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The effect of pulsed electromagnetic frequency therapy on health-related quality of life in military service members with chronic low back pain

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ABSTRACT

Background: In the U.S. military, chronic low back pain is among the most frequent complaints for medical visits, lost work time, and attrition from active duty and the deployed setting by service members.
Purpose: The aim of this pilot study was to determine whether adjunctive treatment with pulsed electromagnetic frequency (PEMF) produced significant variability in chronic low back pain symptoms and secondary health-related quality of life, mental health and disability outcomes.
Methods: Prospective, randomized pilot study with repeated measures at baseline, post-treatment, and 1 month follow-up for two groups: usual care (UC) vs. UC + PEMF.
Findings: In a convenience sample of 75 service members, health-related quality of life mental and physical component scores were significant: $F(2, 104) = 4.20$, $p = .018$ ($\eta^2 = .075$) and $F(2, 104) = 4.75$, $p = .011$ ($\eta^2 = .084$), respectively; as was anxiety symptom severity: $F(2, 104) = 5.28$, $p = .007$ ($\eta^2 = .092$).
Discussion and Recommendations: Adjunctive treatment with PEMF demonstrated improvements in service members' overall physical health-related quality of life with expected, yet statistically nonsignificant improvements in reported pain and LBP-related disability. There were significant between group differences in anxiety symptom severity with higher symptoms reported by the UC + PEMF group, surprising findings that warrant further investigation.

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Background

In the U.S. Armed Services, mechanical low back pain (LBP) is a significant public health problem that affects the health and fitness of military service members (SMs) and overall mission readiness. It is one of the principal reasons SMs seek care in the deployed setting; and between 2000 and 2009, it was the primary diagnosis for more than 7 million ambulatory care

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visits and 31,625 hospitalizations (Clark & Hu, 2015). In addition, across all branches of the Armed Services, back-related injuries rank among the top five diagnoses seen for outpatient visits accounting for more than 2.35 million limited-duty days ordered by health care providers between 2000 and 2009 (Freburger et al., 2009; Stanton et al., 2008). Lost training time and limited duty are important indicators of the relative cost of LBP as it pertains to military readiness. Furthermore, current estimates are that approximately 25% of people with acute LBP experience recurrent episodes over the course of a year and 7% to 10% progress to a chronic state (Freburger et al., 2009; Stanton et al., 2008). For SMs who progress from acute to chronic low back pain (cLBP), they can experience significant physical, psychological, and social sequelae that affect their long-term functioning, quality of life, and employability (McGeary, McGeary, Moreno, & Gatchel, 2016; Outcalt et al., 2015).

In 2011, the Army Pain Task Force reported that military health care providers overprescribed opioid analgesic medications for the treatment of chronic pain conditions (Office of the Army Surgeon General, 2010). This trend resulted in higher rates of opioid abuse, misuse, and addiction as well as the development of performance-altering side effects among SMs when compared with a decade prior. As a better understanding of the physiologic basis of chronic pain perception and transmission has emerged, there has been a renewed emphasis in exploring alternatives to traditional pharmacologic pain management and documenting their treatment effectiveness.

Lack of scientifically derived evidence to explain the mechanism of action early in the development of devices that delivered electrical microcurrents to treat pain slowed the acceptance of pulsed electromagnetic frequency (PEMF) therapy as a complementary therapy by the U.S. mainstream medical community despite its widespread use in European countries. The Biomodulator (Senergy Medical Group, Irving, TX), although approved by the Food and Drug Administration as a transcutaneous electrical nerve stimulation (TENS) device, is not actually a TENS device in the traditional sense, other than it delivers an electrical current transcutaneously (Tennant, 2005). Unlike TENS devices that deliver 1 to 80 mA of electrical current, PEMF devices deliver short bursts of electrical microamperes (μA), which are millionths of an ampere, to injured tissues without producing heat or interfering with nerve or muscle function (Al-Mandeel & Watson, 2008). Microcurrent levels between 20 and 500 μA, such as those delivered by the Biomodulator device, appear to realign the natural electrical balance that exists within the cells that became disrupted because of injury (Strauch, Herman, Dabb, Ignarro, & Pilla, 2009). The proposed biophysical mechanism of action is that the PEMF waveform affects ion/ligand binding at cellular surfaces and modulates a cascade of biochemical effects that accelerates tissue repair, diminishes edema, and decreases pain by increasing blood and lymph flow (Hagendoorn et al., 2004), and promotes tissue regeneration and remodeling through the increased production of growth factors (Aaron, Boyan, Ciombor, Schwartz, & Simon, 2004). To date, studies demonstrated the efficacy of PEMF therapy in treating chronic pressure ulcers (Kloth et al., 1999); decreasing edema in acute ankle sprains (Martinelli et al., 2015); decreasing pain in acute whiplash injuries (Foley-Nolan et al., 1991); improving postmastectomy lymphedema (Mayrovitz, Macdonald, & Sims, 2002); and promoting bone growth for the treatment of nonunion fractures, failed fusions, and pseudoarthrosis (Brighton, 1981).

Borrowing from the Biopsychosocial Model of Chronic Pain (Turk & Monarch, 1996), comorbid mental health conditions and disability have been well-established correlates with chronic pain conditions (Kazis et al., 1998; Niles, Mori, Lambert, & Wolf, 2005; Otis et al., 2010; Phillips et al., 2016). Patients with a history of chronic depression, post-traumatic stress disorder (PTSD), and anxiety have a psychological vulnerability to developing chronic pain syndromes (Ratzliff, Unutzer, Katon, & Stephens, 2016). In addition, this affective vulnerability can increase the intensity of a person's response to pain or increase their likelihood of developing pain-related disability (Ratzliff et al., 2016). Given the 14 years of sustained war and multiple deployments, rates of depression, anxiety, and PTSD have increased dramatically among SMs, as have chronic pain conditions (Outcalt et al., 2015; Phillips et al., 2016). At the individual level, patient self-reports of health-related quality of life (HrQoL) have become important measures to assess treatment effectiveness, especially for patients with cLBP, because the complete absence of pain may not be an attainable treatment goal (Sofko, Currier, & Drescher, 2016). To date, no rigorous studies were found that demonstrated the effectiveness of PEMF in treating cLBP symptoms or explored the effect of PEMF treatment on the secondary biopsychosocial sequelae of chronic pain in military SMs. The purpose of this study was to determine whether quantitative differences in cLBP symptom intensity differ between individuals receiving usual care (UC) comprising medication management and cLBP education and those receiving UC plus adjunctive PEMF treatment delivered via the Biomodulator device. The secondary effects of these treatments on the biopsychosocial secondary sequelae of chronic pain (comorbid depression, anxiety, and PTSD symptoms, and mental and physical HrQoL) were also examined.

Methods

Design

This was an open-label prospective randomized controlled study with repeated measures at