Pulsed electromagnetic energy as an adjunct to physiotherapy for the treatment of acute low back pain: a randomised controlled trial

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ABSTRACT

The intention of this study was to investigate any additional benefits of pulsed electromagnetic energy used as an adjunct to routine physiotherapy for the treatment of acute non-specific low back pain. To address this aim, a single centre, double blinded, placebo controlled randomised control trial was conducted. Forty participants presenting to the University of Otago, School of Physiotherapy Clinic with acute non-specific low back pain (<6 weeks) were recruited. The Oswestry Disability Index was employed as the primary outcome measure. Secondary outcomes included the Patient Specific Functional Scale and the Numeric Pain Rating Scale. Outcomes were collected at baseline, one week and four weeks (or discharge). Baseline characteristics exhibited no differences between groups. The group treated with active pulsed electromagnetic energy failed to demonstrate any significant additional improvements in Oswestry Disability Index, Patient Specific Functional Scale or Numeric Pain Rating Scale scores ($p>0.05$). Irrespective of group allocation, all participants experienced significant improvements in Oswestry Disability Index, Patient Specific Functional Scale and Numeric Pain Rating Scale scores over both follow-up periods ($p<0.05$). Concisely, pulsed electromagnetic energy provides no significant additional benefit to physiotherapy in the treatment of acute non-specific low back pain.

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INTRODUCTION

Low back pain (LBP) is a costly and disabling disorder that plagues the modern world, creating substantial personal, societal and financial burden (Hoy et al 2010). The global lifetime prevalence of LBP is estimated at 60-80 percent of people (Airaksinen et al 2006, Walker 2000, WHO 2003), with up to 65% suffering from recurrent, long lasting episodes (Itz et al 2013). Globally, LBP is the second leading cause of sick leave (Lidgren 2003). In New Zealand, the prevalence of reduced activities attributable to LBP is estimated at 18% and work absenteeism at 9% (Widanarko et al 2012). There is therefore a pressing need within the healthcare system to identify and commence time and resource efficient treatment strategies for LBP.

The multifaceted nature of LBP constitutes a considerable challenge for primary health professionals and researchers alike. Despite a myriad of treatment options available for LBP, there is not yet one modality or therapeutic approach that stands out as a definitive solution. Currently, there is consensus with recommendations to stay active, provide education, use manipulative therapy and discourage bed rest (Airaksinen et al 2006, Arnau et al 2006, Savigny et al 2009, van Tulder et al 2006). Additionally, almost every clinical guideline available for LBP advocates the provision of analgesia and non-steroidal anti-inflammatory drugs (NSAIDs) for relief of activity limiting symptoms (Roelofs et al 2008).

Each class of medication is associated with unique and important adverse effects. In particular, NSAIDs are associated with serious gastrointestinal (Hawkey 2000, Hernandez-Diaz and Rodriguez 2000), renovascular (Ejaz et al 2004), cardiovascular (Amer et al 2010, Bresalier et al 2005, Juni et al 2004, Kearney et al 2006), bone (van Esch et al 2013) and connective tissue (Mishra et al 1995, Proto and Huard 2013, Shen et al 2008) adverse effects. While back pain sufferers may benefit in terms of analgesia, research suggests that long-term NSAID use may be detrimental to the healing process and serious complications may occasionally occur with brief exposure to these drugs (Mishra et al 1995, Proto and Huard 2013, Shen et al 2008). A drug free pain relief alternative is pulsed electromagnetic energy (PEME), a non-thermal, risk-free option that works to enhance cellular activity healing and repair. PEME has been used in various forms for decades, as a means of treating injury and disease (Mourino 1991). Now, with advances in technology it is possible to deliver non-thermal PEME from small, lightweight, wearable devices.

