J Int Acad Phys Ther Res 2020; 11(2): 2096~2101
ISSN 2092-8475
www.iaptr.org
https://doi.org/10.20540/JIAPTR.2020.11.2.2096

Effects of Lumbar Mobilization for Lower Limb Strength in Healthy Individuals: A Protocol for Systematic Review and Meta-Analysis

Background: The effect of mobilization on lumbar back pain has been fully described in several clinical aspects, but evidence for muscle strength would be still less clear.
Objective: To assess the effect of lumbar mobilization on lower limb strength in healthy individuals.
Methods and Analysis: Healthy people aged 18-65 will be included regardless of race or sex. Original peer-reviewed primary reporting randomized controlled trials (RCTs) will be included. Electronic databases, such as MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Web of Science, Pedro, CINAHL, ClinicalTrials.gov will be searched from inception until July 30. Only studies published in English will be included in this review.
Two reviewers will complete the screening for eligibility independently, and the other two reviewers will also complete the risks of data extraction and bias assessment independently. Lower Limb strength will be assessed as primary outcome, and particular intervention or participant characteristics will be assessed as the secondary outcomes. Meta-analysis will be conducted using Review Manager 5.3.3, and evidence level will be assessed using the method for Grading of Recommendations Assessment, Development and Evaluation. Outcomes will be presented as the weighted mean difference or standardized mean difference with 95% CI. If $I^2 \leq 50\%$, P>.1, the fixed effect model will be used, otherwise, random-effects model will be used.
Ethics and dissemination: This review might not be necessary ethical approval because it does not require individual patient's data; these findings will be published in conference presentations or peer-reviewed journal articles.
PROSPERO registration number: CRD42020150144.

Keywords: *Lumbar mobilization; Lower limb strength; Protocol; Systematic review*

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Received : 07 May 2020
Revised : 10 June 2020
Accepted : 14 June 2020

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INTRODUCTION

Rationale

Spinal mobilization is one of the proven manual therapies used by clinicians to manage spinal related musculoskeletal disorders.[1] In particular, the mobilization technique is safer than manipulation (or HVLA, high-velocity low amplitude), and has the advantage that practitioners can be applied on the spot. Representative effects of mobilization include pain reduction, increased joint mobility, tendon reflex, and sensory improvement. Interestingly, about ten years ago, there have been reports of changes in strength or muscle activation induced by mobilization.[2]

Research that suggested spinal mobilization could contribute muscle strength (muscle activation) emphasized that spinal mobilization affects spinal nerve releasing from the spine in reaction of physical compression or disability.[3] Differences in the muscle strength of both arms and legs of an individual could occur not only in healthy people but also in people with pain in the neck or back. This imbalance in strength would affect the functioning of the arms and legs, making it difficult for active daily life.[4]

There has been mentioned controversy over whether the strength should be balanced by participating in muscle strength training or not.

Recently, however, several studies have reported that lumbar mobilization would influences changes in lower extremity strength and has begun to consider lumbar regions when the person has lower extremity muscle imbalances.[5] If the investigator set their priorities on muscle strength training under condition of the participant's lumbar spine is not the leading cause, the lower extremity is easy to have been inclined to do unbalanced strength after the lumbar spine has recovered.

Then, if there is an imbalance in the lower extremities, it may be necessary to apply lumbar mobilization, and then observe the results before training to increase muscle strength of the lower extremities.[6] Researchers who agree with this comment have reported changes in muscle strength after lumbar mobilization using various study designs. Lumbar mobilization techniques include central posteroanterior (PA) mobilization, translatoric glide mobilization, unilateral mobilization, and rotation mobilization. Muscle strength is measured by electronic instrument such as a hand-held dynamometer or Cybex.

To date, several studies have also demonstrated and established the potential effects of using lumbar mobilization to improve the muscle strength of lower limbs. However, there are few attempts to consolidate the results of individual studies to quantify the impacts of lumbar mobilization on muscle strength of lower extremity in healthy person. Therefore, the purpose of this study is to systematically review over randomized controlled trials (RCTs) comparing the effect of lumbar mobilization (intervention) with other interventions (comparisons) or sham (placebo) or for muscle strength of lower extremity in healthy individuals (participants).

Objectives

To assess the effectiveness of interventions using lumbar mobilization compared with sham (placebo) control groups on lower limb strength in healthy individuals.

Primary objective: Quantify the effect of each lumbar mobilization interventions on lower extremity strength in healthy adults.

Secondary objective: Quantify if participant characteristics or particular intervention have influence for the effect of interventions on lower limb strength.

Methods and analysis

This systematic review protocol will be addressed to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA).[7]

Eligibility criteria

Studies will be selected according to the criteria outlined below:

Study designs

Original peer-reviewed primary reporting randomized controlled trials (RCTs) will be included. Only articles published within 10 years will be included.

Participants

Healthy people within 18-65 years of their age will be included regardless of sex or race. Subjects with adolescents (under 18 years of age) and elderly people (over 65) who have low back pain or have had back surgery will be excluded. No restrictions will be made on subject demographics.

