Pulsed Electromagnetic Field Therapy in the Treatment of Pain and Other Symptoms in Fibromyalgia: A Randomized Controlled Study

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Running title: BEMER Magnetic Field Therapy in Fibromyalgia

Grant sponsor: The Medical Research Foundation of Jyväskylä Central Hospital, grant number KSSHPB1601.

Conflict of interest: none

ABSTRACT

Low-energy pulsed electromagnetic field (PEMF) therapy has been suggested as a promising therapy to increase microcirculation, which is of great concern in patients with fibromyalgia. This study evaluated the effectiveness of PEMF therapy on the treatment of fibromyalgia. A group of 108 women with fibromyalgia were allocated to a 12-week treatment period with an active Bio-Electro-Magnetic-Energy-Regulation (BEMER) device and a similar treatment period with an inactive device. Each patient received active and sham treatment in a random order. Pain and stiffness were assessed on a visual analog scale (VAS, 0-100), and functional status was assessed by the Fibromyalgia Impact Questionnaire (FIQ). Mean VAS pain scores before the active and sham treatment periods were 66 (SD 22) and 63 (22), respectively. After the treatment periods, mean VAS pain scores had decreased significantly in active treatment, -12, 95% CI [-18, -6], and in sham treatment, -11, 95% CI [-17, -5]. Similarly, the decrease in stiffness and the FIQ index after both treatments was statistically significant. However, per-protocol analysis showed no differences between active and sham treatments at any of the outcomes. This study demonstrated that low-energy PEMF therapy was not efficient in reducing pain and stiffness or in improving functioning in women with fibromyalgia.

Keywords: pulsed electromagnetic field; magnetotherapy; fibromyalgia; microcirculation; chronic pain; sham treatment.

INTRODUCTION

Fibromyalgia is a common syndrome, with a prevalence of approximately 5% in women and 1% in men [Vincent et al., 2013]. It is a condition of soft tissue pain, subjective muscular stiffness, unremitting fatigue, disturbed sleep, and cognitive dysfunction. Numerous possible mechanisms have been postulated to cause fibromyalgia, such as pain hypersensitivity [Gracely et al., 2002], hormonal influences [Cuatrecasas, 2009; Sadreddini et al., 2008], neurotransmitter imbalances [Becker and Schweinhardt, 2012], inflammation [Kadetoff et al., 2012], sleep dysfunction [Hussain et al., 2011; Moldofsky, 2010], mitochondrial dysfunction [Gardner and Boles, 2011; Pieczenik and Neustadt, 2007], small fiber neuropathy [Caro and Winter, 2015], and central sensitivity syndrome [Burgmer et al., 2009; Clauw et al., 2011; Yunus, 2007].

Patients with fibromyalgia have been reported as having lower peripheral circulation compared to controls, which has been assumed to be due to lower capillary density as well as due to altered autonomic regulation [Choi and Kim, 2015; Morf et al., 2005]. Research also suggests that the arteries of patients with fibromyalgia are often stiffer and less efficient than those of healthy controls [Lee et al., 2011], which has been seen as leading to poor circulation and a less efficient blood supply to connective tissues. The exact pathomechanism of fibromyalgia is still unknown, and there is no specific treatment for fibromyalgia.

Electric current therapies have been shown to relieve pain significantly in the short-term in fibromyalgia. These include both transcutaneous and percutaneous electrical nerve stimulation [Carbonario et al., 2013; Dailey et al., 2013; Deare et al., 2013; Mutlu et al., 2013;

Salazar et al., 2017] and a combination of different stimulation techniques, such as interferential current and ultrasound (US) [Almeida et al., 2003], and high-voltage pulsed galvanic current and US [Citak-Karakaya et al., 2006]. Pulsed electromagnetic fields (PEMF), which are one application of magnetotherapy, have also been used for the management of a variety of musculoskeletal conditions [Markov, 2015]. PEMFs differ from other electrotherapy modalities primarily because they are a subthreshold, low-power, and low-frequency electromagnetic waveform [Thomas et al., 2007]. PEMF has shown beneficial effects on osteoarthritis [Bagnato et al., 2016; Li et al., 2013], as well as on peripheral blood circulation [Sun et al., 2016], and healing of skin ulcers [Ieran et al., 1990] with a device producing magnetic field intensity of 2.8 mT. However, not all findings on the topic concur [Gupta et al., 2009; Hug and Röösli, 2012]. In patients with fibromyalgia, PEMF with a portable headset device has not shown significant effects on pain [Shupak et al., 2006; Thomas et al., 2007] whereas the application of a whole-body PEMF mat has been suggested to decrease pain in fibromyalgia patients [Sutbeyaz et al., 2009].

A PEMF system called Bio-Electro-Magnetic-Energy Regulation (BEMER, Innomed International AG, Triesen, Lichtenstein) has been reported as increasing vasomotion and microcirculation for improved organ blood flow using a series of half-wave–shaped sinusoidal intensity variations [Bohn et al., 2013; Klopp et al., 2013]. To date, however, there are no randomized controlled trials (RCT) where the effect of this PEMF device treatment on pain or other symptoms of fibromyalgia has been studied. Therefore, we wanted to test whether low-energy PEMF might have positive responses on symptoms in patients with fibromyalgia possibly via increased microcirculation. The purpose of this study was to investigate whether PEMF therapy can decrease pain and stiffness as well as improve functioning in fibromyalgia.

