RENO, C., ALEXANDER, L. and SWINTON, P. 2023. The effectiveness of shockwave therapy in the treatment of adhesive capsulitis in people with type 2 diabetes: a systematic review with meta-analysis protocol. [Protocol]. *PROSPERO* [online], item number CRD42023459778. Available from: https://www.crd.york.ac.uk/PROSPERO/view/CRD42023459778

# The effectiveness of shockwave therapy in the treatment of adhesive capsulitis in people with type 2 diabetes: a systematic review with metaanalysis protocol. [Protocol]

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2023



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## NIHR National Institute for Health and Care Research

**PROSPERO** International prospective register of systematic reviews

## The effectiveness of shockwave therapy in the treatment of adhesive capsulitis in people with type 2 diabetes: A systematic review with meta-analysis protocol

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#### Citation

Crystal Reno, Lyndsay Alexander, Paul Swinton. The effectiveness of shockwave therapy in the treatment of adhesive capsulitis in people with type 2 diabetes: A systematic review with meta-analysis protocol. PROSPERO 2024 Available from <a href="https://www.crd.york.ac.uk/PROSPERO/view/CRD42023459778">https://www.crd.york.ac.uk/PROSPERO/view/CRD42023459778</a>

## **REVIEW TITLE AND BASIC DETAILS**

#### **Review title**

The effectiveness of shockwave therapy in the treatment of adhesive capsulitis in people with type 2 diabetes: A systematic review with meta-analysis protocol

#### **Review objectives**

The objective of this review is to synthesise the best available evidence on the effectiveness of extracorporeal shockwave therapy (ESWT) in the treatment of adhesive capsulitis in the Type 2 Diabetes Mellitus population, compared to other forms of current electrotherapy intervention or standard care.

Specifically, the review question is: What is the effectiveness of ESWT in the treatment of adhesive capsulitis in people with Type 2 Diabetes Mellitus in comparison to other conservative treatment?

## SEARCHING AND SCREENING

#### Searches

The databases to be searched include: MEDLINE, CINAHL, ScienceDirect, Sports Discus, PEDro, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL). The trial registers to be searched include: UK clinical trials gateway, ClinicalTrials.gov; EU trials registry. The search for unpublished studies will include: Google Scholar, EThOS. Limits: English language & 2012-2023. MEDLINE and CINAHL search strategy: ["extracorporeal shockwave therapy" OR "extracorporeal shock wave therapy" OR "ESWT" OR "shockwave therapy" OR "shock wave therapy" OR "radial extracorporeal shockwave therapy" OR "radial extracorporeal shock wave therapy" OR "rESWT"] AND ["adhesive capsulitis" OR "frozen shoulder" OR "shoulder pain"] AND ["diabetes type 2 or diabetes mellitus type 2 or diabetes 2" OR "diabetes or diabetes mellitus"]

#### Study design

This review will include randomised controlled trials only.

## ELIGIBILITY CRITERIA

#### Condition or domain being studied

Type 2 diabetes adhesive capsulitis / frozen shoulder

#### Population

The current review will consider studies that include individuals aged 18 years and over, have Type 2 Diabetes Mellitus, with primary or secondary adhesive capsulitis, regardless of gender, ethnicity, or geographic location.

#### Intervention(s) or exposure(s)

The current review will consider ESWT (focused or radial) in the treatment of adhesive capsulitis. This includes any dosage and treatment locations, with or without an exercise programme delivered by a physiotherapist or trained specialist.

#### Comparator(s) or control(s)

This review will consider other electrotherapy interventions (such as but not limited to low-level laser therapy, shortwave diathermy, ultrasound therapy, pulsed electromagnetic field therapy); standard care (such as but not limited to pharmacological care, injection therapy, physiotherapeutic care, and exercise), or placebo/control.

#### Context

Any setting where ESWT interventions are provided will be considered for inclusion (such as, but not limited to physiotherapy departments, outpatient departments, rehabilitation clinic, and primary care settings).

