

INPLASY PROTOCOL

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None declared.

INTRODUCTION

Review question / Objective: To conduct a meta-analysis of randomized controlled trials on the effect of aquatic exercise on the improvement of disability and quality of life in patient with chronic non-specific low back pain (CNLBP), and conduct a comprehensive quantitative analysis of the

Meta-analysis of intervention effect of aquatic exercise on disability and quality of life in patients with chronic non-specific low back pain

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Review question / Objective: To conduct a meta-analysis of randomized controlled trials on the effect of aquatic exercise on the improvement of disability and quality of life in patient with chronic non-specific low back pain (CNLBP), and conduct a comprehensive quantitative analysis of the rehabilitation effect of aquatic exercise on patients with CNLBP, providing a scientific and effective evidence-based basis for the practical application of aquatic exercise in rehabilitation medicine and sports medicine.

Information sources: Pubmed, Embase, Web of Science, Cochrane Library, PEDro, OVID, EBSCO, China Biomedical Journal Citation Database, CNKI, Wanfang data knowledge service platform, VIP Chinese journal full-text database were searched for randomized controlled trials of patients with CNLBP undertaking aquatic exercise therapy. The retrieval period was from database building to November 2021.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 December 2021 and was last updated on 08 December 2021 (registration number INPLASY2021120042).

rehabilitation effect of aquatic exercise on patients with CNLBP, providing a scientific and effective evidence-based basis for the practical application of aquatic exercise in rehabilitation medicine and sports medicine.

Condition being studied: According to the Global Burden of Disease Study 2019, low

back pain has become one of the diseases leading to an increase in the Global Burden of Disease. Chronic non-specific low back pain (CNLBP) is one of the most common types of low back pain, which refers to the pain from below the 12th costal margin to above the hip line caused by the duration of disease ≥ 3 months and with no clear cause. The recurrence rate is high, which not only affects the patients' work and life, but also decrease the patients' quality of life. Currently, CNLBP is mostly treated by non-surgical treatment, including exercise therapy, intramuscular binding, extracorporeal shock wave, acupuncture, etc.. In terms of exercise therapy, aquatic exercise (AE) has been widely used in rehabilitation and scientific research of CNLBP in recent years, and has been recommended by international authoritative treatment guidelines, including deep water running, aquatic walking, aquatic core stability training and other forms. Aquatic exercise has been shown to reduce the compression of spinal joints, promote analgesic substances secreted in the brain, promote the blood circulation, activate lumbar muscles, increase postural stability, etc., The mechanism above are able to improve CNLBP patients in different degree of pain, muscle atrophy, neuromuscular function decline, To improve the disability and restore the quality of life to play a certain role in rehabilitation of CNLBP. Although the research studies of aquatic exercise are increasing year by year, most of the studies have some problems such as small sample size and inconsistent conclusions, and there is still some controversy about the difference in the efficacy of aquatic exercise and conventional rehabilitation therapy on CNLBP.

METHODS

Participant or population: Subjects who has been clinically diagnosed as CNLBP, or meets the diagnostic criteria of CNLBP in the Chinese Expert Consensus on the Diagnosis and Treatment of Acute/Chronic Non-Specific Low Back Pain, or the National Institute for Health and Care Excellence (NICE, UK), or the Clinical

Practice Guidelines of the American Physical Therapy Association (APTA, USA) and the American College of Physicians (APT, USA), or the International Classification of Diseases (11th Revision) of WHO with CNLBP diagnostic criteria (code ME84.2z).

Intervention: Aquatic therapy (code PZA.zy.bs) in accordance with the International Classification of Health Intervention (ICHI Beta-2) by WHO(1) aquatic exercise versus blank control.

Comparator: Other routine rehabilitations for chronic non-specific low back pain.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: (1) Participants: subjects who has been clinically diagnosed as CNLBP, or meets the diagnostic criteria of CNLBP in the Chinese Expert Consensus on the Diagnosis and Treatment of Acute/Chronic Non-Specific Low Back Pain, or the National Institute for Health and Care Excellence (NICE, UK), or the Clinical Practice Guidelines of the American Physical Therapy Association (APTA, USA) and the American College of Physicians (APT, USA), or the International Classification of Diseases (11th Revision) of WHO with CNLBP diagnostic criteria (code ME84.2z).(2) Intervention: aquatic therapy (code PZA.zy.bs) in accordance with the International Classification of Health Intervention (ICHI Beta-2) by WHO(1) aquatic exercise versus blank control.(3) Comparison: aquatic exercise versus other treatments, or aquatic exercise combined with other treatments versus other treatments, or aquatic exercise versus blank control.(4) Outcomes: ① Pain: VAS(visual analogue scale), NRS (numerical rating scale), PRI(pain rating index); ②Diasbility: RMDQ(Roland Morris disability questionnaire), ODI (Oswestry disability index), QBPDS(Quebec back pain disability scale); ③ Quality of Life: SF-36(The MOS-36-item Short-Form Health Survey), SF-12(The MOS-12-item Short-Form Health Survey) including physical health

