PILOT TRIAL: DOUBLE-BLINDED PLACEBO-CONTROLLED TREATMEN WITH A SPECIFIC PULSED LOW FREQUENCY MAGNETIC FIELD.

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ABSTRACT

Exposure to a specific pulsed electromagnetic field (PEMF) has been shown to produce analge (antinociceptive) effects in many organisms. In a double-blind, placebo controlled, and randomized prot chronic pain patients were exposed to PEMF (400 µT) through portable devices fitted to their head du twice-daily 40 min treatments for 7 days. The effect of PEMF on pain reduction was recorded using Visual Analogue Scale (VAS) and other measures. A significant net reduction in pain equivalent t moderate dose of opioid analgesic was observed due to active treatment (versus placebo) and the p returned during the following washout week.

INTRODUCTION

Low frequency pulsed electromagnetic field (PEMF, ≤ 1000 Hz, 400 mT/sec) has been shown to h analgesic effects in humans, mice and snails [1-5]. It is increasingly being used to treat a variety of dise and disorders in humans [6-8]. PEMF exposure is often correlated with pain reduction and the directio the effect is influenced by the specific magnetic field parameters and the availability of light/dark conditi [9]. Effects of magnetic field exposure on pain behaviours have been reported in rats, mice, snails, pige and humans [6,10]. Recently, a significant increase in thermal pain thresholds was reported among hu volunteers exposed to PEMF [8]. Encouraging work in our laboratory with chronic pain patients, specific rheumatoid arthritis and fibromyalgia patients has revealed a significant reduction in pain ratings follo the exposure to PEMF [1]. The present study was carried out to determine the analgesic effects of PE exposure on chronic musculoskeletal pain in humans.

MATERIALS AND METHODS

Subjects

Fifty chronic musculoskeletal pain patients (age range 18-80 years) were recruited from the Outpatient Cl at St. Joseph's Hospital, London, Ontario, Canada. The patient's health information such as past and pre diagnosis, sites of pain and medications were obtained in discussion with physicians. Informed consent obtained from all subjects after explaining the study orally and through printed information sheets. T protocol was approved by the University of Western Ontario Review Board for Health Sciences Resea Involving Human Subjects.

Data Collection

The entire study took 4 weeks. Twenty-four and 26 patients (N = 50) were double-blindly randomized to PEMF (treatment) and sham control exposure groups, respectively. Patients, who were assigned to PE were given a headset containing coils beneath the plastic ear coverings that were connected by wire to portable magnetism generating unit, which generated extremely weak PEMF (400 µT, = 1000 Hz, mT/sec) at the headset. Headsets given to sham control patients were identical to those given to PE exposed patients except for not delivering a PEMF waveform. In the first week, patients were asked to w the headset just above the ears twice daily for 7 days only. Each exposure session was for 40 minutes l

and at least 4 hours apart from the end of the previous session. Effect of headsets with and without PE was measured immediately before and after each session VAS (Visual Analog Scale), which rates the le of pain in patients at a particular time by striking a line between 0 (no pain) and 14 cm (worst possible pa During the experimental period, patients were allowed to keep their eyes open or closed and to continue t regular activities with the exception of activities that could cause the wetting of headset. Effect of one-w exposure to PEMF and sham control on pain levels was assessed daily during the second week (wash week), and weekly on the beginning of the third and fourth week using VAS. Pain measurements were d daily by subjects during the first two-weeks and the researcher separately carried out the weekly p measurements for all four-weeks. Data were analyzed using SPSS software (SPSS, Inc., Chicago, IL). M and standard errors were reported.

RESULTS AND DISCUSSION

Overall, there is a marginally significant interaction of pre-exposure versus post-exposure VAS (Tables 1 by treatment condition (sham versus active treatment) [$F_{1, 28} = 4.04$, $P = 0.05$, $Eta^2 = 0.15$, power = 0. However, power was sufficiently low to urge caution in interpreting the results and suggesting further st with a larger N. When examining the data (VAS) across the 7 treatment days, the treatment condition (sh versus active treatment) approaches significance but again with low power [$F_{1,24} = 3.23$, $P = 0.81$, Et 0.13, power = 0.42].

Patients exposed to PEMF showed higher reduction in VAS ratings and chronic musculoskeletal pain le in both sessions compared to sham control exposed patients during the first week (Table 1). This indic that the magnetic field plays a role in pain reduction. In people with chronic knee pain, two-week exposur magnetic field produced significant improvement in the individual's self-rated pain and physical functio [11]. In the present study, the percentage of pain reduction was not uniform throughout the first week study in both patients exposed to PEMF and sham control, and it slightly increased on the third day of first week in sham control and then decreased. It may be due to the fact that the headsets might not h fitted each individual correctly, which may lead to discomfort, and therefore, lead to interference.

In the washout week, an asymmetric pattern of VAS ratings and pain reduction percentage was reporte both PEMF and sham control exposed patients (Table 2). However, the patients who exposed to PE showed a slow increase in pain to return to initial pain levels. The patients who had the sham control de showed an initial increase in pain, followed by a decrease in pain toward the middle of the week, and fin an increase in pain at the end of the week. The specific pulsed MF exposure might have played a major in delaying the return of pain in PEMF exposed patients. The variation that occurred in the VAS rating the patients who received the sham controls in the second week may be due to the placebo effect.