## OUTCOMES TO BE ANALYSED

#### Main outcomes

The current review will consider studies that include the primary outcome of pain, measured by any recognized method (such as but not limited to visual analogue scales, Numeral Rating Scales or verbal rating scales).

#### Additional outcomes

The current review will consider shoulder joint range of movement measured by a manual or electro-goniometry, and disability (measured by but not limited to Shoulder Pain and Disability

Index (SPADI), Constant Shoulder Score (CSS), Oxford Shoulder Score (OSS), and Disabilities of Arm, Shoulder, Hand Questionnaire (DASH)).

## DATA COLLECTION PROCESS

#### Data extraction (selection and coding)

Data will be extracted from papers included in the review using the standardized data extraction tool available in JBI SUMARI by two independent reviewers. The data extracted will include specific details about the interventions, comparators, populations, study methods and outcomes of significance to the review question which include pain, range of movement and disability/function. Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer. Authors of papers will be contacted to request missing or additional data where required.

#### Risk of bias (quality) assessment

Selected studies will be critically appraised by two independent reviewers at the outcome level using the Cochrane risk-of-bias tool for randomized trials (RoB 2; Sterne et al. 2019). Any disagreements that arise will be resolved through discussion, or with a third reviewer. Transparent reporting of risk of bias will be completed by recording reasons for each domain selection across all outcomes and studies, which will be made available in supplementary files.

### PLANNED DATA SYNTHESIS

#### Strategy for data synthesis

All primary and secondary outcome measures will be obtained from continuous scales and therefore effect sizes will be calculated from mean differences and standardised for pooling where required. Where possible, data extracted from studies will be pooled into a statistical meta-analysis featuring random effects models. Initially, plausibility of univariate random effects models for pain, joint range of motion, and disability will be assessed. Studies obtained for this review are likely to report data across multiple time points, therefore where possible hierarchical random effects models will be investigated to account for correlations between effects sizes reported in the same study (Van den Noorgate et al. 2014). In the event that studies consistently report effect sizes across all outcomes and these are correlated, suitability for a multivariate random-effects meta-analysis will be investigated to obtain more precise estimates (Jackson et al. 2011). Models investigated will also include length of time from baseline as a covariate to reduce heterogeneity. For each outcome, overall assessments regarding the certainty in cumulative evidence will be made using the GRADE guidelines (Schünemann et al. 2013).

#### Analysis of subgroups or subsets

None planned.

## REVIEW AFFILIATION, FUNDING AND PEER REVIEW

#### **Review team members**

• Ms Crystal Reno, University of Stirling

- Dr Lyndsay Alexander, Robert Gordon University
- Dr Paul Swinton, Robert Gordon University

#### **Review affiliation**

University of Stirling, Robert Gordon University

Funding source

### TIMELINE OF THE REVIEW

#### **Review timeline**

Start date: 14 September 2023. End date: 31 December 2023

## Date of first submission to PROSPERO

05 October 2023

#### Date of registration in PROSPERO

05 October 2023

## CURRENT REVIEW STAGE

#### Publication of review results

The intention is not to publish the review once completed.

#### Stage of the review at this submission

Review stage	Started	Completed
Pilot work	$\checkmark$	
Formal searching/study identification	$\checkmark$	$\checkmark$
Screening search results against inclusion criteria		
Data extraction or receipt of IP		
Risk of bias/quality assessment		
Data synthesis		
Review status		

The review is currently planned or ongoing.

#### ADDITIONAL INFORMATION

#### **PROSPERO version history**

• Version 1.0 published on 05 Oct 2023

#### **Review conflict of interest**

None known

#### Country

#### Scotland

#### **Medical Subject Headings**

Bursitis; Conservative Treatment; Diabetes Mellitus, Type 2; Electric Stimulation Therapy; High-Energy Shock Waves; Humans; Meta-Analysis as Topic; Systematic Reviews as Topic

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