



BRIEF REPORT

A Pulsed Electromagnetic Field Therapy Device for Non-Specific Low Back Pain: A Pilot Randomized Controlled Trial

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ABSTRACT

Introduction: Low back pain (LBP) poses a significant burden of disease worldwide, and identifying safe and effective non-pharmacologic treatment options for LBP is a research priority. The aim of this study was to pilot a clinical trial of a portable pulsed electromagnetic field (PEMF) therapy device for subjects with mixed duration non-specific LBP.

Methods: This work was a randomized, double-blind, sham-controlled, parallel-group study conducted at a chiropractic school outpatient clinic. The primary end point was functional capacity measured by the Oswestry Disability Index (ODI) at baseline, 6 weeks, and 12 weeks. Analysis was conducted on the intent-to-treat population and as a trend of change in pain scores over time using the Freidman test of repeated measures.

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Results: Forty-two participants were randomized to receive usual care plus PEMF therapy or usual care plus sham, and 25 completed the study. Significant improvements in ODI scores from baseline to week 6 were reported in the experimental group ($\chi^2 = 14.68$, $p < 0.001$, compared with patients in the sham group, $\chi^2 = 4.00$, $p = 0.135$, n.s.). This difference persisted at week-12 follow-up. Adverse events were rare and mild.

Conclusion: It is feasible to conduct a clinical trial of a PEMF therapy device for non-specific LBP. This work shows that the device was safe and provides preliminary evidence of effectiveness in improving function in patients with non-specific LBP.

Trial Registration: ClinicalTrials.gov identifier, NCT03053375.

Funding: Aerotel Ltd.

Keywords: Electromagnetic fields; Low back pain; Pilot randomized controlled trial

INTRODUCTION

Low back pain (LBP) is among the most common health conditions accounting for the greatest individual and societal burden worldwide [1]. Results from the Global Burden of Disease study show that in 2015 over half a billion people worldwide had LBP of > 3-month duration, and LBP and neck pain are the leading

causes of years lived with disability in most countries and age groups [2].

It is typically not possible to identify precise anatomic causes to account for the appreciable negative impact LBP has on patients; consequently, most instances of LBP are labeled non-specific LBP [3]. This is widely described as “low back pain not attributable to a recognizable, known specific pathology (e.g., infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular syndrome, or cauda equina syndrome)” [4]. A range of different classes of interventions has been developed and tested in adults with non-specific LBP, and current clinical practice guidelines recommend a number of non-pharmacologic options as first-line therapies [5]. These include heat, massage, acupuncture, spinal manipulation, yoga, exercise, cognitive behavioral therapy, and others. While all of these interventions have demonstrated clinical benefit, none have been shown to consistently provide substantial, long-term reductions in pain with increased function for the majority of LBP sufferers [6, 7]. Pharmacologic therapies are also commonly used, although these have no greater evidence of effectiveness [5]. Particularly concerning is that opioid pain relievers are often used for LBP, despite limited evidence of effectiveness [8] and substantial evidence of risk of serious adverse events including death [9].

Identifying safe and effective non-pharmacologic treatment options for LBP is aligned with the Institute of Medicine’s national priorities for pain management [10]. Pulsed electromagnetic field (PEMF) therapy is one such treatment that is supported by promising results. PEMF therapy has been shown to improve bony fusion after spinal fusion surgery [11, 12] and decrease postoperative pain and swelling after plastic surgery [13]. Recently, investigators have demonstrated improvements in patients with chronic back pain after using PEMF therapy [14, 15]. However, these trials are preliminary and need to be replicated in rigorous fashion. Determining the effectiveness of a portable PEMF device as a treatment for LBP can significantly improve the management of LBP patients.

The purpose of this project is to conduct a randomized controlled pilot study comparing a portable PEMF device with a sham device for participants with mixed-duration non-specific LBP.