A number of laboratory experiments have demonstrated the healing and analgesic effects of PEME at the level of cellular and animal studies (Li et al 2011, Shupak et al 2004a, Shupak et al 2004b). Research suggests that the mechanism by which PEME mediates its healing effects is by way of induction of ionic currents within target tissue. These currents in turn stimulate changes in cellular calcium and cyclic adenosine monophosphate

levels (Thumm et al 1999), along with increased synthesis of collagen, proteoglycans, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) (Goodman et al 1989, Pezzetti et al 1999). PEME has also been shown to increase levels of reactive oxygen species (ROS) and nitric oxide (NO) production (Kim et al 2002), all essential for the healing and remodelling of damaged tissue. While the exact mechanism by which PEME generates its analgesic effects is unclear, a number of experiments have suggested that exposure to PEME may stimulate endogenous and exogenous opiate pathways (Moffett et al 2012).

When the direct effects of PEME are measureable, as in cellular and animal studies, it is difficult to dispute that PEME has an effect on the healing process. Clinically, research suggests that PEME may have benefit for ankle injury (Pennington et al 1993), neck pain or acute whiplash (Foley-Nolan et al 1990, Foley-Nolan et al 1992), osteoarthritis (Ay and Evcik 2009, Pipitone and Scott 2001, Trock et al 1994), LBP (Harden et al 2007) and lumbar radiculopathy (Omar et al 2012). However, when it comes to human clinical trials where the outcome measures are mostly indirect measures of effects, the evidence is at best mixed (Bachl et al 2008). This is due to a number of confounding factors such as application technique, treatment regime and dose/response relationship resulting in conflicting and heterogeneous results.

This project aimed to explore the putative additional benefits of a novel PEME device, delivering a much lower flux density over a longer period than traditional machines, used as an adjunct to routine physiotherapy treatment in an acute non-specific LBP population. The experimental hypothesis was that the use of PEME as an adjunct to normal physiotherapy techniques would be effective in reducing pain and disability in patients suffering from LBP.

METHOD

Design

The study was a double blind, placebo controlled randomised controlled trial (RCT). Ethical approval was provided by the Health and Disability Ethics Committee (Ref No 13/NTA/30). This trial was also registered with the Australia New Zealand Clinical Trials Registry (ACTRN 1261 3000 328 774).

Recruitment

A total of 40 participants presenting with acute non-specific LBP were recruited from the University of Otago, School of Physiotherapy Clinic and provided with treatment. Participants were assessed against the inclusion/exclusion criteria during a routine physiotherapy examination. Eligible patients were invited to participate and provided with the relevant information and consent forms. Informed consent was obtained from all participants before commencing the trial.

Inclusion criteria

Patients over the age of 18 suffering from acute non-specific LBP with or without leg pain that has been present for six weeks or less.

Exclusion criteria

Exclusion criteria were as follows: cauda equina symptoms or known presence of tumour, metabolic disease, rheumatoid arthritis, osteoporosis, prolonged history of steroid use, signs consistent with nerve root compression, spinal fracture, history of lumbar spine surgery, current pregnancy, cardiac pacemaker, cardioverter defibrillator, neuro-stimulator or any active medical device or metallic implant within the area of the lower back.

Randomisation

Block randomisation was used to achieve balance in the allocation of participants to the two treatment arms (PEME or placebo). Four blocks of 10 were formulated using a computer generated random block list. For each block list, the clinic receptionist assigned participants to one of the two groups by asking them to select any one of 10 identical opaque sealed envelopes. Each envelope contained the letter A or B. Each letter corresponded to either an active or placebo PEME device. The investigator, treating physiotherapist and participant were blinded to group allocation. Randomisation codes identifying allocation were held by the research administrator until after the data were analysed.

Intervention

According to group allocation, participants were distributed either a placebo or active PEME device. Participants were asked to wear the PEME device continuously for the first seven days, after which use was discontinued. The device antenna was placed over the site of LBP and kept in place by a comfortable elastic Velcro wrap worn around the waist. All participants were educated on the use of the device by their physiotherapist and received typical physiotherapy treatment as deemed necessary. The treating clinician was responsible for determining the content of each session (typically manipulation, mobilisation, advice and exercise; singularly or in any combination). Participants received physiotherapy treatment twice per week for up to four weeks. If further treatment was deemed necessary after four weeks, it was continued, however no further measures were used during study analysis. Any participant that failed to attend three consecutive treatments or comply with the PEME user guidelines was removed from the trial. In all such cases, the relevant reason for non-attendance/compliance was ascertained, and relevant outcome measures were performed as far as possible.

