Treating Chronic Pain Using the *Oska Pulse* Device: A double blind clinical trial with placebo.

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Abstract. Disrupting the day-to-day lives of 100 million people, chronic pain is the leading cause of long-term disability in the United States and affects more people than diabetes, heart disease and cancer combined. Pain management techniques vary case-to-case, dependent on pain severity and location, patient medical history, and clinician recommendations along with other variables. One emerging pain attenuation technique is Pulsed Electromagnetic Field Therapy, or PEMF. Utilizing optimized electromagnetic wavelengths targeting chronic pain, preliminary studies on PEMF suggest it is a promising nonpharmacological pain management tool. The present study examined the efficacy of the *Oska Pulse* in a double blind clinical trial with a placebo device. **Participants.** 30 patients with chronic shoulder, back, or knee pain from local pain management clinics and were randomly assigned to either the *Oska Pulse* or *placebo* group before participating. With full informed consent, each subject agreed to use the device on his or her chronic pain area for two weeks, according to an established clinical protocol, recording progress in a daily log. **Results.** Using a one-tailed t-test to compare group means, statistical analyses revealed significant reduction in pain in the experimental group ($M_{Oska\ Pulse}$ = -0.9, $SD_{Oska\ Pulse}$ = 1.14) compared to the placebo group ($M_{Placebo}$ = -0.09, $SD_{Placebo}$ = 0.7) after 14 days; t(17) = 2.03, p = .029. **Conclusion.** PEMF using the *Oska Pulse* provided significantly greater pain reduction in the participants using the *Oska Pulse* compared to those using the placebo. These results support the efficacy of PEMF therapy in treating chronic shoulder, back or knee pain. Further research should include larger sample sizes and explore the use of the *Oska Pulse* on other areas important in chronic pain management. These are promising results for nonpharmacological interventions in pain attenuation.

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Recently declared a nationwide public health emergency, the misuse and abuse of opioids in the United States takes the lives of more than 90 Americans every day.[1] The most recent report from the Center for Disease Control (CDC) recounted over 65,000 deaths from drug overdose over a 12-month period—a record high.[2] More alarming, however, is that drug

overdose deaths have increased every year since 1999, mirroring a similar trend in increased opioid sales.[3, 4] In fact, both the amount of prescription opioids sold and overdose deaths involving opioids have more than quadrupled since 1999.[4] As one of the most commonly prescribed medications to the 100 million patients experiencing chronic pain in the U.S. annually, opioids are integral to many pain management practices.[5 ,6] With the national spotlight increasingly focused on the hazards of opioid misuse, however, the time is now to find additional solutions that can assist in pain management.

While a plethora of addiction screening, education and prevention programs have been instituted in pain management practices, [7, 8] nonpharmacalogical treatment modalities have the potential to make chronic pain care safer. In response to the opioid crisis, one such program mandates that patients who need opioids for nonmalignant pain must first see a psychotherapist to assess suicide risk, and provide psychological support and stress reduction. In addition, these patients must also see an addictionologist to assess risk for addiction. Finally, this opioid safety model includes "non-drug" approaches to pain management, including exercise, physical therapy, and integrative medicine treatments.[9] Overall, there are a wide range of chronic pain treatment strategies, one of which is Pulsed Electromagnetic Field (PEMF) therapy.

Recent research identifies improvements in the treatment of chronic pain using PEMF therapy. Sutbeyaz et al.[10] tested low-frequency PEMF therapy on 56 women with Fibromyalgia. Random group assignment placed 28 women in a PEMF treatment group, while the 28-patient placebo group received a sham therapy. After receiving two 30-minute treatments per day for 3 weeks, researchers reported 52% reduction in life interference in the PEMF group, compared to just 11% reduction in the sham group. Overall, participants in the PEMF group reported statistically significant reductions in pain.[10] In an exploratory study of PEMF therapy's effects on

postoperative pain, Hedèn[11] also reports a three-fold decrease in subjective pain by the PEMF group compared to a placebo after only 3 days. Another study from 2014 evaluated the effects of PEMF and exercise on pain, muscle functioning, and muscle strength in patients with shoulder impingement syndrome (SIS).[12] These 56 patients, randomly assigned to a PEMF + exercise condition or placebo + exercise condition, completed a three week trial. Results indicated significantly higher levels of functioning and reduced pain in the PEMF group. The PEMF group also exhibited greater strength.[12] PEMF appears to be an efficacious adjuvant therapy in pain management. There is a need, however, for additional well-designed clinical trials. The present study evaluates the effectiveness of PEMF therapy on chronic pain patients in a two week double blind clinical trial with placebo using the *Oska Pulse* PEMF device.[13]

Methods

Participants. Thirty-nine patients with diagnosed chronic knee, shoulder, or back pain were enrolled in this study. To be included in the study, participants were required to be older than 18 years of age, be capable of providing full informed consent, and they had to have either chronic should, back, or knee pain. Participants were excluded from the study if they had vestibular disease, epilepsy, cancer, or a pacemaker. All patients participated under full informed consent. Nine patients withdrew throughout the trial for reasons including: lack of pain reduction, inability to follow the protocol, and difficulty using the device. Overall, 30 patients completed the trial.

Design. The trial used a between-subjects design to compare baseline to follow up change in pain between the two groups.

Materials. Each participant was provided a daily log to report their pain, stress, and daily use of the device. Pain and stress scores in daily log were based on a 10-point Likert scale (0 = no pain/stress, 10 = extreme pain/stress). Participants were sent home with either an *Oska Pulse* or a sham device. The sham device looked and functioned the same as the actual device, but did not emit any PEMF waves.

