# INPLASY PROTOCOL

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**Support:** **None.**

**Review Stage at time of this submission:** **Piloting of the study selection process.**

**Conflicts of interest:**
**None declared.**

# The extracorporeal shock wave therapy as a monotherapy for Achilles tendinopathy. A protocol for a systematic review

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**Review question / Objective:** **The research question will be defined by the PICOS format: in patients with Achilles tendinopathy, how effective is shock wave therapy as a monotherapy compared with no intervention or palcebo (sham) treatment or any other conservative treatment in the intensity of pain that was measured using a quantifiable scale (e.g., a numeric rating scale (NRS) or a visual analog scale (VAS)) and patient-reported outcomes for physical function and disability (e.g., Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A), American Orthopaedic Foot and Ankle Society score (AOFAS), Roles and Maudsley score, 6-point Likert satisfaction score), confirmed in the randomized controlled trials.**
**Information sources:** **MEDLINE (PubMed, EBSCOHost and Ovid), EMBASE Databases will be searched from their inception to July 2022. The reference lists of studies meeting the inclusion criteria will be searched to identify additional relevant studies. In order to minimize the risk of omitting relevant sources, the following complementary strategies to explore grey literature will be used: e.g. customized Google search engines, targeted websites and consultation with contact experts. A detailed search strategy and search term alternatives for each database will be available in the appendix. Two researchers will screen references for eligibility independently.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 July 2022 and was last updated on 06 July 2022 (registration number INPLASY202270028).

## INTRODUCTION

**Review question / Objective:** **The research question will be defined by the PICOS format: in patients with Achilles tendinopathy, how effective is shock wave therapy as a monotherapy compared with no intervention or palcebo (sham)**

treatment or any other conservative treatment in the intensity of pain that was measured using a quantifiable scale (e.g., a numeric rating scale (NRS) or a visual analog scale (VAS)) and patient-reported outcomes for physical function and disability (e.g., Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A), American Orthopaedic Foot and Ankle Society score (AOFAS), Roles and Maudsley score, 6-point Likert satisfaction score), confirmed in the randomized controlled trials.

**Rationale:** Extracorporeal Shockwave Therapy appears to be a promising treatment modality in patients with tendinopathies. The meta-analyses conducted so far have assessed the efficacy of radial and focused shockwave therapies in patients with common lower extremity tendinopathies (Liao, Tsauo, et al., 2018a; Liao, Xie, et al., 2018; Mani-Babu et al., 2015). Only Punnoose (2017) and Fan (2020) narrowed down their analysis to patients with Achilles tendinopathy. However, they did not define the strength of evidence for ESWT efficacy in this lower limb condition. Also, Fan et al. (2020) failed to carry out separate comparisons between ESWT receivers and those with sham ESWT, traditional nonsurgical treatments or no treatment. The latter subgroups were collectively analyzed as the control arm. Siddaway et al. (2019) strongly recommend the patient, intervention, comparison, outcome (PICO) model. According to this model the study population, intervention type, control group with another intervention or no intervention and clinical outcome will be clearly defined in our systematic review. The principles of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach will be applied to assess the quality of the body of evidence (Guyatt et al., 2008), which is the novelty of our systematic review. The system offers four levels of quality: high, moderate, low and very low.

**Condition being studied:** Achilles tendinopathy is among the most prevalent musculoskeletal disorders, accounting for 31% of all lower extremity tendinopathies (Riel et al., 2019). Its symptoms, i.e., pain and edema, function impairment and stiffness after prolonged rest, are moderate but persistent (Chimenti et al., 2017; Singh et al., 2017). In patients with noninsertional tendinopathy pain is located over the main body of Achilles tendon 2 to 6 cm proximal to its insertion into the calcaneous (Rompe et al., 2009; Furia 2008). Patients suffering from insertional pathology usually present with lesions in the distal portion of the structure, ie., posterosuperior calcaneal protuberance (Shakked, Raikin 2017).
Achilles tendinopathy is a degenerative condition, with no histological signs of inflammation, which is caused by overloading and accumulation of microinjuries (Rudavsky and Cook, 2014). Repetitive tendon strain promotes cumulative microtrauma (Järvinen et al. 2005). When the reparative capacity of the tendon is exceeded, tendon sheath may become inflamed resulting in edema, pain and/or tendon degeneration (Maffulli et al. 2004; Järvinen et al. 2005).
Histologically, tendinopathy is characterized by the absence of inflammatory cells, poor healing, non-inflammatory intratendinous collagen degeneration, collagen fibre disorientation and thinning, hypercellularity with high concentrations of glycosaminoglycans and proteoglycans, and neovascularization (Maffulli et al. 2004; Khan et al., 2002; Cassel et al. 2015).
Achilles tendinopathy is frequently diagnosed in athletes whose activity is associated with mechanical loading of the musculotendinous unit in the lower limbs that exceeds the tendon's capacity. The etiology of Achilles tendinopathy is associated with a number of intrinsic and extrinsic factors. Intrinsic factors include impaired blood supply, gastrocnemius-soleus dysfunction, age, sex, body weight, metabolic disorders, lateral ankle instability, foot joint hypermobility and foot deformities. Extrinsic factors that might contribute to Achilles tendinopathy are several sport disciplines (volleyball, basketball, running), changes in training schedules, training errors, past injuries, inadequate footwear and unsuitable

training surfaces (Maffulli et al. 2004; Järvinen et al. 2005; Singh et al., 2017).