MATERIALS AND METHODS

Study design

This study was a randomized, double-blind placebo-controlled crossover study (NCT02310386; BEMER in the Treatment of Pain in Fibromyalgia). Recruitment and data collection took place between April 2014 and December 2016. The participants were adult women with fibromyalgia. The study protocol was approved by the Ethics Committee of the Central Finland Health Care District, and complies with the Declaration of Helsinki. All participants gave their written informed consent prior to enrollment, and were free to withdraw from the study at any time for any reason without consequences for the care provided.

Participant recruitment

The participants for this study were recruited through the patient record of the Central Finland Central Hospital. A database search was carried out for patients who had been visiting a specialist between May 2007 and November 2015, and who were diagnosed as having M79.0 (Rheumatism, unspecified), M79.1 (Myalgia), or M79.7 (Fibromyalgia) according to the International Classification of Diseases (ICD). As a result of this search, 1042 patients with established or potential fibromyalgia were sent information about the study and an invitation to participate. A total of 286 subjects indicated their interest in the study, and they were sent a health questionnaire with a prepaid return envelope to assess their preliminary eligibility to participate in the study. In addition to patients' sociodemographic and occupational data, the health questionnaire addressed medical condition, current medication, sleep quality and mood in the last week, alcohol and tobacco use, and treatments received in the previous three months. The eligibility criteria included being a woman aged 18–60 with diagnosed

fibromyalgia, persistent moderate or severe pain for more than 12 months, and a pain intensity of 5 or more on a scale of 0–10 within the last seven days. Twenty-three respondents declined to take part in the trial and 263 responders returned the questionnaire, of which 133 women were excluded from the study due to exclusion criteria. The exclusion criteria were as follows: an inflammatory rheumatic disease, another chronic pain disease besides fibromyalgia, mental illness, opiate addiction, drug/substance abuse, cigarette smoking, intellectual disability, and pregnancy or breastfeeding. The remaining 130 patients were invited to Central Finland Central Hospital for a visit to a physiatrist, who performed a clinical examination to ensure that the participants would not have any limitations to their study participation and to verify the presence of fibromyalgia. Fibromyalgia was defined according to the American College of Rheumatologys's (ACR) classification criteria, and it was confirmed if the patient had widespread pain for at least three months and if she had 11 or more tender points out of 18 specified points [Wolfe et al., 1997]. Fourteen patients did not meet the eligibility criteria during the clinical examinations, and eight participants withdrew from the study, thus leaving a sample of 108 participants for the study. Figure 1 shows the participant recruitment.

Randomization and blinding

The 108 patients who fulfilled the inclusion criteria were assigned to treatment with real electromagnetic field devices or with sham electromagnetic field devices according to a computer-generated randomization procedure with 30 consecutive balanced blocks of four patients (two active, two sham). Patients, the attending physiatrist (JY), the device deliverer (JM), the outcome assessor (AH), and the statistician (HK) were all blinded to the treatment-group assignment.

Treatments

In the first treatment period, 57 patients assigned to the active treatment and 51 patients assigned to sham treatment were instructed to use the electromagnetic field device (Bio-Electro-Magnetic-Energy-Regulation, BEMER) for 12 weeks. The device consisted of a pulse generator and field generation via flat, flexible electric coils, that is, a mat the patients are asked to lie down on twice a day: soon after waking up in the morning and before bedtime. The patients were advised, as suggested by the manufacturer, to drink a glass of noncarbonated lukewarm water prior to the treatments in order to enhance treatment effects. Figure 2 shows the general setup used for treatment application. The device produces a weak, low-frequency, pulsed electromagnetic field with a signal consisting of five series of pulses of half-wave–shaped sinusoidal variations. The pulse structure includes the sequences 1 to 5 as follows. Sequence 1: 0 μT for 1–3 s; sequence 2: 3–12 μT, a "base signal" for 12–16 s with a pulse frequency of 33.3 Hz (pulse width 30 ms); sequence 3: 30–150 μT, an "additional signal" with a pulse width of 100–200 ms; sequence 4: Sequences 2 and 3 are repeated 8 to 10 times; sequence 5: 0 μT for 1–3 s. The amplitudes of the individual pulses within the sequence follow an exponential function with an arcuate pattern. After 2 min, the magnetic field changes its polarity [Gleim and Klopp, 2014]. For this study, the duration of the signal sequences was set to a period of 8 min. The mat has six circular coils (diameter 14 cm) in two rows. The distance between the rows is 30 cm from center to center of the coils. Longitudinally the coils have distances 47 cm and 37 cm from each other. Since the coil geometry is very simple, the field distributions can be easily calculated. The current in the coil was adjusted to give a flux density of 50 μT in the center of the coil and in the plane of the coil (approximately on the mat). According to the manufacturer, the maximum flux density (peak value) is about 50 μT which is roughly the same as the Earth magnetic field.

The graph (A) in Figure 3 shows the magnetic field as a function of distance from the mat along the axis of the coil, and the graph (B) shows the variation of the flux density at a height of 5 cm from the mat. As can be seen, the field is practically localized within the area of the coils. Figure 4 shows the flux density map: the left edge is the axial symmetry axis (coil center) and the outer radius of the coil is 70 mm. The border between the blue and the greenish area corresponds to flux density which is 50% of the flux density at the center of the coil. Prior to the beginning of the study, the manufacturer labelled the devices as active or inactive, and the sealed code was given to only one investigator (SM) to be opened after the final statistical analyses. The active and inactive devices were identical in appearance, with sound and display indicator lights on during the setup and treatment. The handheld device with a light indicating that the magnetic field is on or off was removed from the package that was given to patients for therapy at home.

