

## COMMENTARY ON: ELECTROMAGNETIC INDUCTION FOR TREATMENT OF UNSPECIFIC BACK PAIN: A PROSPECTIVE RANDOMIZED SHAM-CONTROLLED CLINICAL TRIAL

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We read with interest the paper by Hartard et al. (1). Back pain is a highly prevalent disorder, which poses a significant burden on healthcare resources and work absence. The authors hypothesized that electromagnetic induction alters nociception, leading to an improvement in symptoms of unspecified back pain. Electromagnetic induction enhances nociceptive markers which are present during inflammation, and are at their highest level during acute phase of injury.

Hartard et al.'s study assesses the effectiveness of electromagnetic induction in the alleviation of symptoms in people with unspecified low back pain. The inclusion criteria for patients in the study needs to be refined further. Back pain of acute nature occurs for a wide range of reasons, giving a very broad base of recruitment of participants (2), which could confound results, especially considering the short-term nature of the disorder and its potential to recover.

The criteria used for enrolling participants into the study may present potential issues as the authors included patients based on a primary screening carried out by physicians; however the reference for the screening was based on chronic low back pain (3), whereas the participants included in this study have unspecified back pain (UBP) of an acute nature. The authors also state that certain conditions (listed in the exclusion criteria) cannot be differentiated based on simple clinical tests.

The study includes all cases of back pain, regardless of location, e.g. neck pain, upper back pain (thoracic) and lower back pain (lumbar). Due to varying loads sustained by different regions of the back, the

mechanism of injury, as well as the disorder is unpredictable. In the short term patients may present with similar symptoms (2), but over time these may develop associated musculoskeletal symptoms due to the chronicity of the disorder. This variation in inclusion of back pain could confound the results, as it is difficult to predict the efficacy of treatment modalities when used over various regions.

The measurable criteria for assessing back pain, and the response to treatment in this study included visual analogue scale, oxygen saturation, heart rate, blood pressure and perfusion index. These provide a good mix of subjective and objective measures to assess the efficacy of treatment. Perfusion index provides a reliable, non-invasive method to assess changes in nociception, enabling reliable assessment of physiological changes post-treatment. An additional outcome measure to evaluate disability index due to back pain prior to, and after, treatment, would have provided conclusive evidence regarding treatment effects.

The limitations of the study have been presented, and we agree that a long-term, follow-up is required to better determine the effectiveness of electromagnetic induction as a treatment alternative for unspecified low back pain. In acute conditions nociception control may provide relief, and allow patients to resume activities of daily living; however, as the cause of back pain becomes apparent (in conditions which do not resolve), pain management may not be sufficient, and a more permanent solution (surgery for e.g.) will be required for resolution of back pain.

## REPLY TO THE COMMENTARY ON: ELECTROMAGNETIC INDUCTION FOR TREATMENT OF UNSPECIFIC BACK PAIN: A PROSPECTIVE RANDOMIZED SHAM-CONTROLLED CLINICAL TRIAL

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We thank Khan et al. for their insightful comments on our paper (1). We appreciate the opportunity to engage in constructive dialogue regarding the methodology used in our study (1).

The first comment concerns the inclusion criteria (Box 1). We concur with Khan et al. regarding the multifaceted aetiology of acute back pain, which contributes to a broad base of participant recruitment. We agree that diversity among the participants may introduce confounding variables. This is especially significant considering the transient nature of acute back pain and its inherent potential for recovery. Therefore, future studies will further differentiate causes/classifications (according to the International Statistical Classification of Diseases and Related Health Problems (4)); time course and stages of back/low back pain chronification (5). Moreover, we have explored the effect of electromagnetic induction (EMI) on nociceptive markers during the acute phase of an injury. However, acute pain becomes inflammatory pain when the noxious stimulus persists long enough to allow nociceptive neurones to release their pro-inflammatory markers and sensitize or activate responsive cells in their local environment (6, 7). External factors, such as extra-low-frequency electromagnetic fields, have demonstrated an impact on pain and inflammation by modulating G-protein coupled receptors, downregulating cyclooxygenase-2 activity, and reducing inflammatory modulators such as tumour necrosis factor alpha and interleukin-1 $\beta$ , as well as the transcription factor nuclear factor kappa B (4, 8–10). It is relevant

to note that our paper discusses the external validity and applicability of the results, explicitly stating that: "Our findings can only be transferred to one population with corresponding exclusion and inclusion criteria".