## METHODS

**Search strategy:** A range of text words and indexed terms related to 'achilles tendinopathy', 'achilles tendonitis', 'achilles tendonopathy', 'shockwave therapy', 'shock wave therapy', 'shock-wave therapy', 'extracorporeal shockwave', 'eswt', 'treatment', 'intervention', 'therapy', 'management', 'rehabilitation' will be used. MEDLINE (PubMed, EBSCOHost and Ovid), EMBASE Databases will be searched.
A detailed search strategy for PubMed:
Piloting formula for PubMed is as follows: ((achilles tendinopathy [tiab] OR achilles tendonitis [tiab] OR achilles tendinosis [tiab] OR achilles tendinitis [tiab]) AND (shockwave therapy [tiab] OR shock wave therapy [tiab] OR extracorporeal shockwave [tiab] OR shock wave [tiab] OR eswt [tiab]) AND (therapy[tiab] OR treatment)).

**Participant or population:** Studies of adult human participants (18 years or older or according to study authors' definitions of adult), with chronic and acute Achilles tendinopathy. In addition, studies of patients with insertional or non-insertional Achilles tendinopathy and patients who are non-active individuals, recreational and/or elite athletes will be included. Trials will be excluded if they evaluated patients with painful heel spur and/or plantar fasciitis, patients with chronic or acute ruptures of Achilles tendinopathy, patients with chondromalacia, meniscus injury, and/or degenerative osteoarthritis of the knee joint. In addition, studies of children and animals will be excluded.

**Intervention:** Radial shock wave therapy or focused shock wave therapy (as a monotherapy).

**Comparator:** Sham (placebo) electrical stimuation, no active treatment, other conservative treatment (e.g., eccentric training, laser therapy, platelet-rich plasma) will be included in this review. Potential groups which will be included in this review are: radial shock wave therapy or focused shock wave therapy versus placebo; radial shock wave therapy or focused shock wave therapy versus no intervention; radial shock wave therapy or focused shock wave therapy versus other conservative treatment (e.g., eccentric training, laser therapy, platelet-rich plasma).

**Study designs to be included:** This review will include published randomised controlled trials (RCTs) and full-text of a peer-reviewed original research article. Retrospective studies, case series, conference abstracts, proceedings, secondary analyses, reviews, meta-analyses, quasi-RCTs, crossover trials and non-experimental studies will not be included.

**Eligibility criteria:** Eligibility criteria will be based on the PICOS elements. Inclusion criteria: Population: adult human participants (18 years or older or according to study authors' definitions of adult), chronic and acute Achilles tendinopathy, patients with insertional or non-insertional Achilles tendinopathy, studies in patients with lower limb tendinopathies and other soft tissue disorders only if the data for patients with Achilles tendinopathy were presented separately, non-active individuals, recreational and/or elite athletes.Intervention: radial shock wave therapy or focused shock wave therapy (as a monotherapy). Comparison: no active treatment, sham (placebo) electrical stimulation, other conservative treatment (e.g., eccentric training, laser therapy, platelet-rich plasma). Outcome: intensity of pain that was measured using a quantifiable scale (e.g., a numeric rating scale or a visual analog scale), the successful treatment rate that was measured using a ranking scale (American Orthopaedic Foot and Ankle Society score (AOFAS), Roles and Maudsley score, 6-point Likert satisfaction score), patient-reported outcomes for physical function and disability that were assessed using questionnaires (Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A) Exclusion criteria: patients with painful

heel spur and/or plantar fasciitis, patients with chronic or acute ruptures of Achilles tendinopathy, patients with chondromalacia, meniscus injury, and/or degenerative osteoarthritis of the knee joint, only children, animals. Intervention: radial shock wave therapy combined with focused shock wave therapy within the same treatment session (as an experimental group), shock wave therapy combined with another conservative treatment intervention (as an experimental group).Comparison: surgical treatment, pharmacological treatment.Outcome: trials only assessing the adverse effects of shock wave therapy and/or health economics (e.g. costs of interventions, resource implications)RCT methodological quality and time-point of therapeutic efficacy evaluation (time from therapy completion to follow-up examination) will not be considered review inclusion criteria.

**Information sources:** MEDLINE (PubMed, EBSCOHost and Ovid), EMBASE Databases will be searched from their inception to July 2022. The reference lists of studies meeting the inclusion criteria will be searched to identify additional relevant studies. In order to minimize the risk of omitting relevant sources, the following complementary strategies to explore grey literature will be used: e.g. customized Google search engines, targeted websites and consultation with contact experts. A detailed search strategy and search term alternatives for each database will be available in the appendix. Two researchers will screen references for eligibility independently.

