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Non-pharmacological, non-operative management of shoulder conditions: a protocol for an updated systematic review

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ADMINISTRATIVE INFORMATION

Support - The Clinical Compass (https://clinicalcompass.org/), a non-profit evidence-synthesis think tank, will provide funding for this study and the project lead and primary author will receive financial compensation from the Clinical Compass. The funding source had no influence on the design of this protocol and will not have any influence on the execution of this study.

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

Conflicts of interest - The funding source had no influence on the design of this protocol and will not have any influence on the execution of this study. No conflicts of interest were reported for this study protocol.

INPLASY registration number: INPLASY202470027

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 July 2024 and was last updated on 09 July 2024.

INTRODUCTION

Review question / Objective What is the effectiveness of non-pharmacological, non-operative interventions, either alone or in combination, for primary conditions of the shoulder?

Rationale Primary shoulder pain or pain originating from structures of the shoulder complex (e.g., glenohumeral joint, acromioclavicular joint, rotator cuff, bicipital tendon, or bursas) is a leading musculoskeletal complaint. Shoulder pain complaints are recurrent and the incidence increases with age. The community prevalence rate for shoulder pain ranges from 0.7 to 55.2% (median 16.0%). Prevalence is generally higher in women than in men, and high-income nations are reported to have higher median prevalence (16.9%, range 1.0 to 55.2) compared to upper-middle income (8.0%, range 3.6 to 24.0%), lower-middle income (9.5%, range 2.0 to 22.7%) and low-income (0.7%) countries.

Of the primary painful conditions of the shoulder, the most common condition is non-specific shoulder pain, meaning that no specific underlying shoulder complex structures are identified as the etiology of the pain or disability. Common specific structural etiologies of primary shoulder pain include adhesive capsulitis (AC), calcific tendinitis (CT), rotator cuff-associated disorders (RCs), and subacromial impingement syndrome (SIS). These specific structural pathologies have expected historical patterns, physical and orthopedic exam findings, and have unique ultrasound characteristics.

There are many treatment options available for the patients with primary shoulder pain complaints ranging from watchful waiting to surgical intervention. Established nonpharmacological and non-operative management treatments for primary shoulder pain include manual therapies, exercise, dry needling (DN), low-level laser therapy (LLLT), extracorporeal shockwave therapy (ESWT), transcutaneous electrical stimulation (TENS), and acupuncture. The quality of research and effectiveness range for specific diagnoses. For example, there is low- to moderate-quality evidence supporting the use of manual therapies for AC, SIS, RC, and non-specific shoulder pain, while moderate evidence supports ESWT for calcific tendinitis RC.

There are numerous established and emerging non-pharmacological and non-operative modalities for management of primary shoulder pain complaints. A comprehensive evaluation of the most current literature is necessary to support clinical decision-making.

Condition being studied The primary purpose of this systematic review (SR) is to update our previous SR to determine the effectiveness of non-pharmacological, non-operative interventions, either alone or in combination, for primary conditions of the shoulder.

METHODS

Search strategy Informed by our previous SR, we will collaborate with a health sciences librarian (SW) to revise and update the original search strategy for each database; details of each database's final search strategy will be reported in the final publication.

Search terms related to a broad spectrum of shoulder diagnoses and any non-pharmacological, non-operative interventions that serve as management strategies of these conditions will be included. The terms will be tailored for use in each database along with filters for randomized controlled trials (RCTs).