METHODS

Study Design

This was a pilot, randomized, double-blind, sham-controlled, parallel-group study assessing the effect of a PEMF treatment device on pain and disability in patients with non-specific LBP complaints (ClinicalTrials.gov identifier: NCT03053375). The work was conducted at the University of Bridgeport’s Chiropractic Clinic and was approved by the Institutional Review Board of the University of Bridgeport, Bridgeport, CT, USA (approval no. 2016-05-03). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Study Population

The inclusion criteria were: LBP intensity $\geq 4/10$ in the past week on the numerical rating scale (NRS); diagnosis of a non-specific LBP condition; age 18–75 years; fluency in written and spoken English; for female subjects, be postmenopausal, surgically sterile, abstinent, or agree to practice an effective method of birth control for the duration of the study if sexually active. Exclusion criteria were: LBP intensity $\leq 3/10$ on the NRS; diagnosis or suspicion of LBP caused by cancer, infection, inflammatory arthropathy, or other non-specific process; compression fracture; significant structural deformity; current or planned pregnancy; any electrically based implanted devices such as pacemakers defibrillators, spinal cord stimulators, insulin pumps; metallic implants (e.g.,

surgical fusion constructs, disc replacements) in the low back; status post any lumbosacral spine surgery; severe depression, schizoaffective disorders, or suicidal ideation.

Participants were recruited from the UBCC patient population through informational flyers, posters, and word of mouth among staff clinicians and trainees. We recruited among consecutive patients presenting for their first visit for an LBP complaint. If an individual expressed interest in participating, a member of the study team met with that person to assess eligibility. Those determined to be eligible were given full details about the study and invited to participate. Those who agreed to participate provided written informed consent prior to their involvement in the trial.

Study Procedures

Participants were randomized into active device or sham group using computer-generated tables to sequentially assign devices at the time of enrollment. Participants were instructed to self-treat with the device for 30 min, two times per day (8–12 h apart), every day for the first 6 weeks (initial treatment dose). After that, they were instructed to use the device for 30 min, one time per day, 2–3 days per week for the next 6 weeks (maintenance dose). A research assistant called the participants up to three times per week for the first week and then weekly thereafter to monitor for any changes or adverse effects and encourage compliance.

The PEMF device used in this study (MDcure[®], Aerotel Ltd., Holon, Israel, and Aerotel Inc. USA, New York, NY, USA) is an FDA Class 1 listed therapeutic device that delivers an extremely low-intensity electromagnetic field (nT; 10^{-9}) at a set of low (range 1–100 Hz) frequencies. Sham devices were externally identical to the active devices, except they were deactivated so that no electromagnetic field energy was generated when the devices were turned on. All other features were indistinguishable from the active units. Neither active nor sham devices generated any vibration, heat, or other tactile stimuli.

Usual Care

Participants in each group continued to receive usual care at their discretion throughout the study. We did not modify the treatment plans of the UBCC clinicians, nor did we restrict subjects from any treatments outside of the clinic. We examined the number of overall visits to the UBCC as a rudimentary measure of healthcare service usage. We did not assess any healthcare received outside of the UBCC clinic.

Patient-reported Outcomes

The primary end point was functional capacity assessed via the Oswestry disability index (ODI). We also measured pain intensity via the NRS. These were assessed at baseline, 6 weeks, and 12 weeks.

Statistical Analysis

Differences in age were assessed using Mann-Whitney, while differences in sex, marital status, and ethnic origin were assessed using chi-square tests. Analysis of the primary end point was conducted on the intent-to-treat population and as a trend of change in pain scores over time, using the Friedman test of repeated measures. Adverse events were summarized by number and type. Level of significance is 5%.

RESULTS

In total, 68 individuals were screened and 42 were enrolled in the study (Fig. 1). Subject demographics and baseline characteristics, including symptom duration and mean Oswestry and NRS scores, were similar between study groups (Table 1). Of the 42 enrolled, 25 completed the study and were analyzed. One missing measurement was imputed using the median scores method.

Primary End Point

As shown in Fig. 2, participants in the experimental group reported a significant

