

# BMJ Open Effects of pulsed low-frequency magnetic field therapy on pain intensity in patients with musculoskeletal chronic low back pain: study protocol for a randomised double-blind placebo-controlled trial

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## ABSTRACT

**Introduction** The aim of the present study is to investigate the effectiveness of pulsed low-frequency magnetic field (PLFMF) on the management of chronic low back pain (CLBP).

**Methods and analysis** A randomised double-blinded controlled clinical trial will be conducted, involving 200 patients with CLBP. Participants will be randomised in a 1:1 ratio to receive either active PLFMF (experimental arm) or sham treatment (control arm) using a permuted-block design which will be stratified according to three subtypes of musculoskeletal CLBP (nociceptive, peripheral neuropathic or central sensitisation). The intervention consists of three sessions/week for 6 weeks. The primary outcome is the percentage change in Numerical Rating Scale (NRS) pain at week 24 after treatment completion with respect to the baseline. Secondary outcomes include percentage NRS pain during treatment and early after treatment completion, short form 36 quality of life, Roland and Morris Disability Questionnaire; Depression Anxiety Stress Scale 21, Patient Specific Functional Scale, Global perceived effect of condition change, Pittsburgh Sleep Quality Index and Modified Fatigue Impact Scale. Measures will be taken at baseline, 3 and 6 weeks during the intervention and 6, 12 and 24 weeks after completing the intervention. Adverse events between arms will be evaluated. Data will be analysed on an intention-to-treat basis.

**Ethics and dissemination** The study is funded by Imam Abdulrahman Bin Faisal University (IAU). It has been approved by the institutional review board of IAU (IRB- 2017-03–129). The study will be conducted at King Fahd Hospital of the University and will be monitored by the Hospital monitoring office for research and research ethics. The trial is scheduled to begin in September 2018. Results obtained will be presented in international conferences and will be published in peer-reviewed journals.

**Trial registration number** ACTRN12618000921280, prospectively.

## Strengths and limitations of this study

- The present study is a well-designed trial to investigate the long-term efficacy and safety of pulsed low-frequency magnetic field (PLFMF) on the management of musculoskeletal chronic low back pain (LBP).
- Subgroup analysis investigating the efficacy of PLFMF on various subtypes of pain based on pain mechanism will be performed. This may help to explain controversial results reported by previous clinical trials.
- Outcome measures include various aspects of LBP problems (pain intensity as well as disabilities, functional limitations, sleep quality and quality of life).
- All outcome measures used in the present trial are self-report which may potentiate pain and other measured outcomes.

## INTRODUCTION

Chronic low back pain (CLBP) is a pain or discomfort localised in the lumbosacral region, with or without leg pain (sciatica) that persists for more than 3 months.<sup>1</sup> Eight out of every ten adults will experience low back pain (LBP) at least once in their life with more than 60% of such cases have a recurrent LBP.<sup>2</sup> Evidence suggests that LBP has a lifetime prevalence of 40%, and a mean point prevalence of 20%.<sup>3</sup> The causes of LBP are many, they can range from simple spasm or mechanical causes to more serious causes such as herniated disc and different types of cancer.<sup>4</sup> Symptoms of LBP may vary from one patient to another. In many patients, the symptoms may go beyond pain to lead to severe consequences such as sleep disturbances, psychological and social problems which may

affect the quality of life.<sup>5</sup> CLBP accounts for about 15% of all cases of LBP; however, it has been reported to be the world-leading source of disability.<sup>6</sup> In addition, CLBP is often associated with the socioeconomic burden and psychological distress.<sup>7</sup> There is no published evidence of LBP cost in Saudi Arabia, the treatment cost for LBP in the USA is estimated to be more than \$90 billion per year<sup>8</sup> and \$17 billion per year in the UK.<sup>9</sup>

LBP can be classified based on several criteria. It has been classified into acute and chronic based on how long the pain has persisted. It can also be classified into inflammatory and neuropathic based on the underlying mechanism.<sup>10</sup> The main issue is how to differentiate the various subtypes clinically. In many occasions, differentiating the various phenotypes clinically is difficult. Smart *et al*<sup>11–13</sup> proposed a mechanism-based classification to differentiate between different types of musculoskeletal LBP (central sensitisation, peripheral neuropathic and nociceptive).