After the first treatment period in weeks 1–12, there was a washout period in weeks 13–16, during which there was no treatment and the participants visited the hospital in order to exchange the device for one labelled the opposite of what it had been during the first period for a second treatment period in weeks 17–28. The participants kept a daily diary in which they recorded the actual application of the electromagnetic field therapy device and the use of drugs for the treatment of fibromyalgia symptoms.

Outcome measures

Patients were evaluated at inclusion as well as at the follow-up measurements after the first treatment period, the washout period, and the second treatment period. The outcome measures were visual analog scale assessments of pain and stiffness of the past week ranging from 0 to

100 mm [McCormack et al., 1988]. In addition, all patients answered the Finnish version of the validated Fibromyalgia Impact Questionnaire (FIQ) [Gauffin et al., 2012]. The FIQ is a multidimensional self-administered questionnaire including 10 questions evaluating physical function, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and wellbeing. The resulting score (FIQ total score), which indicates the impact of the disease on life, ranged from 0 (no impact) to 100 (maximum impact) [Burckhardt et al., 1991]. We used the 10-item method for deriving a total score.

Sample size

Before the study, the estimated sample size for power calculation was determined with the goal of measuring an improvement in the VAS pain score as found in a previous study of fibromyalgia populations [Sutbeyaz et al., 2009]. Power calculations indicated that a sample of 110 patients (55 in each treatment), assuming a dropout rate of approximately 10%, would provide an 80% ($\beta = 0.20$) chance of detecting a 40% ($\alpha = 0.05$) difference in improvement between the active and sham treatments.

Statistical analyses

Mean and standard deviations are given as descriptive statistics. The main outcome variables were analyzed according to the per-protocol analysis principle by using the random effects models. The models were adjusted for period effect. The association between use of active and treatment devices and the changes in pain were examined with Pearson's correlation coefficient. The level of statistical significance was set at $\alpha \leq 0.05$. The data were analyzed using the STATA 14.1 statistical software package (StataCorp, College Station, TX).

RESULTS

Study population and baseline characteristics

Baseline demographic characteristics are presented in Table 1. The 108 patients had a mean age of 47.1 ± 10.0 (range 24–61) years and a mean body mass index 28.9 ± 5.4 (range 18.3–46.9). The mean fibromyalgia illness duration, determined as the time since the fibromyalgia diagnosis, was 7.1 ± 7.0 (range 0–31) years. The most commonly used medication to treat or reduce the symptoms of fibromyalgia was analgesics. Eighty-six patients (80%) were taking either prescription or over-the-counter analgesics at the beginning of the study. Ninety-two patients (85%) had one or more comorbidities. The most common comorbidities were different musculoskeletal problems, such as osteoarthritis, spondylosis, and low back pain (47%), lung and respiratory diseases (29%), cardiovascular diseases (22%), thyroid diseases (19%), neurological disorders (15%), mild mental disorders (12%), allergies (8%), and Type 1 or 2 diabetes (7%).

Dropout rate and harms

Of the 108 patients who started the treatments, nine dropped out during the study. Four patients dropped out during the active treatment period. The reasons were the following: worsened previous backache (n = 1) and unwilling to continue (n = 3). Five patients dropped out during the sham treatment period. The reasons for those dropouts were amplified overall pain and worsened irritable bowel syndrome (n = 1), lumbar herniated disc (n = 1), cervical herniated disc surgery (n = 1), chronic pneumonia (n = 1), unwilling to continue (n = 1). See Figure 1. Of the enrolled patients, 92% completed the study.

Considering the harms of the study, one patient experienced an amplified overall pain sensation and had worsened irritable bowel syndrome during the sham treatment period. A seven-day treatment break was used as a cure. After continuing the treatment with the same

sham device, the symptoms returned and the patient was withdrawn from the study. No adverse events occurred during the active treatment period.

Treatment results

After the experiment, both active and sham treatment showed a significant improvement in pain, -12, 95% CIs [-18, -6] and -11 [-17, -5] respectively; stiffness, -9 [-15, -4] and -11 [-17, -5]; and FIQ -5 [-8, -2] and -6 [-9, -3]. The baseline values and changes of pain, stiffness and FIQ after treatments are given in Table 2. There were no significant differences at any of the outcome measures between active and sham treatments (Fig. 5).

Mean treatment compliance, measured as attendance at all 168 planned, 8-min treatment sessions, was 134 ± 41 (80%) when using the active devices and 131 ± 44 (78%) when using the sham devices. There was no correlation between the frequency of using the device and a decrease in pain, being r = -0.11, 95% CI [-0.31, 0.10] in active treatments and r = -0.10, 95% CI [-0.31, 0.12] in sham treatments.

DISCUSSION

To the best of our knowledge, this is the first randomized, double-blind, sham-controlled study to examine the effect of low-energy PEMF treatment on pain, stiffness, and functional status in patients with fibromyalgia. This study showed that the treatment with an active device had no statistically significant improvement in pain, stiffness, or FIQ index over the sham treatment. All patients reported decreased pain, stiffness, and FIQ ratings across time, an occurrence describing the placebo effect. However, the reductions of pain and stiffness values in VAS, in the range of 9 to 12 mm, lacked hardly any clinical significance in magnitude [Bird and Dickson, 2001]. By the end of the study, the patients still experienced severe pain and stiffness. Treatment was tolerated well, and the treatment adherence was high (~80%).