score(PHS) and mental health score(MHS)
 (5) Study: randomized controlled trials.(6)
 Language is English or Chinese.(7) Journal
 articles with full-text.

Information sources: Pubmed, Embase, Web of Science, Cochrane Library, PEDro, OVID, EBSCO, China Biomedical Journal Citation Database, CNKI, Wanfang data knowledge service platform, VIP Chinese journal full-text database were searched for randomized controlled trials of patients with CNLBP undertaking aquatic exercise therapy. The retrieval period was from database building to November 2021.

Main outcome(s): (1) Pain: VAS(visual analogue scale), NRS (numerical rating scale), PRI(pain rating index); (2) Disability: RMDQ(Roland Morris disability questionnaire), ODI (Oswestry disability index), QBPDS(Quebec back pain disability scale); (3) Quality of Life: SF-36(The MOS-36-item Short-Form Health Survey), SF-12(The MOS-12-item Short-Form Health Survey) including physical health score(PHS) and mental health score(MHS)
 (1) Pain: VAS(visual analogue scale), NRS(numerical rating scale), PRI(pain rating index); (2)Disability: RMDQ(Roland Morris disability questionnaire), ODI(Oswestry disability index), QBPDS(Quebec back pain disability scale); (3)Quality of Life: SF-36(The MOS-36-item Short-Form Health Survey), SF-12(The MOS-12-item Short-Form Health Survey) including physical health score(PHS) and mental health score(MHS).

Quality assessment / Risk of bias analysis: Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding of participants and personnel; 4. Blinding of outcome assessment; 5. Incomplete outcome data and how it was addressed; 6. Selective reporting of the outcome; 7. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 7 items

in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Strategy of data synthesis: Since the outcomes included were continuous variables, data is entered as mean \pm standard deviation, and the measurement units of some outcomes were different, Standard mean difference (SMD) and its 95% confidence intervals (95% CI) will be calculated for the outcomes in each included trial. The significance level was $\alpha=0.05$. I^2 statistics were used to test the heterogeneity between studies. If $I^2 \leq 50\%$ and $P \geq 0.1$, the included studies had small heterogeneity, and the fixed-effect model was conducted for analysis. If $I^2 > 50\%$ and $P < 0.1$, heterogeneity was indicated and random effect model was conducted to pool SMD.

Subgroup analysis: Subgroup analysis was used to determine whether the summary effects vary in relation to clinical characteristics of the trials included are pre-specified. Combined with the basic characteristics of the included studies, subgroup analysis was conducted according to the patients' age, intervention method, intervention duration, and evaluation method, which may affect the outcomes. 4 subgroups analyses were undertaken: ① The first to assess if the different ages(≤ 60 yoa and >60 yoa) produce different treatment effects; ② The second to investigate whether different intervention methods(aquatic exercise combined with other treatment and other treatment comparison, aquatic exercise and other treatment comparison, aquatic exercise and blank control comparison) were equally effective among different patient groups; ③ The third to assess if the different intervention durations (≤ 8 weeks and > 8 weeks) produce different treatment effects; ④ The fourth to assess if the different evaluation tools durations produce different treatment effects, pain intensity measurements included VAS, NRS and PRI, disability measurements included RMDQ, ODI and QBPDS, and measurements of quality of life included

SF12 and SF36, of which SF12 could be specifically divided into physical health (PHS) and mental health (MHS).

Sensitivity analysis: Sensitivity analysis was used to assess robustness of results. In the analysis of pain, disability, and quality of life, the included studies showed high heterogeneity among studies, and neither the elimination method one by one nor the transformation of different effect models could significantly change the heterogeneity test results. Stata16.0 was used for sensitivity analysis of the above outcome indicators.

Language: Chinese.

Country(ies) involved: China.

Keywords: aquatic exercise; chronic non-specific low back pain; Meta-analysis; Randomized Controlled Trial.

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