Most of the mechanical LBP respond to rest and various physical modalities. Different conservative and surgical interventions have been used to manage CLBP; however, optimal therapy is still debatable.<sup>14</sup> Many physical therapy interventions were tried in the management of CLBP such as soft tissue mobilisation and neurodynamic techniques,<sup>15 16</sup> massage therapy,<sup>17</sup> ultrasound, laser therapy, and shock wave therapy,<sup>18</sup> exercises,<sup>19</sup> Pilates practice,<sup>20</sup> and acupuncture.<sup>21</sup> While some of the rehabilitation interventions were effective in the short term, none of such interventions produce long-term effectiveness in the management of CLBP.<sup>2</sup>

Many pharmacological interventions have been used to manage CLBP. For example, non-steroid anti-inflammatory drugs and trammel were mild to moderately effective in reducing pain without much effects on function.<sup>17</sup> Similarly, opioids, benzodiazepines and duloxetine effects on reducing CLBP were small without inducing any improvement in function.<sup>22</sup> Other drugs such as tricyclic antidepressants and gabapentin were used; however, their efficacy was not established.<sup>23</sup> Since CLBP persist for long term, pharmacological interventions are not a suitable solution due to many reasons. Such reasons include toxicity due to long-term use, side and adverse effects in addition to problems with tolerance and addiction.<sup>24</sup> Surgical procedures have been used in some cases of CLBP with a mixed outcome<sup>25</sup>; however, many patients are reluctant to go through surgery. Add to that the high cost of the surgery to the healthcare system. Furthermore, the number of what is called 'failed back surgery syndrome' is in the rise.<sup>26</sup>

Since the conservative approaches currently used to manage CLBP do not seem to be effective on the long term, new approaches are needed to be developed. The new approaches should be safe, non-invasive and cost-effective.

Several lines of evidence indicate that pulsed low-frequency magnetic field (PLFMF) may be an attractive option for the management of CLBP. Magnetic field

blocked the sensory neuron action potential in cultured neurons<sup>27</sup>; however, it enhanced neuronal growth in the presence of growth factor.<sup>28</sup> In rats, magnetic field suppressed the formation of oedema.<sup>29</sup> Weintraub *et al*<sup>30</sup> showed that magnetic field has a pronounced anti-nociceptive effect. Robertson *et al*<sup>31</sup> showed that PLFMF affected pain and thermal signals in normal volunteers. Selvam *et al*<sup>32</sup> reported that PLFMF restored the calcium ATPase activity of the plasma membrane and produced anti-inflammatory effects. PLFMF also inhibited pain processing in a dose-dependent manner.<sup>33</sup> Clinically, PLFMF has been used for the treatment of different types of pain such as plantar fasciitis,<sup>34</sup> lumbar radicular pain,<sup>35</sup> postoperative pain,<sup>36</sup> peripheral neuropathy<sup>30</sup> and osteoarthritis.<sup>37</sup> Recently, we concluded a study which showed that PLFMF was effective in reducing pain, improving sleep and quality of life in patients with carpal tunnel syndrome.<sup>38</sup>