Weekly average VAS ratings and percentage of pain level continued to fall until the third week and bega increase in the fourth week in PEMF exposed patients (Table 3). At the same time, patients exposed to sh control showed gradual decline in pain throughout the study. However, PEMF recorded higher rate of p reduction compared to sham controls in the first three-week. This is consistent with previous findings [that have shown that PEMF reduced refractory feet neuropathic pain in patients with peripheral neuropa even on 30-day follow-up. In the present study, an increase in pain begins in the fourth week after PE exposure, which suggests that the effects may last for up to 2 weeks after treatment. This increase in r pain may be due to the patient's increase in physical activity in response to the decrease in pain. It woul interesting to look at the amount of physical activity the patients took part in during the length of the stud the physical activity were to remain constant throughout the study then the treatment would have aided in reduction of pain for longer duration and subsequently increased the level of physical activity.

The results obtained in this study correlates with information collected through the McGill pain questionn and brief pain inventory (data not shown). The net reduction in pain was equivalent to a moderate dos opioid analgesic in PEMF exposed patients. It is often pointed out that both the endogenous and exoger opioid systems are influenced by PEMF exposure sessions in animals and humans [13-15]. When an op such as morphine used in combination with PEMF, the side effects of the opiate were reduced [4].

Table 1. Daily changes in VAS (Mean ± standard error) ratings and pain levels (%) in patients with chronic musculoskeletal pain during the exposure to PEMF and sham control in the first week. Initial VAS ratings for all patients were ≥ 5. The patients collected data before and after each session. PEMF = Pulsed electromagnetic field. VAS = Visual analogue scale.

Day in first week	PEMF						Sham control					
	First session			Second session			First session			Second session		
	VAS before exposure	VAS after exposure	Changes in pain level (%) after exposure	VAS before exposure	VAS after exposure	Changes in pain level (%) after exposure	VAS before exposure	VAS after exposure	Changes in pain level (%) after exposure	VAS before exposure	VAS after exposure	Changes in pain level (%) after exposure
1	10.739±0.827	9.400±1.104	– 12.469	9.202±1.381	8.794±1.351	– 4.434	9.037±0.641	8.250±0.639	– 8.709	8.497±0.592	7.973±0.491	– 6.167
2	9.663+1.395	8.603+1.282	– 10.970	9.462+1.338	8.263+1.207	– 12.672	8.718+1.022	8.195+0.895	– 5.999	9.262+0.562	8.694+0.383	– 6.133
3	9.744±1.497	8.325±1.307	– 14.563	9.624±0.952	8.034±0.997	– 16.521	9.088±0.876	9.262±0.999	+ 1.915	8.741±1.227	8.998±1.358	+ 2.940
4	10.270±1.420	8.653±1.208	– 15.745	10.278±1.508	8.557±1.408	– 16.745	9.910±1.040	8.890±1.294	– 10.293	9.431±1.035	8.854±1.375	– 6.118
5	8.346+1.854	7.617+1.566	– 8.735	10.218+0.899	8.013+1.279	– 21.580	9.523+1.271	8.292+1.312	– 12.927	9.614+1.250	8.928+1.508	– 7.135
6	7.875±1.740	6.766±1.491	– 14.083	7.817±1.631	6.426±1.603	– 17.795	8.775±1.056	7.713±1.185	– 12.103	8.296±0.982	7.802±1.021	– 5.955
7	7.969±1.442	5.836±1.241	– 26.766	7.651±1.548	7.253±1.641	– 5.202	8.912±0.814	8.174±0.910	– 8.281	9.032±1.153	8.580±1.295	– 5.004

Table 2. Daily changes in VAS (Mean ± standard error) ratings and pain levels (%) in patients with chronic musculoskeletal pain during the washout period in the second week. Initial VAS ratings for all patients were ≥ 5. The data were collected by patients. PEMF = Pulsed electromagnetic field. VAS = Visual analogue scale.

Day in second week	PEMF		Sham control	
	VAS	Changes in pain level (%)	VAS	Changes in pain level (%)
0	11.193±0.500	0	9.392±0.573	0
1	9.551+0.958	– 14.670	8.460+0.586	– 9.923
2	8.595±1.238	– 10.009	9.743±0.626	+ 15.166
3	8.929±1.362	+ 3.886	9.059±0.538	– 7.020
4	9.933+1.163	+ 11.244	7.679+0.561	– 15.234
5	9.510±1.028	– 4.259	7.796±0.658	+ 1.524
6	10.470±0.580	+ 10.095	8.640±0.580	+ 10.826
7	9.749+0.875	– 6.886	9.369+0.569	+ 8.438

Table 3. Weekly changes in VAS (Mean ± standard error) ratings and pain levels (%) in patients, with chronic musculoskeletal pain, who were exposed to PEMF and sham control. Initial VAS ratings for all patients were ≥ 5. The data were collected by the researcher. PEMF = Pulsed electromagnetic field. VAS = Visual analogue scale.

Week After exposure	PEMF		Sham control	
	VAS	Changes in pain level (%)	VAS	Changes in pain level (%)
0	11.193±0.500	0	9.392±0.573	0

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