Our finding is contrary to that of a previous RCT by Sutbeyaz et al. [2009] and a pilot study by Paolucci et al. [2016] showing that both PEMF and a nonpulsed magnetic field delivered by whole-body mats had beneficial effects on fibromyalgia patients' disease impact and pain intensity after somewhat short treatment periods. Instead, our finding is in line with another RCT by Alfano et al. [2001], who found no improvement from static magnetic sleep pads on functional status measured by FIQ, although the active magnetic sleep pads decreased pain intensity significantly more than the inactive pads did in the control group. However, the electromagnetic signals, dosage of the treatments as well as the study durations (three weeks in Sutbeyasz et al., 2009; four weeks in Paolucci et al., 2016; and six months in Alfano et al., 2001) were different than those in the present study. In addition, the results of the above-mentioned previous studies should be interpreted with caution due to the small sample sizes in each treatment arm, which increases the possibility that positive results are due to chance.

For the time being, how PEMF treatment might mediate therapeutic effects in fibromyalgia remains hypothetical. Overall, some evidence has been found that exposure to electromagnetic fields affects pain sensitivity (nociception) and pain inhibition (analgesia) [Del Seppia et al., 2007], whereas the inventors of the device used in this study suggest that functional improvements in microcirculation, lymphatic flow, and the immune system could stimulate local and higher homeostatic autoregulatory mechanisms [Gleim and Klopp, 2014]. However, from a physical point of view the effect of magnetic fields on human cells is via electromagnetic interaction. For static magnetic fields, only Lorentz force is relevant, i.e. force acting on a moving charge. Time-varying magnetic fields induce voltages (induction). Principally, in both cases the primary mechanism is the same: relative movement of magnetic field lines and the organ in question. In this case, time-varying fields are used and the assumed effect is the generated voltage via induction. Time-varying magnetic field induces an electromotive force which is a voltage around a closed loop through which the time-varying magnetic flux goes. We can estimate the value of the induced electric field by taking a loop having an equal size than the coils (r = 70 mm) just above the coil and the amplitude of the flux density of 50 μT at a frequency of 100 Hz. This will give a peak value of 0.48 mV for the electromotive force which corresponds to an electric field of 1 mV/m along the loop. Typically, electric potentials in a human body are some tens of millivolts and the corresponding distances from nanometers up to a millimeter. Even for the distance of 1 mm the estimated electric field would mean a potential difference of 1 μV. For neuron sizes the induced potential difference would be several orders of magnitude less. Therefore it is evident that a magnetic field equal to the Earth magnetic field (50 μT) at frequencies 10 - n x 100 Hz cannot have any physical effects on a human body, which supports the result of this study.

Regardless of the above-mentioned and assuming that PEMF therapy increases capillary blood flow in fibromyalgia, the question then arises of why use passive therapy to increase circulation, as it may not have an effect on tissue metabolism and pain. It has been well established that exercise increases microcirculation and tissue metabolism [Shang et al., 2012] as well as having many other benefits for health issues which may be of great concern in patients with fibromyalgia. For instance, exercise improves muscle strength and endurance, can help in weight control, and improves mood and sleep [Kujala, 2009]. Active therapy modalities, such as land-based aerobic [Busch et al., 2007] and resistance exercise [Busch et al., 2013; Valkeinen et al., 2004] as well as aquatic training [Tomas-Carus et al., 2008] have been shown to improve function and relieve pain in patients with fibromyalgia, and currently exercise is recommended for the treatment of fibromyalgia in several international guidelines [Ablin et al., 2013; Macfarlane et al., 2017]. In fact, the European League Against Rheumatism (EULAR), in their updated management recommendations, recently pronounced exercise as the only "strong for" therapy for the treatment of fibromyalgia due to the strong evidence for its effect on improvements in pain and physical function [Macfarlane et al., 2017].

This study has several strengths. First, we had a randomized double-blinded placebo-controlled treatment study with a long study duration. Second, all the patients, outcome assessors, and the statistician were blinded to the treatment group assignment. Third, we assume that our study results are rather precise because the sample size was large enough and the crossover design removes between-patient variation [Yang and Stufken, 2008]. Fourth, considering that high dropout rates are a major issue with crossover design [Mills et al., 2009], there were only a few dropouts in this study, so treatment compliance was high.

There are some limitations that might have influenced our study results. We used a crossover design despite some of its known disadvantages, specifically, period effect and carryover effect [Altman, 1991]. These methodological flaws, however, were to some extent overcome in this study by statistically adjusting for the period effect, and by counterbalancing the time between the first and second period sufficiently that the carryover effect was not assumed. Another disadvantage of the crossover design is that when participants are given several treatments, it increases the risk of losses during the study. However, in this study the dropout rate was low (8%) despite the relatively long duration of the study (28 weeks). We chose the crossover design initially because fewer patients are needed for it than for a corresponding parallel trial. In addition, from the ethical point of view, it is important that every patient receives both active and control treatment, though in a random order.

Conclusions

This study revealed that low-energy pulsed electromagnetic field treatment was no more effective than treatment with a sham device in reducing pain and stiffness or in improving functioning in women with fibromyalgia. Thus, pulsed electromagnetic field treatment cannot be recommended for treatment of fibromyalgia symptoms.