In the case of CLBP, few studies were done and produced conflicting results. While Krammer *et al*,<sup>14</sup> Oke and Umebese,<sup>39</sup> and Harden *et al*<sup>40</sup> reported that PLFMF was not superior to sham treatment in patients with CLBP, other studies reported that PLFMF significantly reduced pain intensity in patients with CLBP.<sup>41–43</sup> Most of the studies which tested the effects of PLFMF on CLBP suffered from methodological problems and flaws. Such problems included failure to perform intention to treat as well as lack of proper blindness of patients and researchers. All these studies failed to classify the CLBP into different subgroups since CLBP is heterogeneous. Two of the studies reporting positive findings failed to compare PLFMF with other therapeutic modality.<sup>42 43</sup> All the mentioned studies used small number sample sizes (16–40 patients).<sup>44</sup> Some of these studies did not do any follow-up after the conclusion of the interventions or did a follow-up for a short period.<sup>45</sup> Finally, the six studies used different machines producing different magnetic field intensity and frequency and different treatment protocols. Similarly, various studies reported controversial results regarding the effects of PLFMF on the level of disability and quality of life in patients with CLBP. Some studies reported that PLFMF improved the level of disability and/or quality of life<sup>41 42 46</sup> while other studies reported no effects for PLFMF on disability and/or quality of life.<sup>14 43 47</sup> Two systematic reviews investigated the effects of PLFMF on CLBP. Andrade *et al*<sup>45</sup> concluded that PLFMF treatment is superior to placebo treatment. However, Hug and Roosli<sup>48</sup> concluded that available evidence is not sufficient to recommend the use of PLFMF clinically. Both reviews recommended better controlled randomised studies are needed to clarify the effects of PLFMF on CLBP.

PLFMF is known to be safe, non-invasive, low cost, easy to administer and has no known side effects in the management of patients with CLBP.<sup>48</sup> Improving the condition of patients with CLBP will spare the patient going through several rounds of pharmacological and non-pharmacological treatment as well as invasive procedures like

surgery with the ultimate goal to improve the patients' quality of life.

## OBJECTIVES

The primary objective of this randomised controlled trial is to evaluate the long-term efficacy and safety of PLFMF on the management of CLBP and on increasing the percentage change in Numerical Rating Scale (NRS) pain at week-24 with respect to baseline score. The percentage reduction in NRS pain at week 24 will also be evaluated according to various musculoskeletal CLBP subtypes based on pain mechanism (nociceptive vs peripheral neuropathic vs central sensitisation).<sup>11-13</sup>

The secondary objectives are to evaluate the effects of PLFMF on (1) pain intensity during treatment and early after treatment completion, (2) level of disability, (3) functional levels, (4) sleep quality, (5) quality of life and (6) fatigue in patients with CLBP. The study will also investigate the long-term side effects of PLFMF.

This study will also include subgroups exploratory objectives to clarify the role of PLFMF in the management of patients diagnosed with different subtypes of musculoskeletal CLBP. To the best of our knowledge, this trial is the first randomised clinical trial to explore simultaneously the role of PLFMF in the management of patients with peripheral neuropathic, nociceptive and central sensitisation musculoskeletal LBP together.

## METHODS AND ANALYSIS

### Study design

This is a two-arm randomised, double-blind, placebo-controlled clinical trial. The study will be coordinated at the King Fahd Hospital of the University. All participants will be recruited from the hospital (patients referred to the department, additionally flyers will be distributed inviting people to participate). This study is funded through the Imam Abdulrahman Bin Faisal University (IAU; grant number 2017-308-CAMS). Ethical approval has been obtained from the institutional review board (IRB) of the IAU (IRB- 2017-03-129). This study is prospectively registered with the Australian New Zealand Clinical Trials Registry (Registration Number ACTRN12618000921280). Table 1 shows Trial Registration Data Set. This trial protocol has been prepared according to the Standard Protocol Items: Recommendations for Interventional Trials checklist statement (see online supplementary appendix 1).<sup>49</sup>

### Sample size and power calculation

Sample size calculation was based on two sample t-tests. We used R function `power.t.test` via R V.3.4.1 (<https://cran.r-project.org>). A total sample size of 200 (100 in each arm) will achieve 90% power to detect a mean difference of percentage reduction in NRS pain of 10% between the two treated arms at week 24. The mean percentage reduction in NRS pain is assumed to be 15% in the control arm (patient treated with SHAM programme) and 25% in

patients who receive PLFMF therapy. A 0.2 SD is considered along with a two-sided significance level (alpha) of 5% using a two-sample equal-variance t-test. The sample size allows for 15% of patients lost to follow-up at week 24. A 10% absolute reduction in NRS pain at week 24 will translate into an expected effect size of 0.5. This means the NRS score of the average person in the active PLFMF arm is 0.5 the SD above the average person who have had sham treatment, and hence exceed the scores of 69% of the control group.