Pulsed Electromagnetic Energy Device

Active

The device used in this study was a PEME device (RecoveryRx, BioElectronics Corp) that emits a safe form of non-ionizing electromagnetic radiation. The carrier frequency of this device is 27.12 MHz, the assigned Federal Communications Commission (FCC) medical frequency. It has a pulse rate of 1,000 pulses per second and a 100 µs burst width. The magnetic flux density or field strength of the device is 0.03 milliTesla (mT). The peak burst output power of the 12 cm antenna is approximately 9.8mW covering a surface area of approximately 100 cm^2.

Placebo

The placebo device did not emit a radiofrequency electromagnetic field but was otherwise identical to the active device. The energy from the active device did not produce any sensation, thus it could not be distinguished from the placebo device.

Outcome measures

The primary outcome measure was the Oswestry Disability Index (ODI) (Fairbank et al 1980, Roland and Fairbank 2000). The ODI is an internationally recognised, well-validated tool for measuring the impact of LBP across five domains. It provides

a score between 0 and 50. Standard practice is to double the score and report it as a percentage (0% indicating no disability and 100%, representing a patient that is completely disabled or bed bound by their symptoms).

Secondary outcome measures included the Numeric Pain Rating Scale (NPRS) (Childs et al 2005, Jensen et al 1999, Stratford and Spadoni 2001) and the Patient Specific Functional Scale (PSFS) (Cleland et al 2006, Stewart et al 2007, Stratford 1995). The NPRS quantifies pain using an 11 point visual analogue scale (VAS). Zero indicates no pain while 10 represents the worst pain imaginable. The PSFS is a questionnaire that can be used to quantify activity limitations and functional outcomes for patients with musculoskeletal injuries or conditions. During the initial assessment, patients were asked to identify three everyday activities that they were experiencing difficulty with or unable to complete as a result of their LBP. Using a zero to 10 VAS (zero, the patient is unable to complete the task; 10, the patient is able to perform activity at the same level as before the injury) participants recorded their level of function for the three identified tasks. The average of the three scores was recorded.

For each outcome measure the change in score from baseline to four weeks (or discharge) was compared to the minimal clinically important difference (MCID). The MCID can be defined as the minimal change in an outcome score that is meaningful for patients. The MCID has been established as change between 6-10 points (12-20 percent) for the ODI (Ostelo et al 2008), 2.3 points for the PSFS (Maughan and Lewis 2010) and 2 points for the NPRS (Childs et al 2005).

Data collection

During the initial assessment, baseline characteristics and demographics were recorded. Outcome measures were performed at baseline, seven days and four weeks (or earlier if discharged). Participants were required to discontinue use of NSAIDs because of their possible detrimental effect on the healing process, but were able to continue with simple analgesics such as paracetamol.

Sample size

To detect a difference between groups of 8 points on a 50-point scale (ODI), with alpha set to 0.05 and power of 80%, 20 participants per group, allowing for up to 20% drop out, were required.

Statistical analysis

Statistical analysis was performed using the statistical package for the social sciences software (SPSS). On a per protocol basis (alpha set to 0.05) normal descriptive statistics of the two groups such as means and standard deviations were calculated. ANCOVA was used to analyse the outcome data at initial and follow-up time points.

RESULTS

The first 40 participants meeting inclusion criteria were included in the study. No participants withdrew from the study or were lost to follow-up. In addition, PEME appeared to be well tolerated with no adverse reactions reported. Figure 1 outlines participant flow through the study. Demographic and baseline data are presented in Table 1. No statistical differences in baseline data were observed between groups (p>0.05).