ACKNOWLEDGEMENTS:

We thank Innomed International AG, Lichtenstein and BEMER Nordic who kindly supplied BEMER devices. No additional support was provided. We also thank all of the patients for their valuable contribution to the study.

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FIGURE LEGENDS

Fig. 1. Flow chart of the recruitment process and inclusion of participants.

Fig. 2. Treatment setup with the device comprising a pulse generator and mat for generating a pulsed electromagnetic field.

Fig. 3. Variation of the flux density at a height of 5 cm from the mat (A), and the magnetic field as a function of distance from the mat along the axis of the coil (B).

Fig. 4. The flux density distribution of the coil. The left edge is the axial symmetry axis (coil center) and the outer radius of the coil is 70 mm.

Fig 5. Changes in pain, stiffness, and Fibromyalgia Impact Questionnaire index after 12 weeks of treatments with active device and sham device. The square denotes mean and the bars denote 95% confidence intervals.

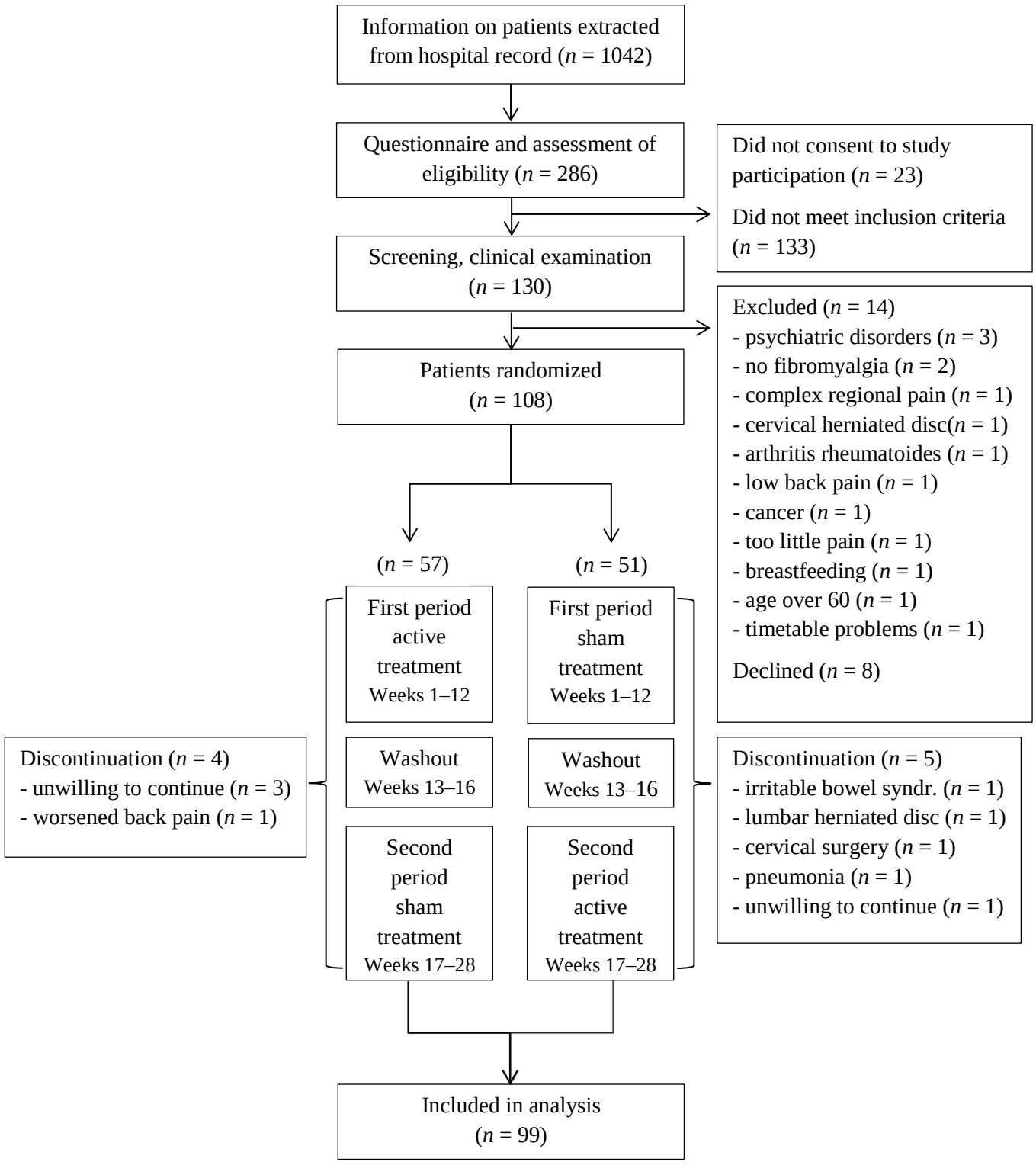

Information on patients extracted from hospital record (n = 1042)
Questionnaire and assessment of eligibility (n = 286)
Did not consent to study participation (n = 23)
Did not meet inclusion criteria (n = 133)
Screening, clinical examination (n = 130)
Excluded (n = 14)
- psychiatric disorders (n = 3)
- no fibromyalgia (n = 2)
- complex regional pain (n = 1)
- cervical herniated disc(n = 1)
- arthritis rheumatoides (n = 1)
- low back pain (n = 1)
- cancer (n = 1)
- too little pain (n = 1)
- breastfeeding (n = 1)
- age over 60 (n = 1)
- timetable problems (n = 1)
Declined (n = 8)
Patients randomized (n = 108)
(n = 57)
(n = 51)
First period active treatment Weeks 1–12
First period sham treatment Weeks 1–12
Discontinuation (n = 4)
- unwilling to continue (n = 3)
- worsened back pain (n = 1)
Washout Weeks 13–16
Washout Weeks 13–16
Discontinuation (n = 5)
- irritable bowel syndr. (n = 1)
- lumbar herniated disc (n = 1)
- cervical surgery (n = 1)
- pneumonia (n = 1)
- unwilling to continue (n = 1)
Second period sham treatment Weeks 17–28
Second period active treatment Weeks 17–28
Included in analysis (n = 99)

Figure 1.