The 38-item clinical criteria checklist developed by Smart *et al*<sup>11-13</sup> will be used to classify patients into different phenotypes of musculoskeletal CLBP. This method of discriminative validity was established.<sup>11-13</sup> All patients will be analysed collectively. Subgroup analysis will be performed to assess the effect of PLFMF on subtypes of pain.

### Statistical analysis

All randomised patients will be analysed on the intention-to-treat basis. Safety analyses will be performed for all patients who received at least one treatment session. Data will be coded and entered into SPSS (version 23; IBM Corp., USA) programme for analysis. Baseline characteristics will be presented by treatment group. Binary and categorical variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of patients for whom data are available. Where values are missing, the denominator, which will be less than the number of patients assigned to the treatment group, will be reported either in the body or a footnote of the summary table. Continuous variables will be summarised by mean and SD as well as by quartiles. Before summarising continuous outcomes, a test of normality will be performed. If the outcome is normally distributed, it will be summarised by mean (SD) in each arm and the difference between arms will be tested using t-test. However, if no evidence of normality, data will be summarised using the median (IQR). In such case, the Wilcoxon rank sum test will be used to test the difference between arms.

Treatment effect for the primary and continuous secondary outcomes will be assessed through analysis of covariance adjusted for the baseline measurement score. Overall treatment effect over time on all continuous outcomes, repeatedly collected over the course of the study, will be estimated using mixed linear models to take into account the correlation within each individual. The mixed linear model will include random intercept adjusted with the baseline score, time as categorical and the interaction between treatment and time. P values will not be adjusted for multiplicity. However, the outcomes are clearly categorised by degree of importance (primary, main secondary and other secondary) and a limited number of subgroup analyses are pre-specified.

Categorical binary efficacy measures will be primarily analysed using logistic regression. All tests will be two-sided with p values less than 0.05 will be considered significant.

**Table 1** Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trial Registry ACTRN 12618000921280)
Date of registration in primary registry	31/05/2018
Secondary identifying numbers	IAU-2017–308–CAMS
Source(s) of monetary or material support	King Fahd Hospital of the University
Primary sponsor	Imam Abdulrahman Bin Faisal University
Secondary sponsor(s)	None
Contact for public queries	Fuad A. Abdulla, PhD, PT +966 13 3331308 faabdullah@iau.edu.sa
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Public title	Effects of Pulsed Low Frequency Magnetic Field Therapy on Pain Intensity in Patients with Musculoskeletal Chronic Low Back Pain: A Randomised Double-Blind Placebo Controlled Trial
Scientific title	Effects of Pulsed Low Frequency Magnetic Field Therapy on Pain Intensity in Patients with Musculoskeletal Chronic Low Back Pain: A Randomised Double-Blind Placebo Controlled Trial
Countries of recruitment	Saudi Arabia
Health condition(s) or problem(s) studied	Chronic Low Back Pain
Intervention(s)	Active comparator: PLFMF, an average of 14 $\mu$ T for 20 min) and the conventional physical therapy programme (three times per week for 6 weeks) Placebo comparator: sham PLFMF (the machine will not be activated, ie, no magnetic field will be generated, for 20 min) and the conventional physical therapy programme (three times per week for 6 weeks) The conventional physical therapy programme consists of: <ul style="list-style-type: none"> <li>• Hot packs for 20 min</li> <li>• Back, hamstring and calf muscles stretching (performed from the long sitting position)</li> <li>• Lumbar erector spinae muscles self-stretching</li> <li>• Back muscles strengthening (back extension and bridging)</li> <li>• Abdominal muscles strengthening (posterior pelvic tilt and sit-ups)</li> </ul> Participants will be asked to hold the above positions for 5 s. Each exercise will be done five times per session with 1 min rest between any two repetitions
Key inclusion and exclusion criteria	Ages eligible for study: 18–60 years Sexes eligible for study: both Accepts healthy volunteers: no Inclusion criteria: <ul style="list-style-type: none"> <li>• Clinical evidence of musculoskeletal chronic low back pain including subtype classification (nociceptive vs peripheral neuropathic vs central sensitization)</li> <li>• Age 18–60 years old</li> <li>• Primary complaint of pain (at least a score of 5 out of 10 on a 0–10 NRS) in the area between the 12th rib and buttock crease, with or without leg pain for 3 months or more</li> </ul> Exclusion criteria: <ul style="list-style-type: none"> <li>• Pregnant or lactating</li> <li>• Significant spinal pathology (eg, spinal fracture, cauda equina syndrome, spinal infective or inflammatory diseases, metastatic)</li> <li>• Spinal surgery within the preceding 6 months</li> <li>• Recent organ transplants</li> <li>• Heart pacemaker</li> <li>• Cardiac arrhythmia, tachycardia conditions or large aneurysm</li> <li>• Heavy psychosis</li> <li>• Epileptic episodes</li> </ul>
Study type	Interventional Allocation: randomised Allocation concealment: sealed opaque envelopes Sequence generation: permuted-block randomization Intervention model: parallel assignment Masking: double-blind (subject, caregiver, investigator, outcomes assessor) Primary purpose: treatment