Figure 1: Participant flow through the study.

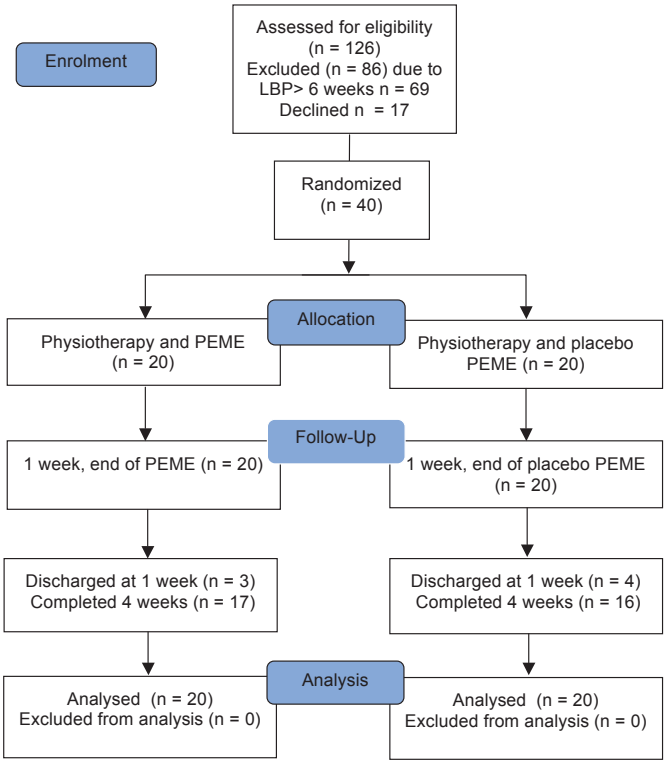


Table 1: Participants mean demographic and baseline data.

Characteristics	PEME group (n=20)	Placebo group (n=20)	p
Age (y)	35.7	30.2	>0.05
Sex (F/M)	9/11	11/9	>0.05
Disability (ODI)	35.60 (SD 15.39)	35.20 (SD 20.82)	>0.05
Function (PSFS)	4.10 (SD1.21)	3.99 (SD 1.75)	>0.05
Pain (NPRS)	5.00 (SD 1.39)	4.91 (SD 1.92)	>0.05

PEME – Pulsed Electromagnetic Energy; y – years; F – Female; M – Male; ODI – Oswestry Disability Index; PSFS – Patient Specific Functional Scale; NPRS – Numeric Pain Rating Scale.

†ODI, PSFS, and NPRS scores expressed as Mean±SD

Table 2 displays the results of ANCOVA analysis for each of the outcome measures (ODI, PSFS, NPRS). Results show that although group allocation was not determinative of results, there was a significant time effect for all outcome scores. Group/time interactions indicated that there were no significant differences in outcome measure scores between groups at any of the follow-up periods (p>0.05). Effect sizes are also displayed.

While there were no significant differences in pain, disability and function outcome measure scores between groups (figures 2-4), the results of within group analysis indicate that all ODI, NPRS and PSFS scores improved significantly from baseline to week one, baseline to week four and week one to week four

Table 2: Results of ANCOVA analysis for Oswestry Disability Index (ODI), Patient Specific Functional (PSFS) and Numeric Pain Rating Scale (NPRS).

	DF	F	p	Effect Size
ODI				
Group	1	0.03	0.85	0.00
Time	2	43.16	0.00	0.43
Group/time	2	0.02	0.97	0.00
PSFS				
Group	1	0.21	0.65	0.02
Time	2	81.4	0.00	0.58
Group/time	2	0.015	0.99	0.00
NPRS				
Group	1	.044	0.83	0.00
Time	2	77.11	0.00	0.57
Group/time	2	0.07	0.93	0.00

ANCOVA – Analysis of Covariance; DF – Degrees of Freedom; F – F test; ODI – Oswestry Disability Index; PSFS – Patient Specific Functional Scale; NPRS – Numeric Pain Rating Scale.