Procedure. Both patients and investigators were blinded as to real or placebo *Oska* device. Each participant was randomly assigned to either the *Oska Pulse* group (n = 15) or *Placebo* group (n=15). At intake, after signing full informed consent, each participant was briefed on the protocol. For two weeks, participants used the *Oska Pulse* or placebo while recording their pain, stress, and number of times using the device in a daily log. For the first seven days, all participants were instructed to use the device 4-6 times per day for 30 minutes at a time, recording their daily log scores around the same time (i.e. after dinner, before bed). For the second week, participants were asked to use the device only 2-4 times per day for 30 minutes at a time. Again, participants recorded their pain, stress, and usage in the daily log.

Upon completion of the trial, participants returned their devices and daily logs to the clinical trial coordinator. The coordinator then manually entered all data points into Excel, using the Data Analysis package to run between-subjects one-tailed t-tests. Assuming no detrimental side effects of the *Oska Pulse*, we chose a one-tailed t-test to evaluate pain and stress scores. This one-directional test focuses on *improvements* in pain conditions.

Results

A one-tailed between subjects t-test was performed to evaluate mean group differences in changes in pain and stress after days 7 and 14. After 7 days, the *Oska Pulse* group reported a

slight decrease in pain ($M_{Oska\ Pulse}$ = -0.455, $SD_{Oska\ Pulse}$ = 1.57), while the *Placebo* group reported a small increase ($M_{Placebo}$ = 0.091, $SD_{Placebo}$ = 1.44). Group differences were nonsignificant; t(20) = .847, p = .20). Further analyses showed significantly greater pain reduction in the *Oska Pulse* group ($M_{Oska\ Pulse}$ = -0.9, $SD_{Oska\ Pulse}$ = 1.14) compared to the placebo group ($M_{Placebo}$ = -0.09, $SD_{Placebo}$ = 0.7) after 14 days; t(17) = 2.03, p = .029 (See Figure 1) Group comparisons of stress produced no differences after day 7 or day 14.

Conclusion

This double-blind clinical trial with placebo provided valuable information on the efficacy of PEMF therapy in treating chronic pain. First, there was significantly more reduction in pain in the *Oska Pulse* group after 14 days of use than *Placebo*. These results suggest that the *Oska Pulse* is an effective tool in pain attenuation. Data analyses showed interesting trends in subjective pain scores. First, there was a slight increase in pain in the *Placebo* group after day 7, while the *Oska Pulse* group, on average, reported a decline in pain intensity.

This trial encountered some limitations. Incomplete trials and participant attrition, though expected, eliminated a number of participant datasets from analyses. These exclusions from analyses decrease statistical power and contribute to lower external validity of the *Oska Pulse* intervention. Future trials for this device will include larger sample sizes to account for participant dropout. Participants also cited using the *Oska Pulse* 4-6 times per day as a possible drawback. On the other hand, this study recruited any chronic pain patient from three busy private pain management practices. The results of this study are encouraging and suggest further research needs to be done to support the efficacy of PEMF in pain management solutions. The current opioid epidemic in the United States may be partially alleviated by adjunctive pain

management solutions. These techniques would be integral to the successful treatment of chronic and complex pain in patients.

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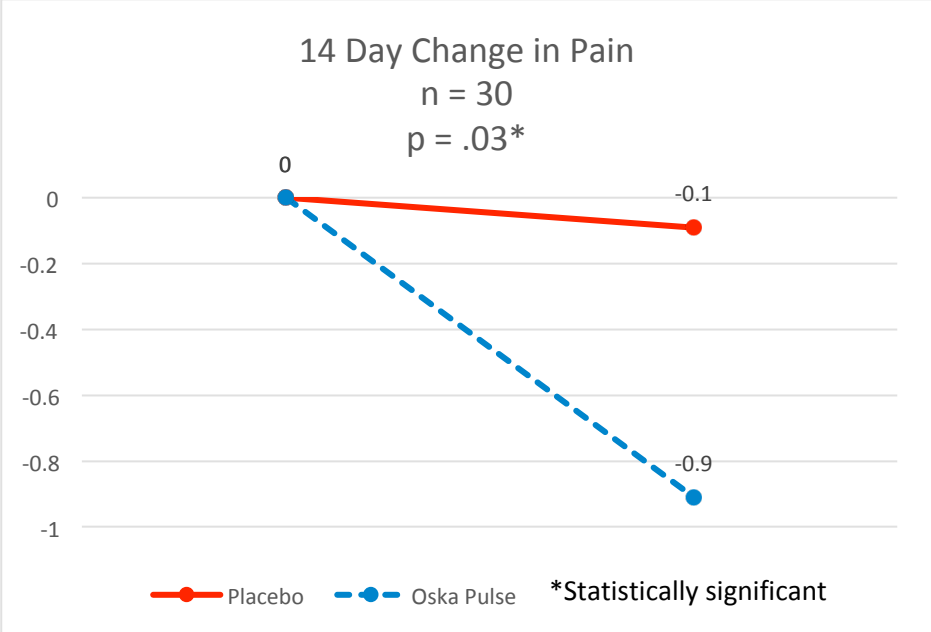
Figures


14 Day Change in Pain
n = 30
p = .03*
0
-0.1
-0.9
0
-0.2
-0.4
-0.6
-0.8
-1
Placebo
Oska Pulse
*Statistically significant