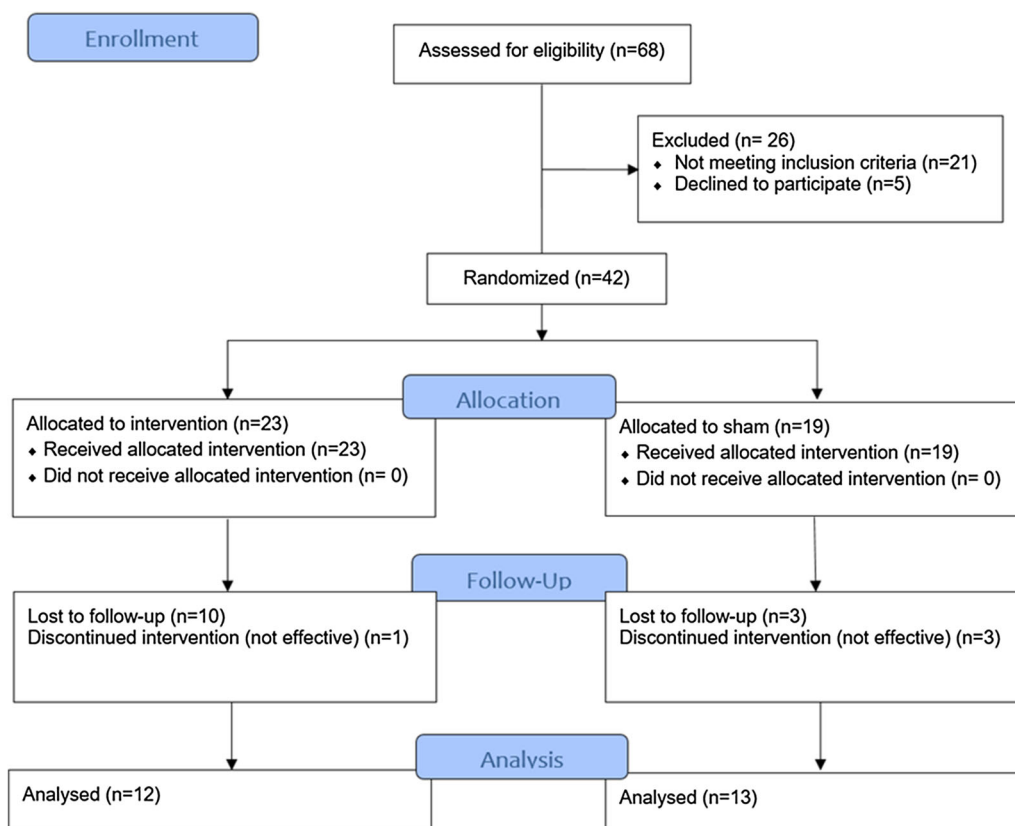


Fig. 1 Study flow diagram

improvement in ODI scores between baseline and week 6 (end of initial treatment), which persisted through the week-12 follow-up. Specifically, patients in the experimental group reported a more rapid improvement in functionality between baseline and week 6 ($\chi^2 = 14.68$, $p < 0.001$, compared with patients in the sham group, $\chi^2 = 4.00$, $p = 0.135$, n.s.).

Secondary End Point

The NRS analysis showed a trend of difference between groups. As seen in Fig. 3, subjects in the experimental group reported a significant decrease in pain intensity between baseline level and the week 6 end of treatment, which persisted through the week-12 follow-up. Specifically, patients in the experimental group reported a more rapid decrease in pain between baseline and week 6 ($\chi^2 = 17.33$, $p < 0.001$, compared with patients in the sham group,

$\chi^2 = 16.80$, $p < 0.001$) (66% vs. 42%). NRS scores were similar for the two groups at week 12.

Safety

Adverse events were reported in one participant (4.3%) in the active group and one (5.2%) in the sham group. None of the events were considered serious. Back pain from a new sports injury was reported in the active group and menstrual spotting, determined to be related to an intrauterine device, in the sham group.

Other Treatments

Groups were similar with respect to usual care received from the UBCC clinic during the study period. The active group received an average of 7.4 clinic visits and the sham group 7.1 visits. Visits consisted of multimodal chiropractic care,

Table 1 Subject demographics and baseline characteristics

	Sham (<i>n</i> = 23)	Active (<i>n</i> = 19)	<i>p</i> value
Female, <i>n</i> , (%)	14 (60.8)	10 (52.6)	0.756
Age (mean years)	37 ± 15	34 ± 13	
Marital status (%)			0.823
Single	65.2	73.6	
Married	26.1	21	
Divorced	8.7	5.2	
Race (%)			0.175
Asian	4.3	10.5	
Black	17.4	31.6	
White	60.9	26.3	
Not identified	17.4	26.3	
Symptom duration (%)			
Acute	39.1	47.4	
Subacute	4.3	5.3	
Chronic	56.5	47.4	
ODI (mean)	37.50 ± 15.77	37.36 ± 15.29	0.875
NRS (mean)	6.78 ± 1.67	6.52 ± 1.42	0.661

n number of subjects, *ODI* Oswestry disability index, *NRS* numerical rating scale

including spinal manipulation, manual therapies, and exercise instruction.