($p<0.05$). Changes for both pain and function exceeded the MCID for each outcome measure, indicating a meaningful improvement in both pain and function by all participants during the treatment period.

The mean and standard deviation of number of treatments for the placebo and treatment groups were 5.8 (2.3) and 4.6 (1.8) respectively, although this was not significantly different ($p = 0.82$). Post hoc analysis of study results revealed that three out of 20 participants in the PEME group were discharged after one week, while four out of 20 from placebo group were discharged at one week. In the PEME group, 18 out of 20 participants did not require all 8 treatments, and in the placebo group, 13 did not require all treatments.

DISCUSSION

This study investigated the potential additional benefits of a novel PEME device used as an adjunct to physiotherapy for treatment of acute non-specific LBP. Results suggest that PEME provides no additional benefit to routine physiotherapy in the treatment of acute non-specific LBP. The group treated with active PEME failed to demonstrate any significant additional improvements in ODI, PSFS or NPRS scores. However, all participants, irrespective of group allocation demonstrated significant improvements in ODI, NPRS and PSFS scores from baseline to week one, baseline to week four and week one to week four (or discharge) ($p<0.05$).

Figure 2: Between group mean differences in Oswestry Disability Index (ODI) scores over all of the follow-up periods (baseline, week one and week four/discharge).

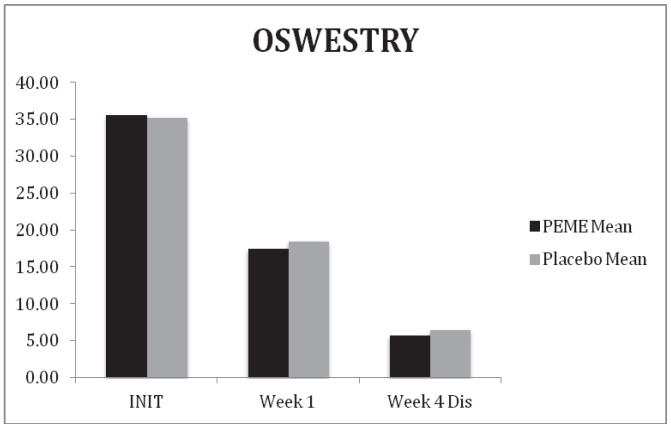


Figure 3: Between group mean differences in Patient Specific Functional Scale (PSFS) scores over all of the follow-up periods (baseline, week one and week four/discharge).

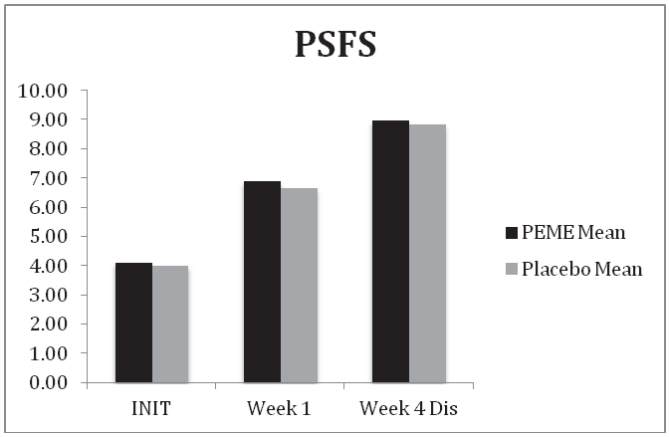
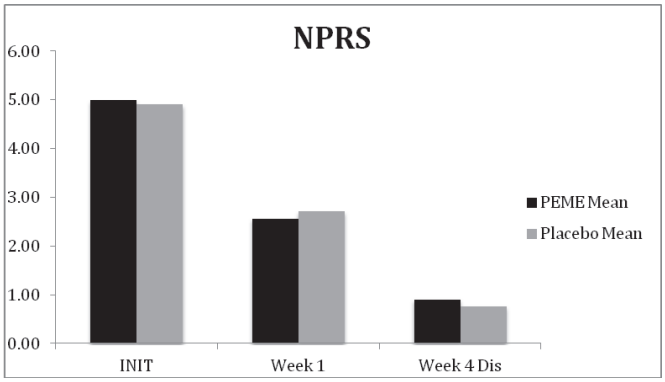


Figure 4: Between group mean differences in Numeric Pain Rating Scale (NPRS) scores over all of the follow-up periods (baseline, week one and week four/discharge).