As an example for PubMed:
1 shoulder
2 pain or bursitis or tendinitis
3 1 and 2
4 rotator cuff
5 adhesive capsulitis
6 shoulder impingement syndrome
7 "shoulder diagnosis"[Title/Abstract:~5]
8 "shoulder peripheral diagnosis"[Title/Abstract:~5]
9 3 or 4 or 5 or 6 or 7 or 8
10 chiropractic manipulation or musculoskeletal manipulations or spinal manipulation or "Ultrasonography, Interventional"[Mesh] or physiotherap* or physical therap* or manual therap* or ultrasound or ultrasonograph* or "TNS" or "TENS" or shockwave or electrotherap* or mobili* or rehabilitat* or kinesiotaping or "LLLT" or low level laser therapy or microcurrent or "PEMF" or pulsed electromagnetic field therapy or acupuncture or electroacupuncture or "dry needling" or diathermy
11 9 and 10
12 11 and English[la]
13 12 and randomized controlled trial[pt] or controlled clinical trial[pt] or pragmatic clinical trial[pt]
14 13 and 2016/05/01:2024[dp].

Participant or population We will include adult (age ≥18 years) patients in ambulatory and outpatient care settings who were eligible for the included trials and had a diagnosis of a primary pain condition of the shoulder (e.g., adhesive capsulitis, nonspecific shoulder pain, rotator cuff-associated disorders, and shoulder impingement syndrome). Studies including acute cases (<4 weeks' duration) will be excluded. No upper limits will be placed on age.

Intervention A non-pharmacological, non-operative intervention must be used in at least 1 of the study groups. This can be any combination of treatments, as long as no pharmacological agents (over the counter or prescribed pharmacotherapies) or operative interventions were a formal part of the intervention. Interventions considered but not limited to include: spinal manipulative therapy (SMT), manual therapy (MT), kinesiotaping, low-level laser therapy (LLLT), microcurrent, extracorporeal shockwave therapy (ESWT), pulsed electromagnetic field therapy (PEMF), transcutaneous Nerve Stimulation (TENS), exercise, acupuncture and electroacupuncture, dry needling (DN), or diathermy.

Comparator There will be no restrictions on the composition of the comparison group(s). Active treatments, placebos or shams, waitlist, usual medical care, and no treatment will all be acceptable comparator groups for study inclusion.

Study designs to be included We will consider RCT study designs. Case reports and series, cohorts, commentaries, pilot studies, non-clinical studies, SRs, meta-analysis, and non-human studies will be excluded. We will not consider conference abstracts or non-peer reviewed publications including pre-print servers.

Eligibility criteria In addition to RCTs from our original 2017 SR, we will include articles RCTs investigating human subjects aged 18 years and older, presenting to an ambulatory or outpatient care setting and published in a peer-reviewed journal between May 1, 2016 and June 30, 2024. All studies will be in the English language, involve non-acute (≥ 4 weeks' duration) shoulder pain/condition, and include at least one intervention group with only nondrug, nonsurgical treatment(s).

We will exclude non-controlled trial experimental designs, interventions delivered only to inpatients, commentaries/editorials/letters, non-peer-reviewed publications, pre-print server publication, conference abstracts, case reports/series, pilot or feasibility randomized controlled trials not designed or powered to assess effectiveness, and SRs. Other reasons to exclude a study will include non-clinical study designs, studies without treatment outcomes, or studies where all treatment groups include a pharmacological agents and/or surgical intervention.

Information sources We will pull forward the included RCTs in our prior SR published in 2017. This updated review will search from the end point of the prior SR, May 2016, to June 2024 from the following electronic databases from: PubMed, Index to Chiropractic Literature, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Physiotherapy Evidence Database (PEDro).

Main outcome(s) For our primary outcomes of interest, we will consider measures of pain (e.g., visual analog scale, numeric pain rating scale) and/or function (e.g., disability) assessed by valid and reliable patient-reported outcome measures (e.g., Disabilities of the Arm, Shoulder and Hand [DASH], Shoulder Pain and Disability Index [SPADI], and Modified American Shoulder and Elbow Surgery questionnaire [MASES]). A secondary outcome will include presence or absence of adverse event reporting (yes/no).

Additional outcome(s) For those included studies that do report adverse events, we will record the reported adverse events in the data extraction. Any other outcomes reported for the study we will exclude from the data extraction.

