INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Extracorporeal shockwave therapy for treating chronic low-back pain: a protocol of a systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **To date, no systematic review was found as the International Prospective Registry of Systematic Reviews (PROSPERO) and Cochrane Database of Systematic Reviews did not have systematic review/meta-analysis records on the subject. Thus, the primary objective of this review is to examine the effectiveness of ESWT on pain relief and improvement in function at the short and intermediate term follow-up compared with control treatment in adults.**
Condition being studied: **Studies with adult (18 years old and above) who had experienced pain in the low-back area (from below the costal margin to the gluteal fold) for over 3 months regardless of age, gender or ethnicity. Studies in which back pain involved in cervical spine, thoracic spine, coccyx or unidentifiable pain region will be excluded. We also excluded RCTs that included participants with a history of trauma, surgery or inflammatory conditions such as ankylosing spondylitis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2021 and was last updated on 19 April 2021 (registration number INPLASY202140100).

INTRODUCTION

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METHODS

Participant or population: Studies with adult (18 years old and above) who had experienced pain in the low-back area (from below the costal margin to the gluteal fold) for over 3 months regardless of age, gender or ethnicity. Studies in which back pain involved in cervical spine, thoracic spine, coccyx or unidentifiable pain region will be excluded. We also excluded RCTs that included participants with a history of trauma, surgery or inflammatory conditions such as ankylosing spondylitis.

Intervention: Studies evaluating the effect of ESWT as an independent or combined intervention will be considered interventions. This systematic review will only adopt low- to medium- energy ESWT (range of energy density<0.28mJ/mm2) because high-energy therapy typically requires local anesthesia which may cause confounding bias.

Comparator: Studies whose control group received no treatment, sham procedures, pharmacotherapies or other interventions will be considered comparators. This systematic review will only include studies with comparisons of clear contrast for the index intervention, so that the independent effects of the intervention can be assessed.

Study designs to be included: Randomised clinical trials (RCTs) that used ESWT in the prevention of CLBP in adults will be selected according to the recommendations of the CBN Group published.

Eligibility criteria: Studies with adult (18 years old and above) who had experienced pain in the low-back area (from below the costal margin to the gluteal fold) for over 3 months regardless of age, gender or ethnicity. Studies in which back pain involved in cervical spine, thoracic spine, coccyx or unidentifiable pain region will be excluded. We also excluded RCTs that included participants with a history of trauma, surgery or inflammatory conditions such as ankylosing spondylitis.

Information sources: We will search the following electronic databases, unrestricted by date or language. However, non-English studies will be excluded in the absence of English abstract and English figure captions. English Databases: Pubmed, Embase, Web of science, Scopus, CINAHL (EBSCO), Cochrane Central Register of Controlled Trials (CENTRAL, via the Cochrane Library), Physiotherapy Evidence Database (PEDro). Non-English databases: China National Knowledge Infrastructure (CNKI, China), Research Information Service System (RISS, South Korea), J-stage (Japan). Trial registries: World Health Organization (WHO) International Clinical Trials Registry Platform, ClinicalTrials.gov. Unpublished manuscript/conference letter: Research square, Google scholar. The reference lists of retrieved trials and previous systematic reviews will be searched for citation of potentially eligible trials. In case that any questions about trials arise, the corresponding author of articles will be e-mailed.

Main outcome(s): Mean pain score, or mean change in pain score on VAS, NRS or substitutional categorical rating scale (in that order of preference).

Additional outcome(s): Disability or function. Where trialists reported outcome data for more than one function scale, we extracted data on the scale that was highest on the following an a priori consensus-based list. Therapeutic

parameters (energy level, frequency, number of pulses) of ESWT in each trial. For studies of participants with laboratory tests, the mean change of values were included. Adverse events.

Quality assessment / Risk of bias analysis: The risk of bias for each included RCTs will be assessed by two reviewers independently using the bias tool recommended by the Cochrane Back and Neck (CBN) Group and the overall quality of each included trials will be assessed by Jaded score. Any disagreement will be resolved by discussion by the whole group. The graphical presentation of assessment of risk of bias will be generated by RevMan 5.3. Afterwards, the initial interobserver reliability of the risk of bias assessment will be evaluated and reported.

Strategy of data synthesis: We will also apply Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) to evaluate the overall quality of the evidence for each outcome, which ranges from high to very low quality and is based on five domains: limitations of design, inconsistency of results, indirectness, imprecision, and other factors (e.g., publication bias). GRADE approach evaluates the quality of evidence as 'high', 'moderate', 'low', or 'very low' by the outcome.

Subgroup analysis: To detect possible heterogeneity of the results, subgroup analysis will be performed according to the primary outcomes. We will investigate the effects in three subgroup analyses: Severity of pain: Moderate baseline pain (pain scale<5/10) vs intense baseline pain (pain scale≥5/10). Energy level of treatment: Low-energy level (energy density<0.08mJ/mm2) vs middle-energy level of ESWT (energy density=0.08-0.28mJ/mm2). Age: Participants of younger adult vs participants of older adults.

Sensitivity analysis: To confirm the robustness of our findings, a sensitivity analysis will be conducted by merging the data from 'grey literature' (e.g., unpublished trials) to the metadata.

Language: No limit.

Country(ies) involved: China.

Keywords: Low-back pain, shockwave therapy.

Contributions of each author:

Author 1 - Lei Yue - The author drafted the manuscript.
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