Given the results of the present study, it may be suggested that PEME is ineffective in a clinical setting and fails to produce statistically significant results. The results of clinical trials are inconsistent and conflicting on this issue (Bachl et al 2008). Some studies have demonstrated positive, clear and measurable effects for PEME at the level of cellular and animal studies (Li et al 2011, Shupak et al 2004a, Shupak et al 2004b) and a recent meta-analysis found PEME to be associated with statistically significant improvements for pain, edema and healing in non-postoperative, postoperative and wound healing applications (Guo et al 2012). However, only eight out of the 14 studies focusing on non-postoperative PEME applications reported positive effects for pain and function following soft tissue injuries such as ankle sprains, neck pain, whiplash, lacerations, algoneurodystrophy and heel neuromas (Guo et al 2012). Whilst it may appear that PEME is effective in soft tissue, non-postoperative applications, numerous studies report neutral or insignificant results.

To the best of our knowledge, no other study has investigated the therapeutic effects of PEME for acute non-specific LBP. However, PEME has been researched in both chronic LBP (Harden et al 2007) and lumbar radiculopathy populations (Omar et al 2012). Harden et al (2007) conducted a randomised, placebo controlled pilot study to investigate the efficacy of PEME for chronic LBP. In contrast to the present study, Harden et al (2007) reported statistically significant improvements in pain using the McGill pain questionnaire and the VAS. Additionally, another recent trial conducted by Omar et al (2012) demonstrated PEME to be associated with significant improvements in both pain and disability for participants suffering with lumbar radiculopathy.

Between studies, there is much methodological and clinical heterogeneity, making comparisons difficult. Studies differ in terms of device technology, physical parameters, treatment duration and frequency, outcome measures, study periods and participant inclusion/exclusion criteria. Unlike the present study, both Harden et al (2007) and Omar et al (2012) utilised non-portable PEME devices with larger magnetic flux densities. The device employed by Harden et al (2007) had a magnetic flux density of 15 mT, a pulse rate of 120 pulses per second and covered surface area of 747 cm2. The device used by Omar et al (2012) was also non-portable and had a field strength that ranged from 0.5 to 1.5 mT and a frequency that varied between 7 Hz and 4 kHz. In contrast, the device used in the present study was small, portable and wearable. It delivered a low-dose (0.03 mT), pulsating electromagnetic field continuously over a time span of seven days. It had a frequency of 27.12 MHz, pulse rate of 1000 pulses per second and covered a surface area of 100 cm2.

Dosage is a complex but critical aspect of PEME therapy. The degree to which an electromagnetic field elicits a biological or clinical effect is dependent upon exogenous (field strength, energy exposure, mode of delivery) and endogenous (anatomical and pathological) variables (Guo et al 2012). Like pharmacotherapy, different dosages and dose regimes will produce different effects in different target tissues under differing conditions of exposure (Markov 2007). There are vast combinations of PEME parameters, creating a wide range of treatment conditions and effects. Unfortunately, there are no set guidelines for PEME therapy. Small effect sizes and insignificant or conflicting results may be the outcome of insufficient dosages and a lack of standardisation around dose parameters.

Despite failing to generate significant results in the present study, the RecoveryRx anti-patch device has demonstrated positive and significant effects in several other studies. A recent RCT conducted by Brook et al (2012) used this device to investigate the effects of low-dose PEME on plantar fasciitis. Comparative to the present study, participants were instructed to wear the device over a period of seven days. Brooke et al (2012) reported PEME therapy to be associated with statistically significant reductions in self-reported morning pain.