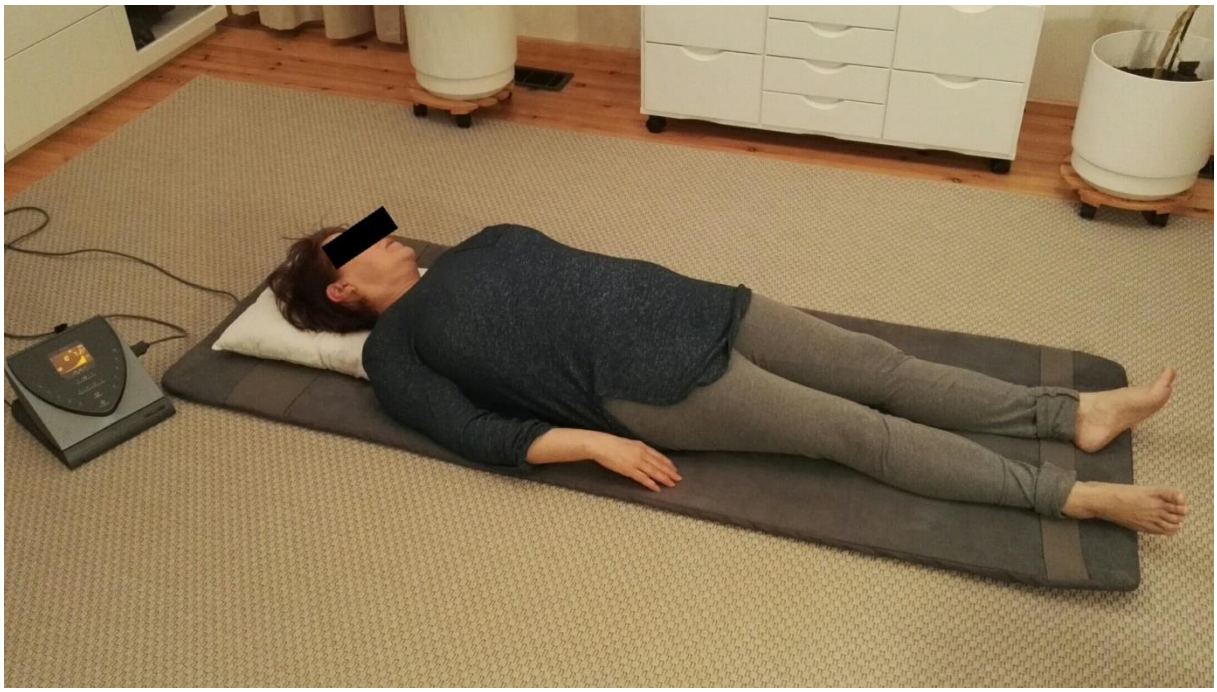
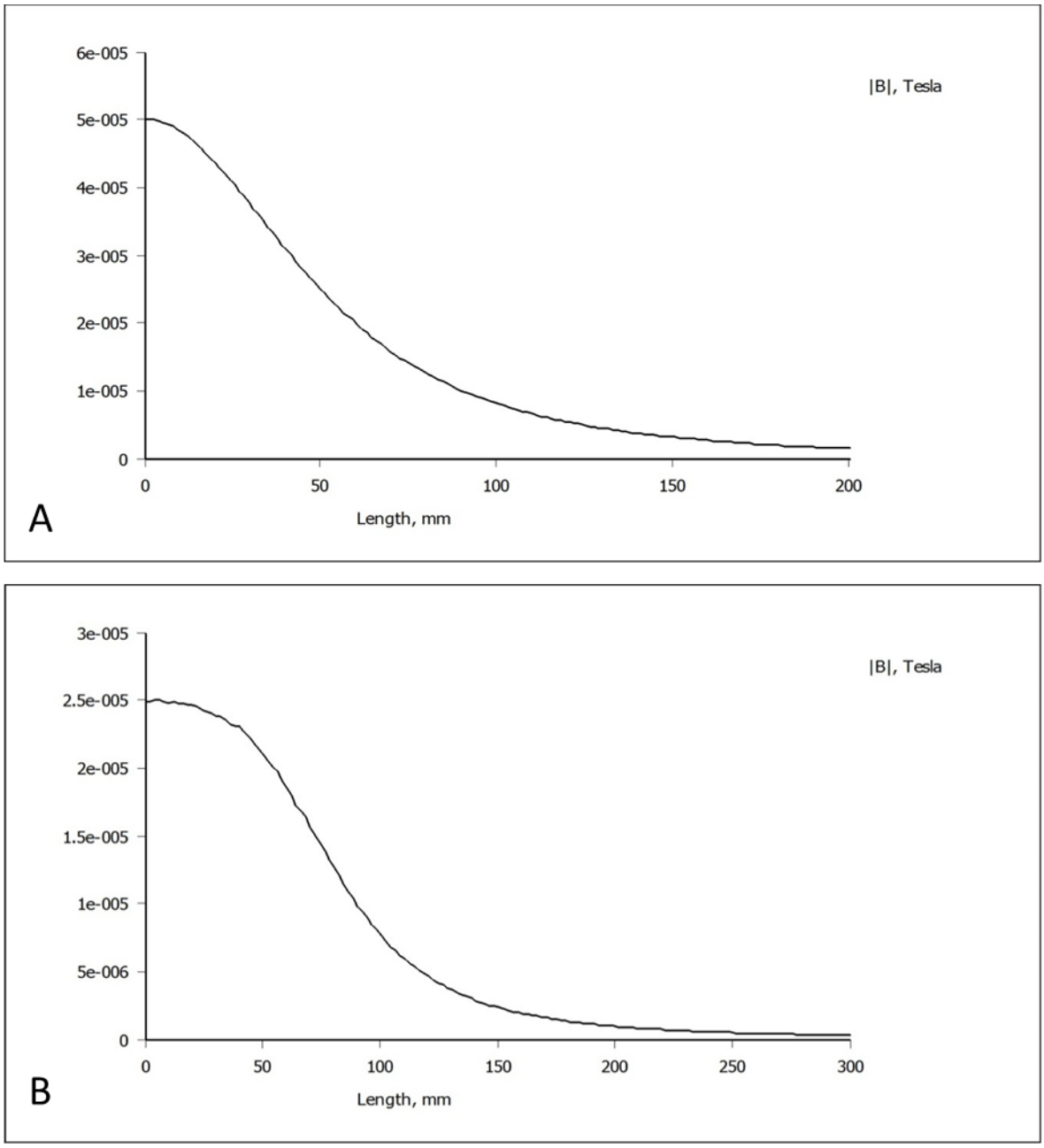