Continued

Table 1 Continued

Data category	Information
Date of first enrolment	September 2018
Target sample size	200
Recruitment status	Will begin Recruiting in July
Primary outcome(s)	<p>The percentage change in pain intensity by calculating the percentage change in NRS of pain. The percentage change in pain will be calculated at each post-baseline assessment as:</p> $100 \times \frac{(\text{difference between baseline and post-pain NRS scores})}{\text{baseline NRS score}}$ <p>All patients will be evaluated at baseline, end of the third and the sixth week from the beginning of the intervention. To assess for effects persistence, participants will be also evaluated at 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p>
Key secondary outcomes	<p>a. Quality of life assessed using Short Form 36 quality of life questionnaire. Time points: baseline, end of the third and the sixth week from the beginning of the intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p> <p>b. Disability assessed by the Roland and Morris Disability Questionnaire. Time points: baseline, end of the third and the sixth week from the beginning of intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p> <p>c. Depression, anxiety and stress assessed by Depression Anxiety Stress Scale 21 questionnaire. Time points: baseline, end of the third and the sixth week from the beginning of the intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p> <p>d. Function measurement assessed by the Patient Specific Functional Scale. Time points: baseline, end of the third and the sixth week from the beginning of the intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p> <p>e. Change in condition assessed by Global perceived effect of condition change. Time points: baseline, end of the third and the sixth week from the beginning of the intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p> <p>f. Quality of sleep assessed by the Pittsburgh Sleep Quality Index. Time points: baseline, end of the third and the sixth week from the beginning of the intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p> <p>g. Fatigue assessed by Modified Fatigue Impact Scale. Time points: baseline, end of the third and the sixth week from the beginning of the intervention. 6 weeks, 12 weeks and 24 weeks after the end of the intervention sessions</p>

NRS, Numerical Rating Scale; PLFMF, pulsed low frequency magnetic field.

### Eligibility criteria

Subjects will be recruited from King Fahd Hospital of the University. Subjects will be included in the study if they fulfil the following criteria:

- ▶ Clinical evidence of musculoskeletal CLBP including subtype classification (nociceptive vs peripheral neuropathic vs central sensitisation);
- ▶ Age 18–60 years old;
- ▶ Primary complaint of pain (at least a score of 5 out of 10 on a 0–10 NRS) in the area between the 12th rib and buttock crease, with or without leg pain for 3 months or more;

Patient will be excluded if they have any of the following criteria:

- ▶ Pregnant or lactating
- ▶ Significant spinal pathology (eg, spinal fracture, cauda equina syndrome, spinal infective or inflammatory diseases, metastatic);
- ▶ Spinal surgery within the preceding 6 months;
- ▶ Recent organ transplants;
- ▶ Heart pacemaker;
- ▶ Cardiac arrhythmia, tachycardia conditions or large aneurysm;
- ▶ Heavy psychosis;
- ▶ Epileptic episodes.