**Main outcome(s):** Main outcome measures will be:
- the intensity of pain that was measured using a quantifiable scale (e.g., a numeric rating scale (NRS) or a visual analog scale (VAS))
- the successful treatment rate that was measured using a ranking scale (American Orthopaedic Foot and Ankle Society score (AOFAS), Roles and Maudsley score, 6-point Likert satisfaction score)
- patient-reported outcomes for physical function and disability that were assessed using questionnaires (Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A).

**Additional outcome(s):**
- global assessment of self-reported outcomes for physical function.
- the number of patients with Achilles tendinopathy with subjective cures or improvement, defined as the number of patients with self-reported improvement or cured.

**Data management:** The selection of studies will be conducted in two stages. During the first stage, study titles and abstracts will be used to select the retrieved articles for further assessment and to eliminate the studies that failed to meet the inclusion criteria. During the second stage, studies that will appear to meet the inclusion criteria, will be downloaded and the full paper will be reviewed. The decision concerning the ultimate inclusion of the study will be then made on the basis of the pre-specified inclusion and exclusion criteria. Two authors (MS and DC) will independently search for articles and screen the studies in a blinded manner. Any disagreements between the authors will be resolved through consensus, with other research team member (JM) acting as arbiter. Data will be extracted independently by two investigators (MS and DC) for each study. The following data items will be sought: basic publication characteristics (first author, publication year, country), data on participant characteristics, ESWT intervention (ESWT type, procedure description), outcomes (primary and secondary, method and timing of assessment) and results. We will use GRADEpro Guideline Development Tool (McMaster University, 2015; developed by Evidence Prime, Inc.; available from gradepro.org.) to create the 'Summary of findings' table. Statistical analyses will be performed using Statistica Software (Data Analysis Software System, serial number Statistica AWF Katowice: JPZ009K288211FAACD-Q, version 13.3, Plus Set package).

**Quality assessment / Risk of bias analysis:** A judgement of 'low risk' of bias, 'high risk' or bias, or 'unclear risk' of bias will be provided by two reviewers. Any disagreements will be resolved by discussion or by involving a third reviewer until consensus is reached. The methodological quality of randomized clinical studies will be determined using the Physiotherapy Evidence Database (PEDro) scale consisting of 10 questions pertaining to the internal validity and statistical information provided. Based on the PEDro score, the methodological quality of trials will be rated as high (PEDro scores ≥7), medium (4 to 6), or low (≤ 3). Two reviewers (MS, DC) will independently assess the methodological quality of the articles included in this meta-analysis. In cases of disagreement, consensus will be sought by involving a third researcher (JM).

**Strategy of data synthesis:** We will combine data from individual studies in a meta-analysis only where appropriate. For continuous data, we will presented the mean difference (MD) with a 95% confidence interval (CI). For dichotomous data, a random effects method will be used to pool the summary risk ratio (RR) with 95% confidence interval (CI). A random effects model will be used if a high level of clinical heterogeneity is expected due to the study design differences, such as different interventions, intervention parameters, outcome measures and trial settings. Otherwise, we will apply a fixed effects model. If any meta-analysis cannot be performed, we will report the results as the narrative description. Heterogenity will be assessed with I2 statistics (25% - low, 50% moderate, and 75% high heterogeneity). Statistical significance will be set at $p<0.05$.

**Subgroup analysis:** If we find substantial heterogeneity ($I^2$ more than 50%), we will investigate the possible causes and carry out subgroup analyses if appropriate.

**Sensitivity analysis:** Sensitivity analysis will be conducted by excluding the included RCTs at high risk of bias for any one or more of selection, attrition, or detection bias. The meta-analysis will be undertaken again after removing the lower-quality studies. The results of syntheses will be compared and discussed according to the pooled effect size.

**Language:** The article published in English will be considered for inclusion.

**Country(ies) involved:** Poland; Czech Republic; Jerzy Kukuczka Academy of Physical Education, Mikołowska 72a, 40-065 Katowice, Poland; Faculty of Physical Education and Sport, Physiotherapy Department, Charles University, José Martiho 31, Prague.

**Keywords:** achilles tendinopathy; achilles tendonitis; achilles tendonopathy; shockwave therapy; shock wave therapy; shock-wave therapy; extracorporeal shockwave; eswt; treatment; intervention; therapy; management.

**Dissemination plans:** We are planning to submit the article with a results of syntheses to an international peer-reviewed journal with impact factor.

**Contributions of each author:**
Author 1 - Magdalena Stania - Author 1 conceiving the review; designing the review; data collection; data management; analysis of data; interpretation data; writing the protocol.
Author 2 - Jitka Malá - Author 2 coordinating the review; data collection; data management; interpretation data.
Author 3 - Daria Chmielewska - Author 3 designing the review; data collection; data management; analysis of data; writing the protocol.

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