promise in treating mental health and symptoms associated with other conditions. However, before the current study, these effects had only been demonstrated in a small study on mild traumatic brain injury (Huang et al., 2017). In this article, we expanded the scientific basis for the effectiveness of I-MCN on persons with depression, anxiety, and PTSD. This study should be built on to develop an evidence-based practice foundation for IASIS practitioners to follow to facilitate therapeutic efficacy. Finally, although we found I-MCN to have a significant positive effect on mental health symptoms overall, and that there are trends for which site placements, protocol levels, and exposures were efficacious, we also noted that there were outliers. This reinforces our knowledge that everyone's brain is different, and that contextual factors must be taken into consideration before initiating therapy. There is tremendous need for expanding noninvasive therapies for increasing mental health problems noted today. IASIS microcurrent neurofeedback may be helpful in meeting the ever-increasing mental health challenges experienced in today's world.

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