INPLASY PROTOCOL

To cite: Liu et al. Effect of Baduanjin on pain caused by lumbar disc herniation: a meta-analysis of randomized controlled trials. Inplasy protocol 202120065. doi: 10.37766/inplasy2021.2.0065

Received: 18 February 2021

Published: 19 February 2021

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Support: **Master funds.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Effect of Baduanjin on pain caused by lumbar disc herniation: a meta-analysis of randomized controlled trials

Liu, ZD[1]; Li, QQ[2]; Cheng, YL[3]; Li, WX[4]; Huang, YR[5]; Zou, Y[6]; Li, YQ[7].

Review question / Objective: **①Can the small sample RCT study of multiple Baduanjin in the treatment of lumbar disc herniation better confirm its clinical efficacy? ②Can Baduanjin relieve lumbar and leg pain caused by lumbar disc herniation? ③Can Baduanjin improve the activities of daily living of patients with lumbar disc herniation?**

Condition being studied: **Lumbar disc herniation (LDH) is a clinical syndrome caused by the stimulation and (or) compression of nerve root and cauda equina nerve by the herniated intervertebral disc tissue on the pathological basis of different degrees of LDH. According to the epidemiological data, the prevalence of LDH in China is the most serious, with the prevalence rate as high as 15.2%, and the prevalence trend is younger and younger.In the outpatients with low back and leg pain, the disease accounts for about 15%, and the hospitalization rate is relatively high, about 40%.Baduanjin is one of the traditional Chinese martial arts. It has a long history, easy to learn, low requirements of the site, and has a unique therapeutic effect on lumbar disc herniation. However, there are few related studies, and a large number of clinical studies are needed to prove its clinical efficacy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 February 2021 and was last updated on 19 February 2021 (registration number INPLASY202120065).

INTRODUCTION

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METHODS

Search strategy: We will search, with no time restrictions, the following databases for relevant literature: CNKI, WangFang, VIP,CBM, PubMed, the Cochrane Library, Embase, Chinese Clinical Trials Registry (ChiCTR) and US National Library of Medicine (ClinicalTrials gov.). The electronic database search will be supplemented by a manual search of the reference lists of included articles. (PubMed)The search string will be built as follows: ①: lumbar disk hernia OR lumbar disc herniation OR lumbar disc protrusion OR lumbar disk herniation OR lumbar herniated disk OR lumbar intervertebral disc herniation OR lumbar intervertebral disc prolapse OR prolapse of lumbar intervertebral disc; ②ba duan jin OR eight section brocade OR brocades OR eight trigrams boxing OR eight-treasured exercises OR eight pieces of brocade OR qigong OR Qigong-Brocad OR Brocade Aerobic OR Health Qigong Ba Duan Jin; ③randomized controlled trial OR randomized OR placebo OR RCT; ① AND ② AND ③.

Participant or population: ①Adults with Lumbar disc herniation (as diagnosed by a clinician, or using any recognized diagnostic criteria) will be included, and without other serious diseases. ②Age, gender, course of disease, case source, region and race were not limited, but the baseline of the two groups were the same, that is, there was no significant difference in gender, age and course of disease, which was comparable.

Intervention: The intervention scheme was that the experimental group was treated with Baduanjin alone or Baduanjin as the main treatment method.

Comparator: The control group was treated with other treatment methods, including massage, electroacupuncture, ordinary acupuncture, traditional Chinese medicine, oral western medicine, etc.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Research type, research object, intervention measures, control measures, outcome indicators and so on conform to the pre-set Baduanjin clinical randomized controlled trial in the treatment of lumbar disc herniation.

Information sources: We will search, with no time restrictions, the following databases for relevant literature: CNKI, WangFang, VIP, CBM, PubMed, the Cochrane Library, Embase, Chinese Clinical Trials Registry(ChiCTR) and US National Library of Medicine(ClinicalTrials gov.). The electronic database search will be supplemented by a manual search of the reference lists of included articles. The references of the included literatures were traced and the unpublished studies were obtained by contacting the authors.

Main outcome(s): Visual Analogue Scale/ Score(VAS).Observation time: the end of treatment or follow-up. Visual Analogue Scale/Score: Continuous variable selection SMD / MD.The mean ± SD was calculated to obtain the P value and 95% confidence interval.

Additional outcome(s): Japanese Orthopaedic Association Scores, Oswestry disability index, SF-36, Clinical effect.Observation time: the end of treatment or follow-up. Japanese Orthopaedic Association Scores, Oswestry disability index, SF-36:Continuous variable selection SMD / MD.The mean ± SD was calculated to obtain the P value and 95% confidence interval. Clinical effect:Binary variable selection RR.Calculate the incident rate, P value and 95% confidence interval were obtained.

Data management: Two authors will independently extract data. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author.The following data will be extracted: author, year, sample size, gender, age, course of disease, diagnostic criteria, intervention measures, outcome indicators, conclusion, baseline comparability, random allocation method, hidden allocation scheme, etc.

Quality assessment / Risk of bias analysis: Two reviewers will independently assesses the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories:Low risk of bias, unclear bias and high risk of bias. The following characterstics will be evaluated: Random sequence generation (selection bias), Allocation concealment (selection bias), Blinding of participants and personnel (performance bias), Incomplete outcome data(attrition bias), Selective reporting (reporting bias), Other biases Results from these questions will be graphed and assessed using Review Manager5.3.

Strategy of data synthesis: Risk ratio(RR) for both fixed and random effects models(weighting by inverse of variance) will be used.A continuity correction will also be used for cells with zero values. Between-study heterogeneity will be assessed using the t2, x2(Cochran Q) and I^2 statistics. According to the Cochrane handbook, the I^2 will be considered non-important(<30%), moderate(30%-60%) and substantial(>60%).Results will be assessed using forest plots and presented as RRs for the main outcome and secondary outcomes.An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies. Publication bias will be assessed by a funnel plot for meta-analysis and quantified by the Egger method.Statistical analysis will be conducted using STATA software for Mac v15.0 (Stata Corp, College Station , Texas) [module“meta"] and R studio v1.0.136 (The R Foundation for Statistical Computing) [package"meta v4.2"].

Subgroup analysis: For the main outcome, when there was significant heterogeneity in the results of meta-analysis, subgroup analysis was performed according to the disease condition, course of treatment and other regulations.

Sensitivity analysis: For the major outcomes with significant positive significance, when the literature conditions are met, according to the quality comparison of literature methodology, whether the randomized method is clear and whether double-blind is used. When the merger results are in a critical state and the heterogeneity is small, the results of random effect model and fixed effect model are compared.

Language: There are no restrictions.

Country(ies) involved: China and Malaysia.

Keywords: Baduanjin ;Meta-analysis; lumbar disc herniation Systematic review; Randomized controlled trial.

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