### Exit criteria

Participants will be withdrawn from the study if:

- ▶ Become pregnant;
- ▶ Back pain intensify during the trial to a point which needs emergency medical intervention;
- ▶ Decided to leave the study voluntarily;
- ▶ Added new medications (was not taken before) which may affect the patients LBP condition.
- ▶ Lack of compliance.

Patients will be instructed to continue any medication they regularly take before the trial; however, they will be instructed not to add any new medications that may affect their back pain during the trial period. All prescription and over the counter medications taken by the participants will be recorded.

### Randomisation

Eligible participants will be randomised in a 1:1 ratio to receive either active PLFMF treatment (experimental arm) or sham treatment (control arm). Randomisation list will be centrally generated, in a stratified fashion, using a random permuted-block design of size four and six. The stratification factor will be subtypes of musculoskeletal CLBP based on pain mechanism (nociceptive vs peripheral neuropathic vs central sensitisation).

A researcher who is not part of the study screening, evaluation or treatment will allocate the participants in one of the groups using sealed dense, tamperproof and numbered envelopes, prior to recruitment.

### Tool

The BEMER 3000 (BEMER Int. AG) will be pre-programmed to deliver PLFMF (an average of 14  $\mu$ T) a pulse frequency of 30 Hz and a pulse duration of 30 ms. The signal comprises a series of half-wave-shaped sinusoidal intensity variations. The signal which starts with low values slowly increases and then decreases but it does not go back to the initial value (ie, stay above zero). The intensity will gradually get denser with the repetition of the sequence leading to an increase in the ups and downs with repetition. Every second this procedure will be repeated 33.3 times with a reversal of polarity every 2 min.<sup>50</sup>

### Blinding

The trial product will be provided in a blinded manner. All the magnetic coils are covered by a cloth. When switched on, the device does not produce any sound or heat to keep patients blinded. Furthermore, to maintain blinding of the investigator (and designated staff), an identical mattress (size) and same colour cloth will be used for all patients independent of treatment group assignment. Patients and all healthcare providers (therapists and physicians) who care for the participants during the study will be strictly blinded to randomised interventions. Only the treating therapist will know what type of treatment the participant will be given. The assessor and the participants will not have access to such information. The blinding codes will be kept at the monitoring office of research and research ethics till the end of the trial unless an emergency developed which requires unblinding. The treating therapist will be asked not to mention or talk about the treatment groups to others. On the completion of the study, each participant will be interviewed to be asked about the group which they think they were at.

### Setting

The trial will be conducted at the department of physical therapy of King Fahd Hospital of the University. King Fahd Hospital of the University is a 800-bed teaching hospital located in the Eastern Province of the Kingdom of Saudi Arabia. All researchers are clinicians at the departments of physical therapy and orthopaedics. The trial is scheduled to begin in September 2018.

### Procedure

All screening, interventions and evaluation will be done by qualified musculoskeletal physical therapists who have 5 or more years of clinical experience. Potential participants will be asked to participate in the study, if agreed they will be screened for inclusion and exclusion criteria then they will be asked to sign a consent form (see online supplementary appendix 2). Subjects will be classified into peripheral neuropathic, nociceptive or central

sensitisation musculoskeletal LBP according to criteria established by Smart *et al.*<sup>11–13</sup> Each participant will be assigned randomly to either the experimental group which will receive PLFMF and the typical physical therapy programme used in our department or the control group which will receive sham PLFMF and the typical physical therapy programme used in our department. Patients will be asked to lie down on the magnetic mattress for 20 min/session, three sessions a week for a total of 18 sessions (6 weeks). In the treatment group, the BEMER mattress will be activated, whereas in the control group (placebo), no magnetic field will be generated. The typical physical therapy programme used in our department consists of:

- ▶ Hot packs (to cover the lower back area) for 20 min;
- ▶ Back, hamstring and calf muscles stretching (performed from the long sitting position)
- ▶ Lumbar erector spinae muscles self-stretching;
- ▶ Back muscles strengthening (back extension and bridging);
- ▶ Abdominal muscles strengthening (posterior pelvic tilt and sit-ups);
- ▶ Participants will be asked to hold the above positions for 5 s. Each exercise will be done five times per session with 1 min rest between any two repetitions.