Interventions

Intervention in the experimental groups of this review will be limited to studies implementing lumbar mobilization using only grade Ⅲ or (and) Ⅳ. Lumbar mobilization therapy referred to central posteroanterior (PA) mobilization, translatoric glide mobilization, unilateral mobilization, and rotation mobilization only in the lumbar region. Manipulation or mobilization to another joint such as the thoracic spine, the pelvis will be excluded. Lumbar mobilization was the only intervention for the experimental groups in the studies, and co-intervention studies will be excluded.

Comparators

Low-grade mobilization (grade I or II), sham (placebo) mobilization, or no treatment in control groups will be included for comparison. Low-grade mobilization refers to grades I or (and) II that do not reach the end of the physiological range, where passive and repetitive movements or oscillations are applied.[8] Besides, this mobilization technique has been employed as control interventions in previous studies and has been known to have no significant effects on muscle strength.[9,10]

Outcomes

The primary outcomes are the movement torque measurements of isometric, concentric or eccentric

muscle contraction and muscle strength. The muscle strength is inclusive of the hip flexor, extensors and knee flexors knee extensors since the purpose of the experiments is mostly to investigate the motor effects of lumbar mobilization. Studies measured by the isokinetic dynamometer, handheld dynamometer, and load cell with numerical readings will be included. However, studies only measuring muscle activities by electromyography (EMG), Doppler ultrasound measuring muscle thickness or change in muscle thickness, or functional tests without muscle strength measurements will be excluded.

Timing

The defined results must be measured and reported at least one point of pre-intervention and one point of follow-up to be eligible for the inclusion. The subsequent measurements closest to the completion of intervention will be extracted and analyzed to focus on the immediate intervention effect.

Settings

Only studies involving healthy participants will be included.

Language

Only studies published in English will be included, and non-English publications will be leaved as exclusion.

Information sources and search strategy

The following electronic bibliographic databases will be searched from inception to 30 July 2020: PubMed (MEDLINE), EMBASE, Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register), Web of Science, Pedro, CINAHL, ClinicalTrials.gov.

Detailed search strategies for each database were developed by Seoyoon Heo, who has previous experience of conducting systematic reviews, with input from Wansuk Choi, Hojung Ahn and one medical librarian. The search strategy contains relevant headings and key words based on previous literatures[11] and is based on the concepts: (1) asymptomatic or healthy adults AND (2) lumbar mobilization interventions AND (3) lower limb strength outcomes AND (4) study designs. The term will be adapted in MEDLINE searches according to each database.

Other resource searches

We will contact experts in the field to ask about unpublished or potentially relevant ongoing RCTs. We also plan to run the search again before the final analysis. Studies that were not searched through paper information or search database will be systematically discovered by each researcher through hand search during the whole research period. The reference lists of previous relevant reviews and included studies will be retrieved to augment the database search results.

Study records

Data management and selection process

The searched articles will be imported into Zotero 5.0.84 software, and duplications will be removed. Two researchers (Taesuk Choi and Jisung Kim) initially will conduct pilot screening identical studies to ensure consistency. Any discrepancies in interpreting eligibility criteria will be discussed among investigators, and a third-party reviewer (Seoyoon Heo) will cooperated with the sequences if necessary. On pilot screening was completed, the remaining titles and abstracts will be judged independently by both authors for inclusion.

The full text of the studies ascertained as potentially relevant will be obtained and double screened according to eligibility criteria to identify the studies to be included in the review. Eligibility will be discussed for agreement (consensus) between the two investigators, and a third investigator will resolve the discrepancies if necessary. We will looked for additional information from the research author to solve the questions about eligibility according to judged necessary.

The reasons for excluding articles from the full-text screening stage will be recorded. When screening articles, the reviewers will not be blinded to institutions, articles or journal.

All articles will be included and combined to make the best use of the data, if the studies are reported in more than one publication. The selection process of the study will be presented through the PRISMA flow chart.[7]

Data collection process

Studies that meet the inclusion criteria will relevant data extracted using data extraction forms. The data extraction form was based on the Consolidated Standards of Reporting Trials statement, the Cochrane data extraction form, and the Cochrane Template for Intervention Description and Replication

to ensure detail and breadth will captured. To identify superfluous or missing data items, the data extraction form will pilot tested by two investigators on three studies. One investigator (Wansuk Choi) will independently complete the data extraction and at least one additional investigator reviewer (Hojung An) will fully check it. The differences will be resolved through discussion and, if necessary, decided by a third investigator (Seoyoon Heo).

Data items

Extracted data include:

General information (eg, authors, funding source, publication year), study details (eg, study design, randomization method, allocation concealment, and blinding), participant information (eg, demographics, sample size, recruitment methods), attrition/adherence (eg, number of subjects at baseline and follow-up measurements, differential attrition, attendance, study withdrawal, lost to follow-up), intervention information (eg, setting, contents, intervention frequency and duration, method of delivery), comparator information (same items as intervention information), outcomes (eg, whether objectively or self-reported measured, follow-up duration, statistical analysis, intervention effect sizes).

For studies with multiple arms, data from arms that meet the inclusion criteria, if possible, will be extracted. If there is any uncertainty or missing data related to the study, the authors will be contacted.