DISCUSSION

This pilot double-blind, randomized clinical trial presents encouraging results for the use of portable PEMF therapy to improve function and pain in patients with non-specific LBP. Both the active treatment and sham groups were closely aligned with respect to the distribution of acute, subacute, and chronic cases. We found

participants receiving usual care plus active PEMF therapy reported greater improvement in LBP at 6 weeks, and LBP-related function at 6 and 12 weeks, compared with those receiving usual care plus sham therapy. Adverse effects were very rare and not serious.

It is interesting that the active group was superior to the sham group regarding the NRS score at week 6 but similar at week 12. Prior work has shown that improvements in LBP intensity scores and function scores are often independent [16] and that functional recovery is a more meaningful outcome [17]. It is possible that differences in compliance with device usage may be related to the duration of pain intensity changes; therefore, future studies on the PEMF device should monitor this closely. While it was beyond the scope of this work to assess differences in responses between subjects with acute pain versus chronic pain, symptom duration may impact both compliance and outcome, particularly in light of the biopsychosocial context of chronic pain.

PEMF therapy has been shown to reduce expression of gene encoding for major proinflammatory cytokine IL-1 α and increase expression of major anti-inflammatory IL-10 in mice [18]. Other work demonstrated that PEMF therapy produces an anabolic effect on osteoblasts and chondrocytes [19, 20].

Prior work has shown that patients want to have information on and access to non-pharmacologic treatment options to manage various musculoskeletal pain conditions [21]. Participants in this study continued to receive usual care—which may have included pharmacologic therapies—at their discretion. The fact that we were able to recruit and enroll participants in this trial supports the hypothesis that there is a demand for PEMF therapy even among those non-specific LBP sufferers who receive other forms of care. Although we did not control for variation in usual care, we expect that this was similar between groups at baseline and after exposure to PEMF.

This work has several primary limitations. Although the study was a randomized, double-blind, sham-controlled trial, the sample size was relatively small because of attrition among enrolled participants. The most common