Each session will last for 60 min as follows:

- ▶ 20 min for active PLFMF or placebo;
- ▶ 20 min for hot packs;
- ▶ 20 min for exercises.

Treating therapist will monitor adherence to the intervention sessions using a study calendar.

All patients will be evaluated at baseline, end of the third and the sixth week. To assess for effects persistence, participants will be evaluated at 6 weeks, 12 weeks and 24 weeks after completing the 6-week treatment (figure 1).

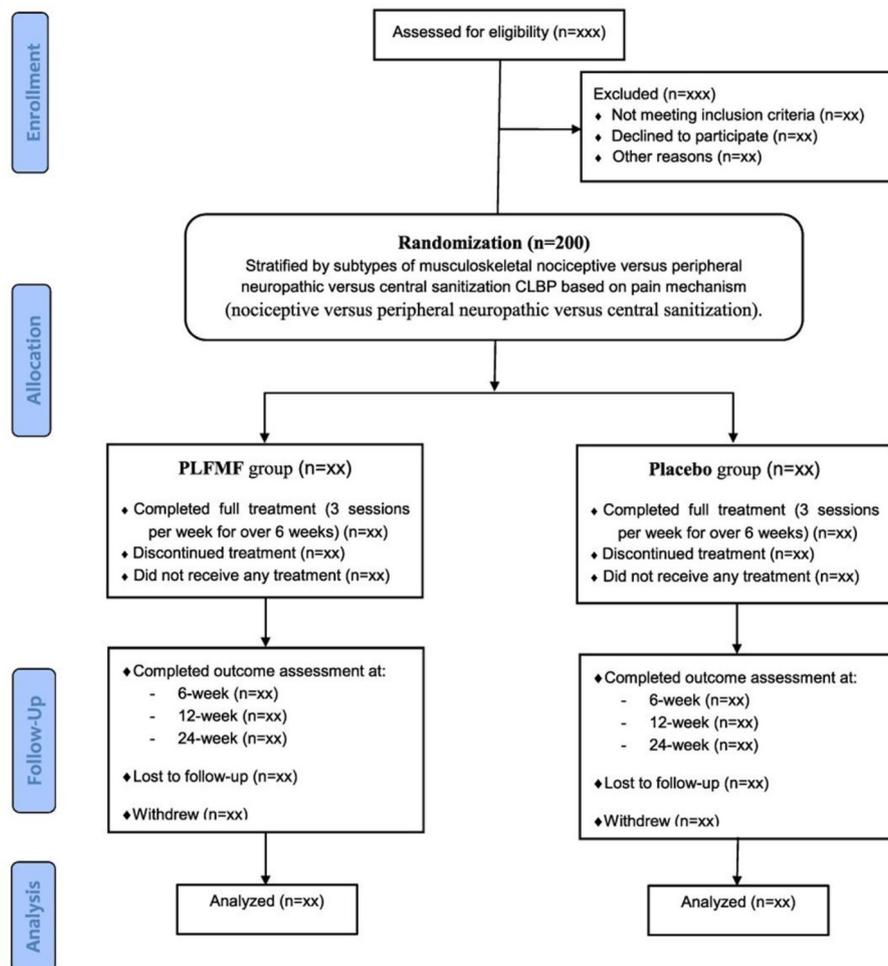
### Outcome measures

1. NRS: Pain severity will be measured by the NRS. It is an 11-point numeric scale with one extreme labelled as no pain (0) and the other extreme worst pain imagined (10). It is a valid and reliable scale.<sup>51</sup> The patient will be asked to indicate the level of his/her pain immediately before the session and 5 min after the intervention.