In addition, three recent clinical trials, using similar devices, have demonstrated the pain relief potential of low-dose PEME post breast surgery (Hedén and Pilla 2008, Rawe et al 2012, Rohde et al 2010). The study by Rawe et al (2012) used an identical device to establish that low-dose PEME delivered continuously over a period of seven days is capable of producing significant improvements in pain and medication use.

Although the aforementioned studies utilised the same PEME device and treatment duration as the present study, the clinical conditions under which they were investigated differed. Colbert et al (2008) emphasise that the most important dosimetry parameter is the dose received by the target tissue. Target tissues will differ in both density and depth from the body surface (Colbert et al 2008). As such, while a specific dose may appear effective for one condition, it may be inappropriate or ineffective for others (Colbert et al 2008). Many studies, including the present, neglect to include estimations of the distance between the site of device application and the target tissue(s) (Colbert et al 2008). Without such measures, it is impossible to judge the strength at which the target tissue received the magnetic field (Colbert et al 2008).

Given the non-specific heterogeneous nature of LBP, the specific tissue responsible for the production of pain and symptoms in each patient, for whatever reason, isn't always identified. However, it could be suggested that the tissues targeted in this RCT were located at a level deeper to the body surface than that of the tissues targeted by Brooke et al (2012) and Rawe et al (2012) and the dosage may be insufficient or inadequate for LBP.

Many of the clinical trials investigated the effects of PEME in isolation, involving only one dependant and one independent variable. Such an approach may have enhanced study internal validity and possibly effect sizes. Notwithstanding, the present study chose to provide all participants, irrespective of group allocation, with individualised physiotherapy treatment two times a week for four weeks (or until discharge). It was noted that the participants in the PEME group received 1.2 treatments less than those in the placebo group, and 90% of them did not require all eight treatments; though statistically insignificant given the sample size. While the tailored approach to treatment may have introduced bias, reduced internal validity and influenced effect sizes, it is well recognised that the LBP population is extremely heterogeneous in nature (Foster et al 2011). The individually tailored approach utilised in the present study is reflective of a real world or clinical setting. Thus, although the internal validity of the study may have been weakened, the external validity was likely strengthened.

All participants, irrespective of group allocation, experienced significant improvements. Because the study examined the effects of PEME in conjunction with physiotherapy, it is impossible to determine the specific variable responsible for

such improvements. However, many studies have confirmed that a high proportion of acute LBP sufferers will experience rapid and significant improvements in pain and disability over the first four to six weeks of recovery (Costa et al 2012, Pengel et al 2003). Given that the present study spanned over a period of merely four weeks, it is plausible to suggest that the widespread and significant improvements observed across both groups may reflect the natural progression of LBP.

Due to time constraints, a long-term follow-up period was unable to be incorporated into the study; this lack of a long-term follow-up period following treatment may limit study findings. Lifetime recurrences of LBP are estimated at 85% of people with 65% experiencing at least one reoccurring episode within 12 months of initial symptom onset (Itz et al 2013). Data on participants' use of simple analgesics was not collected, so this may have been a confounding factor that could have influenced results.

CONCLUSION

The results of the present study suggest that PEME provides no additional benefit to routine physiotherapy for the treatment of acute non-specific LBP. Inconsistent and conflicting results across studies may be reflective of insufficient dosage and a lack of standardisation around parameters.

KEY POINTS

- PEME provided no significant additional benefit over routine physiotherapy treatment for NSLBP.
- All participants improved significantly over time, achieving greater than MCID scores for all outcome measures.

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CONFLICT OF INTEREST

I declare on behalf of myself and the other authors that we know of no competing interests (financial, professional or personal) which may be perceived to interfere with or bias any stage of the writing or publication process. This includes, but is not restricted to, any factors that may influence full and objective presentation of the article, peer review and editorial decisions.

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