Data management Database searches and de-duplication will be conducted by the team health sciences librarian. References will be managed using Zotero (Vienna, Virginia) and imported into Rayyan (Cambridge, MA) for article screening. Extracted data will be stored in a pre-defined Microsoft Excel workbook.

Quality assessment / Risk of bias analysis For previously and newly identified RCTs, we will use the Cochrane risk of bias tool (RoB 2) to independently assess risk of bias for each RCT. RoB 2 tool is the most widely used risk of bias tool and is divided into 5 bias domains, each with signaling questions and response options. At least 2 investigators will evaluate the risk of bias of included articles. Disagreements will be resolved by discussion and adjudicated by a third reviewer if necessary.

The risk of bias determinations for each domain are "low risk of bias," "some concerns," or "high risk of bias". For cluster RCTs, five additional domains will be assessed, as recommended by Cochrane (16.3.2). 'High risk of bias' quality rated RCTs will be excluded from the evidence tables. We will notate and provide citation of the excluded 'high risk of bias' RCTs in a supplemental file upon submission for peer-review.

Strategy of data synthesis We will visualize RoB2 using robvis20, a web app designed to for visualizing risk of bias assessments. The tool creates: 1) "traffic light" plots of the domain-level judgements for each individual result; and 2) weighted bar plots of the distribution of risk-of-bias judgements within each bias domain.

We will use the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to interpret and evaluate the quality of the evidence. The methods and recommendations described in both the Cochrane handbook and by the GRADE working group will be used to assess the quality of evidence using five domains: risk of bias, inconsistency, indirectness of evidence, imprecision of effect estimates and potential publication bias. At least 2 investigators will evaluate the strength of evidence of included RCTs. Disagreements will be resolved by discussion and adjudicated by a third reviewer if necessary.

Subgroup analysis We will organize results for descriptive purposes by condition and informed initially by the results of our prior SR, AC, SIS, RC, and non-specific shoulder pain.

Sensitivity analysis No sensitivity analysis is planned as this is a qualitative rather than quantitative SR.

Language restriction Studies will be limited to English.

Country(ies) involved United States.

Other relevant information This SR will be performed from June 2024 to November 2024. The protocol is designed in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement. Prior to registering this protocol, we searched the Cochrane Database of Systematic Reviews, Open Science Framework, International Prospective Register of Systematic Reviews (PROSPERO), and the International Platform of Registered Systematic Review and Meta-analysis Protocols (INSPLAY) for similar reviews that were registered. The planned SR will be conducted in accordance with PRISMA.
Our prior systematic review: Hawk C, Minkalis AL, Khorsan R, Daniels CJ, Homack D, Gliedt JA, Hartman JA, Bhalerao S. Systematic Review of Nondrug, Nonsurgical Treatment of Shoulder Conditions. J Manipulative Physiol Ther. 2017 Jun;40(5):293-319. doi: 10.1016/j.jmpt.2017.04.001. Epub 2017 May 26. PMID: 28554433.
The views expressed are those of the authors and do not reflect the official views or policies of the Department of Veterans Affairs or the United States Government.

Keywords shoulder pain; rotator cuff; adhesive capsulitis; nonspecific shoulder pain; shoulder impingement syndrome; manual therapies; exercise; acupuncture; non-pharmacological; systematic review.

Dissemination plans Findings from this updated SR will be prepared and submitted to be considered for publication in a peer-reviewed journal. Presentations of the review's findings may be submitted to conference(s). Additional dissemination efforts may include press releases, podcasts, social media and blog posts, and/or continuing education presentations for licensed health care professionals will be used to promote awareness of this publication.

Contributions of each author

Author 1 - Zachary Cupler - Conceived of the updated review, provided project management and oversight, drafted the initial updated review protocol, contributed substantially to the protocol revision, and approved of it before protocol registration.
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Author 2 - Clinton Daniels - Conceived of the updated review, critically revised the protocol for content, contributed substantially to the protocol revision and approved of it before protocol registration.
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