The second comment relates to the recruitment method for our patient cohort, particularly the primary screening process, which focused on chronic low back pain, even though a subset of patients in the study presented with acute UBP. We concur with Khan et al. that this recruitment method might slightly "alter" our findings. Indeed, for acute conditions, effective nociception control can offer relief and enable patients to return rapidly to their daily activities. Nevertheless, as the underlying cause of back pain becomes evident (e.g. in persistent conditions), relying solely on pain management might prove inadequate. It becomes evident that a more enduring solution is needed to address the resolution of back pain.

The third comment relates to the broad inclusion of all cases of back pain, irrespective of their specific location. We recognize that the different regions of the back experience varying loads, leading to unpredictability in both injury mechanisms and resulting disorders. While these regions may exhibit similar symptoms in the short-term, they can evolve into complex complications over time. Acknowledging the potential for diversity in back pain inclusion to introduce confounding variables, especially given the uncertainty regarding treatment efficacy across different regions, we identified this aspect as a limitation. Consequently, within the "study limitations" subsection, we included

**Box 1.** Applied inclusion and non-inclusion criteria in our study (1).

Inclusion criteria	<ul style="list-style-type: none"> <li>• Patients aged 18–80 years</li> <li>• Unspecific back pain within the previous 24 h</li> <li>• Back pain for which no causes can be advanced with simple clinical means that convincingly explain the current symptoms</li> </ul>
Exclusion criteria	<ul style="list-style-type: none"> <li>• Contraindications of electromagnetic induction in specific back pain</li> <li>• Diseases according to the "red flags"</li> <li>• Specific diseases of the spine, inflammatory spondylopathies</li> <li>• Diseases of the internal organs</li> <li>• Vertebral collapse due to osteoporosis or following an accident</li> <li>• Malignant tumour</li> <li>• Diseases with specific origins</li> <li>• Acute inflammatory diseases</li> <li>• Patients with implanted metallic or electronic objects</li> <li>• Pregnancy</li> <li>• Large tattoos</li> </ul>

the following statement: "Third, it was better to report data on success rates in each body area of the unspecific back-pain (e.g. upper shoulder/cervical spine vs medium or lower). Additionally, comparing outcomes between 'upper-middle back' and 'lower back' would have been more informative."

The fourth comment relates to the measurable criteria for assessing back pain and the treatment response (i.e. visual analogue scale, oxygen saturation, heart rate, blood pressure and perfusion index). These measures encompass a mix of subjective and objective indicators, offering a comprehensive assessment of treatment efficacy. Khan et al. suggest an additional outcome measure to evaluate the disability index due to back pain before and after treatment, which would provide conclusive evidence regarding treatment effects of our study. Disability indices are commonly used in medical and rehabilitation fields to quantify the impact of a condition on an individual's daily functioning. Hence, Khan et al.'s proposal to evaluate a disability index is intriguing, since it involves assessing the severity of a patient's impairment or disability using a standardized measurement tool. We addressed this point in our

paper, stating "The other limitations are the exclusive use of the numerical rating scale, the absence of other measurement methods for evaluating the microcirculation, and the short intervention time". Furthermore, in our conclusion, we emphasized that "Follow-up examinations should also include parameters of the microcirculation as well as markers of the inflammation in the serum".

In conclusion, our randomized sham-controlled clinical trial (1) underscores the promising impact of EMI therapy on UBP. This promising result prompts the need for more extensive and comprehensive studies to substantiate the efficacy of EMI across diverse pain indications. Naturally, such studies must adhere to rigorous methodologies, and it is imperative that the concerns outlined by Khan et al. are meticulously addressed and integrated into the research framework.

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