Outcomes and prioritization

Prioritization will be given to units reported as raw data at baseline and post-intervention over data presented as 'mean change' or equivalent for all outcomes. Data will be extracted at both group and study level to permit analysis of stratified and overall data (eg, extract stratified data for analyze moderation by sex) where possible. We will contact the study authors to request data that is not available.

Risk of bias in individual studies

A minimum of two review authors will appraise the Risk of bias (RoB) independently. Two authors will discuss the discrepancies for consensus and will be consulted by a third investigator if necessary.

For assessing the RoB in the included studies, the Cochrane 'RoB' tool will be used. The following study features will be assessed with the tool as 'low risk', 'high risk' or 'unclear': (1) random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data and (6) selective reporting.

Review authors will note other potential biases not covered by this tool. Review authors will not be blinded by the included article's information (such as author names, affiliated institute, journal of publication). The RoB graph and summary table provided by RevMan software will be presented.

Data synthesis

Outcome data will be synthesized with a random-effects meta-analysis (Review Manager V.5.3.5, Cochrane Collaboration) since the predicted diverse intervention types and range of population. Meta-analysis will be performed on the result measurements reported closest to the intervention completion time to focus on the analysis of immediate intervention effects, regardless of the duration of the intervention. standardized mean differences (SMD) will be calculated as the outcome measures range is likely to be identified. SMD will be categorized with thresholds as small (0.2), medium (0.5) and large (0.8). Mean differences (for continuous data) and 95 % CIs will be calculated and reported where possible.

Assessment of heterogeneity and reporting bias

We will use the mean difference with 95% confidence intervals (CIs) for representation for continuous results. We will also calculated the relative risk and 95% CIs for each outcome for the dichotomous results. Potential heterogeneity will be assessed with the I^2 statistic and Chi-squared test in this study. Heterogeneity will be categorized as low (0%-40%), moderate (30%-60%), substantial (50%-90%) and considerable (75%-100%). If $I^2 \leq 50\%$, $P > .1$, the fixed effect model will be used. We will analyze data using a random-effects model when $I^2 > 50\%$ and $P < .1$. A funnel plot will be reported to assess the presence of publication bias in accordance with Cochrane recommendations.

Sensitivity analysis

Sensitivity analysis will be performed to investigate the potential effect of participant characteristics and RoB (Risk of Bias) on the effect estimates if considered valuable after discussion with the review team. If study quality impacts the effect estimates, analysis will be restricted to different RoB levels to assess. Sensitivity analysis will be checked whether the results change or not after excluding unpublished studies, poor quality studies, and missing data. Sensitivity analysis will primarily eliminate each

study involved to determine whether it can have a specific impact on the results of the meta-analysis.

Analysis of subgroups or subsets

Subgroup analysis will be used to find the reason of the heterogeneity, if there is significant heterogeneity. Subgroup analysis typically explores the source of heterogeneity from the perspective of methodologic heterogeneity and clinical heterogeneity. According to population characteristics, treatment time, intervention methods, and so on, we will divide the group to subgroups. Meta-regression techniques will be used to identify and (or) adjust for potential sources of heterogeneity if considered valuable after discussion with the review team and in the presence of sufficient data on essential covariates.

Reporting bias analysis

Funnel plots and Egger regression analysis will be carried out for assessing the publication bias, if there are more than 10 qualified studies are included in our study.

Narrative synthesis

Meta-analysis will be considered inappropriate if significant heterogeneity exists or outcomes cannot be pooled. Narrative synthesis and 'levels of evidence' assessment will be completed if meta-analysis is impossible. This will be provided in and table format and text.

The ' level of evidence', a rating system, will be used to draw conclusions of the effect. This will evaluate confidence in accumulative evidence at an outcome level. According to sample size and study quality, included studies will be assessed on the level of evidence. There are five levels of evidence that can be achieved- strong, moderate, limited, inconclusive and no evidence for effect. At least two-thirds of studies require consistent positive results to achieve level of evidence of a 'strong', 'normal' or 'limited'. We will assess study's level of evidence in a stratified analysis based on the characteristics of the study, intervention or the participant.

Patient and public involvement

A summary of the proposed plan for the systematic review was shared with an established patient and public involvement (PPI) panel. The PPI panel gave feedback on the usefulness and relevance of the review aims and included outcomes. On review completion, the PPI panel will provide input on the certain summary of review findings and dissemination of findings.

ETHICS AND DISSEMINATION

This systematic review and meta-analysis protocol were registered in PROSPERO at https://www.crd.york.ac.uk/PROSPERO/#myprospero. This review does not require ethical approval and the manuscripts will be published in a peer-reviewed journal. This review followed the Cochrane guidelines[12] and was reported in accordance with the recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses.[13] The results of the review will be informative to intervention participants, healthcare practitioners, researchers and policymakers.

Funding: No funding was obtained for this study.

Competing interests: None declared.

Patient consent for publication: Not required.

Ethics approval: Ethical approval is not required as primary data will not be collected.

Provenance and peer review: Not commissioned; externally peer reviewed.

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