Figure 2.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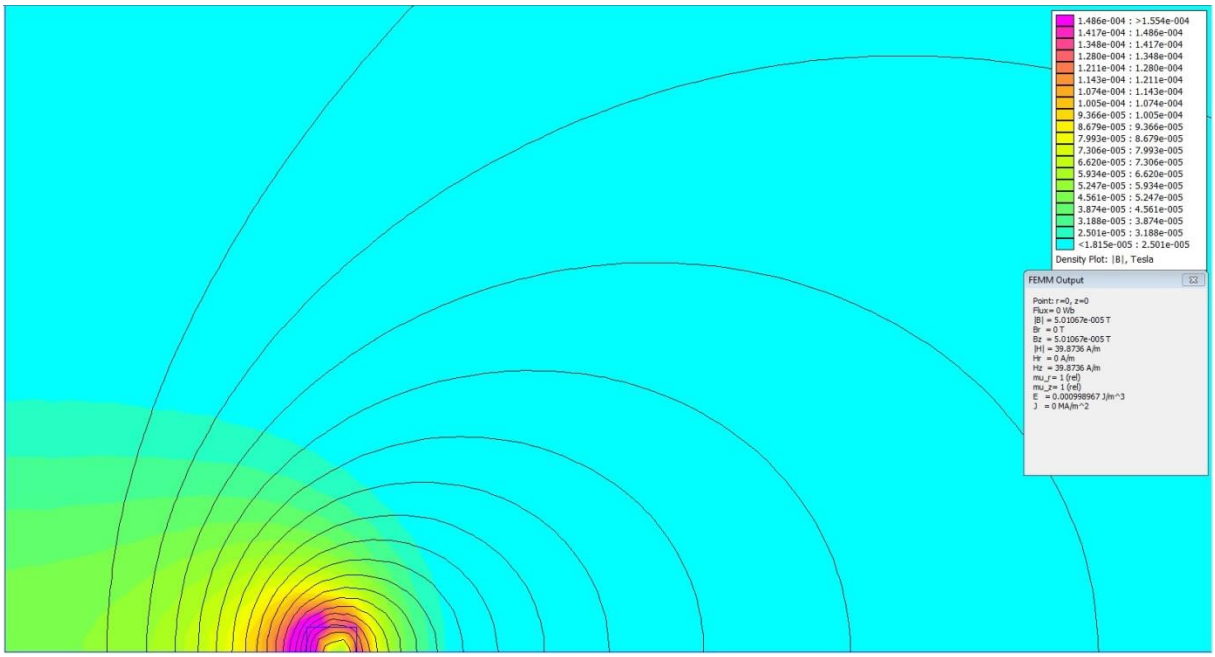
5e-005
4e-005
3e-005
2e-005
1e-005
0
|B|, Tesla
0
50
100
150
200
Length, mm
A
3e-005
2.5e-005
2e-005
1.5e-005
1e-005
5e-006
0
|B|, Tesla
0
50
100
150
200
250
300
Length, mm
B

Figure 3.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1.143e-004 : 1.211e-004
1.074e-004 : 1.143e-004
1.005e-004 : 1.074e-004
9.366e-005 : 1.005e-004
8.679e-005 : 9.366e-005
7.993e-005 : 8.679e-005
7.306e-005 : 7.993e-005
6.620e-005 : 7.306e-005
5.934e-005 : 6.620e-005
5.247e-005 : 5.934e-005
4.561e-005 : 5.247e-005
3.874e-005 : 4.561e-005
3.188e-005 : 3.874e-005
2.501e-005 : 3.188e-005
<1.815e-005 : 2.501e-005
Density Plot: |B|, Tesla
FEMM Output
Point: r=0, z=0
Flux= 0 Wb
|B| = 5.01067e-005 T
Br = 0 T
Bz = 5.01067e-005 T
|H| = 39.8736 A/m
Hr = 0 A/m
Hz = 39.8736 A/m
mu_r= 1 (rel)
mu_z= 1 (rel)
E = 0.000998967 J/m^3
J = 0 MA/m^2

Figure 4.