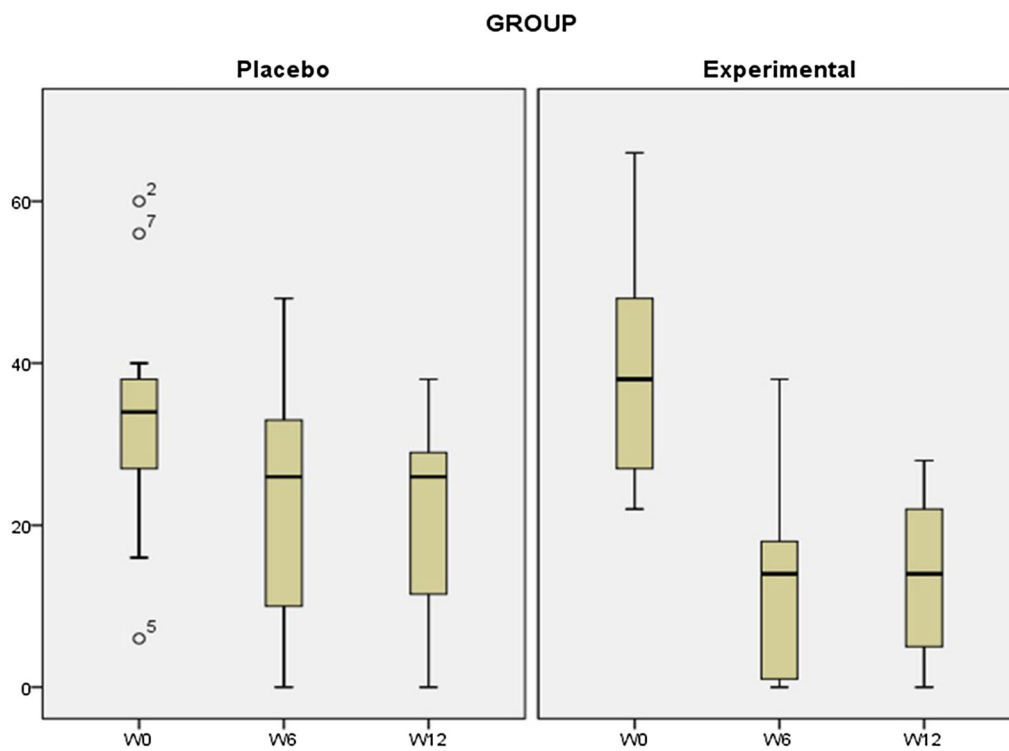


Fig. 2 Oswestry disability index scores

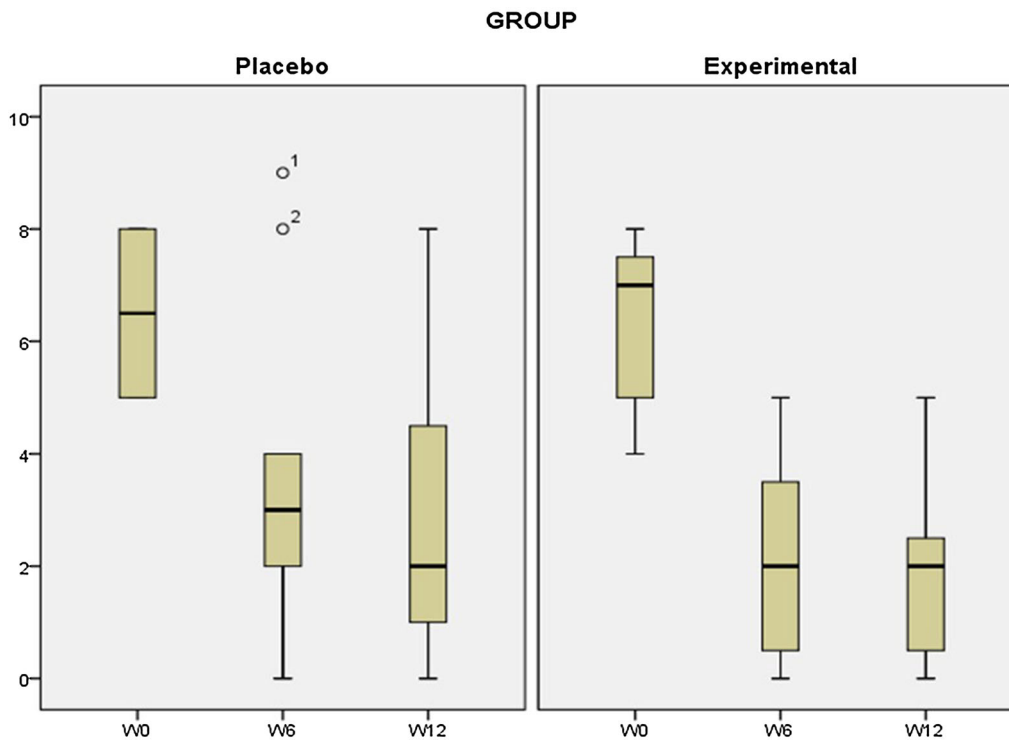


Fig. 3 Numerical rating scale scores

reasons reported for discontinuing were symptoms not improving or no longer interested in participating. We did not provide incentives to participants to encourage adherence, and future work should consider doing this. Nevertheless, we report results that are statistically and clinically meaningful, and data from this study can be used to inform the design and sample size of future studies. Although we encouraged participants to adhere to the device usage schedule, since the usage was self-directed ultimately we could not control the exact PEMF dosage the subjects received. However, this might be considered a positive from a pragmatic perspective since most home treatments for LBP (devices, topicals, medications) are typically used on an as-needed basis. While usual care received at the UBCC was similar between groups, we did not assess any care received outside of that setting.

This work provides evidence that it is feasible to conduct a randomized controlled trial of the MDCure PEMF device on patients with mixed duration non-specific LBP. The outcomes support the hypothesis that this device can be safe and effective for reducing disability and pain intensity in this population. Further investigation with a larger sample size is warranted. Future studies should also examine the optimal patient profile, the relationship between PEMF therapy and the use of other healthcare services, including analgesic medications, and the impact on healthcare costs.

CONCLUSION

It is feasible to conduct a clinical trial of a PEMF therapy device for non-specific LBP. This work shows that the device was safe and provides preliminary evidence of effectiveness in improving function in patients with non-specific LBP.

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Compliance with Ethics Guidelines. This work was approved by the Institutional Review Board of the University of Bridgeport, Bridgeport, CT, USA (approval no. 2016-05-03). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Data Availability. The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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