The percentage change in pain will be calculated at each post-baseline assessment as:

$$100 \times \frac{(\text{difference between baseline and post-pain NRS scores})}{\text{baseline NRS score}}$$

2. Short Form 36 (SF-36): An Arabic version of the SF-36 will be used to assess the quality of life of all participants. The validity and reliability of the Arabic versions of the SF-36 was established in a sample of Saudis.<sup>52</sup>
3. Disability measurement using the Roland and Morris Disability Questionnaire (RMDQ): It is a self-reported, condition-specific questionnaire which consists of 24 questions. It is often used to assess LBP disability. It was translated and adopted into Arabic language.<sup>53</sup>



**Figure 1** Flow chart of participation in the two-arm randomised double-blind trial evaluating the efficacy of PLFMF therapy on CLBP. CLBP, chronic low back pain; PLFMF, pulsed low-frequency magnetic field.

4. Depression Anxiety Stress Scale 21 (DASS 21): It is a 21-question scale which assesses the emotional state of depression, anxiety and stress. Each question is assessed in a four-point likert scale. The validity and reliability of an Arabic version of the scale has been established.<sup>54</sup>
5. Function measurement will be assessed using Patient Specific Functional Scale : It is a valid and reliable measure for physical function in musculoskeletal conditions.<sup>55 56</sup> It measures 3–5 physical activities which are important to the patient and s/he is unable to do without difficulties. Patients rate the difficulty with which they do the function in an 11-point likert scale from 0 (unable to do) to 10 (not at all affected).
6. Global perceived effect (GPE) of condition change: It is a one-question scale which asks the patient to rate improvement/deterioration numerically from –5 (much worse) to 5 (much better). It is has been recommended as one of the outcomes in clinical trials that study chronic pain.<sup>57</sup> The scale validity and reliability has been established.<sup>58</sup>
7. Pittsburgh Sleep Quality Index (PSQI): It is a 19-item questionnaire which assesses several aspects of sleep quality (sleep duration, disturbances, quality, efficien-

cy, sleep onset latency, medication and daytime dysfunction). A global score of sleep quality is the sum of the various components of the questionnaire. The higher the score the worse the sleep quality. The questionnaire was translated and validated into Arabic language.<sup>59</sup>

8. Modified Fatigue Impact Scale (MFIS): It is a 21-item questionnaire which evaluates the fatigue effects on quality of life in patients with chronic diseases. A likert scale from 0 (no effect of fatigue) to 4 (maximum effect of fatigue) is used to score each item of the questionnaire.

### Safety measures

PLFMF has no known side effects; however, long-term side effects of PLFMF have not been evaluated. If side effects developed or the symptoms of any participants get worse during the study or the follow-up period s/he will be given appropriate medical care until the situation is resolved. Such participants will be withdrawn from the trial, if necessary. Any observed side effects will be recorded and reported to the IRB office at IAU.

### Privacy and confidentiality

Screening, assessment and treatment will be done in a private area at King Fahd Hospital of the University in the department of physical therapy. Data will be coded, only one of the researchers will have the key for the codes. All data will be saved in a secured computer protected with a password. Only the researchers will have access to data. On report writing and professional publication, data will be presented collectively, none of the participants' identity will be identified.

### Patient and public involvement

Patients and the public were not involved in the development of this study protocol. However, the obvious lack of satisfactory treatment of CLBP was a major motivator for the study team to develop and conduct this study. The finding of the present study will be disseminated to the participants and the community in general through newsletters and presentations in the community.

### Ethics and dissemination

The trial was approved by the IRB of IAU (IRB- 2017-03-129). Any amendment to the protocol which may impact the conduct of the study will be approved by the IRB at IAU before implementation. The trial is also registered with the Australian New Zealand Clinical Trial Registry (Registration Number ACTRN 12618000921280). The trial was registered 31 May 2018. While the trial being conducted, the monitoring office for research and research ethics at King Fahd Hospital of the University (where the study will be conducted) will monitor the various milestones of the trial. The study will be explained to all participants by one of the researchers. All participants will sign a consent form before the beginning of any procedures of the study.

The results of the present trial will be presented in international conferences and will be published in peer-reviewed journals.

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