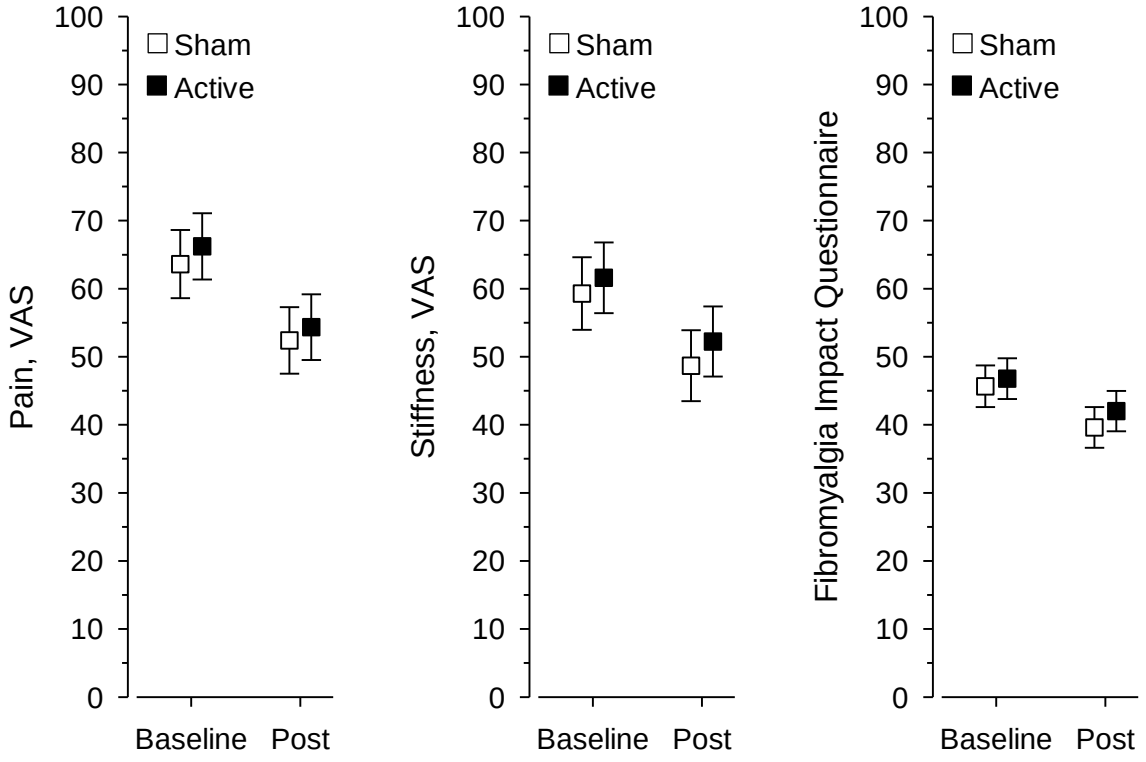
Pain, VAS
Stiffness, VAS
Fibromyalgia Impact Questionnaire
Sham
Active
100
90
80
70
60
50
40
30
20
10
0
Baseline
Post

Figure 5

Table 1. Demographic Characteristics of the Patients with Fibromyalgia

Variables	***N* = 108**
Age (years)	47 (10)
Height (cm)	164 (6)
Weight (kg)	77.6 (14.4)
Body mass index (kg/m^2)	28.9 (5.4)
Working status, n (%)	
Working	53 (49)
Not working	49 (45)
Retired	6 (6)
Time since fibromyalgia diagnosis (years)	7.1 (7.0)
Tender points score (0–18)	16.2 (1.9)
Beighton total score (0–9)	3.2 (2.8)
Pain, past week, VAS (0–100 mm)	70 (17)
Stiffness, past week, VAS (0–100 mm)	65 (22)
Sleep quality[a], past week, VAS (0–100 mm)	33 (26)
Mood[a], past week , VAS (0–100 mm)	29 (22)
Fibromyalgia Impact Questionnaire, total score (0–100)	52.4 (16.3)
Medications, n (%)	
Analgesics	86 (80)
Muscle relaxants	21 (19)
Antidepressants	49 (45)

Values are means (SD) or n (%).

[a]negative number indicates a lower quality of sleep or mood.

Table 2. Baseline, change and significance of change between active and sham treatments.

	Active		Sham		P*
	Baseline mean (SD)	Change mean (95% CI)	Baseline mean (SD)	Change mean (95% CI)	
Pain, VAS	66 (22)	-12 [-18, -6]	63 (22)	-11 [-17, -5]	0.88
Stiffness, VAS	61 (26)	-9 [-15, -4]	59 (25)	-11 [-17, -5]	0.77
FIQ	47 (15)	-5 [-8, -2]	45 (14)	-6 [-9, -3]	0.57

*Adjusting for period effect.

SD = standard deviation, CI = confidence interval, VAS = visual analog scale, FIQ = Fibromyalgia Impact Questionnaire.