

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Title:

Identification 1a) Identify the report as a protocol of a systematic review

Participant eligibility criteria used in Achilles tendinopathy (AT) research: protocol for a systematic review.

Update 1b) If the protocol is for an update of a previous systematic review, identify as such

N/A

Registration 2) If registered, provide the name of the registry (such as PROSPERO) and registration number

N/A.

Authors:

Contact 3a) Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author

Kristian Damgaard Lyng¹: klyng@dcm.aau.dk; Henrik Riel¹: hriel@dcm.aau.dk; Melanie Louise Plinsinga²³: m.plinsinga@uq.edu.au; Seth O'Neill⁴: so59@leicester.ac.uk; Jarrod Antflick⁵: jarrod.antflick@fortiusclinic.com; Richard Norris⁶
Richard.Norris2@liverpoolft.nhs.uk;

1: Center for General Practice at Aalborg University, Fyrkildevej 7, 9220 Aalborg East, Denmark

2: The University of Queensland, School of Health and Rehabilitation Sciences: Physiotherapy: Sports Injury Rehabilitation and Prevention for Health, St. Lucia QLD 4072, Australia

3: Griffith University, School of Allied Health Sciences, Nathan Campus, QLD 4111, Brisbane, Australia

4: School of Allied Health Professions College of Life Sciences University of Leicester, LG20 Maurice Shock Medical Sciences Building Leicester, PO BOX 138

5: Complete Physio, First Floor, 321 Fulham Rd, Chelsea, London SW10 9QL, UK

6: Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK, L9 7AL

Contributions 3b) Describe contributions of protocol authors and identify the guarantor of the review

KL is the guarantor. All authors contributed to the development of selection criteria, data extraction criteria and analysis plan. **KL** will conduct the literature search. **KL, HR, MLP, SO, JA,** and **RN** will screen studies and extract data independently.

All authors are expected to make valuable scientific additions to the draft and will be co-authors on subsequent manuscripts based on these data. The definition of ‘author’ is defined as per ICMJE’s four criteria (1):

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The expected author list is: Lyng K; Antflick J; Norris R; Plinsinga ML; Riel H; O’Neil S.

Amendments

4) If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments

N/A

Support:

Sources 5a) Indicate sources of financial or other support for the review

The review receives no external funding.

Sponsor 5b) Provide name for the review funder and/or sponsor

Center for General Practice at Aalborg University.

Role of sponsor or funder

5c) Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol

Sponsor is part of the study design, data analyses and writing of the manuscript. Sponsor will ensure that the results will be submitted for publication. Sponsor is non-commercial and declares no conflict of interest.

INTRODUCTION

Rationale 6) Describe the rationale for the review in the context of what is already known

Achilles tendon pain (AT) is a painful condition that affects approximately 2% of the general population (2). AT is common among sedentary patients, but most common in patients participating in running-related sports (3). AT is characterized as a clinical diagnosis where the patients experience local pain and swelling near the Achilles tendon and daily functional disability (4). The underlying patho-etiological mechanisms are unclear, although excessive loading is thought to play an important role in development of AT (5). Epidemiological research on AT is influenced by large heterogeneity mainly caused by contrasting methodologies which limits the generalisability (6-8). Previously, it has been suggested to sub-categorise into separate classifications named after their pathoanatomical entities and clinical presentations (9,10). As noted in other research, the absence of sub-categorizing might influence the outcome of interventions (9). To this date, there is a complete dearth of guidelines informing possible criteria to consider when recruiting patients with AT into research. This gap in participant eligibility criteria, may cause similar high variability seen in order musculoskeletal disorders (11,12). Additionally, this could influence the validity and generalisability negatively and hamper recommendations of meta-analysis which potentially can be minimised using identical participant eligibility criteria (13-15). Identification of the actual heterogeneity among participant eligibility criteria used in AT research to date is important before recommendations are being developed.

Objectives 7) Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)

The objectives of this systematic review of published research studies on AT are to answer the following questions:

1. How variable are the participant eligibility criteria utilised amongst published research studies on AT December 2009-2019.
2. Is there an association between the choice and definition of an eligibility criterion and the corresponding clinical characteristics and/or demographic characteristics of participants?

METHODS

Eligibility criteria 8) Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review

We will include published prospective and cross-sectional studies in which eligibility criteria were determined prior to the inclusion of participants (i.e. no retrospective studies, case-series without a statement of eligibility criteria or studies that investigate the prevalence of AT in any given population) of an adult population with mean age of 18 or above describing the condition as either AT, insertional AT, Triceps Surae tendinopathy, mid-portion tendinopathy, Achilles tendinitis, Achillodynia or Achilles tendinosis. Studies that examine differential diagnoses of AT such as tibialis posterior tendinopathy, superficial calcaneal bursitis, Retrocalcaneal bursitis, posterior ankle impingement, ankle osteoarthritis, calcaneal apophysitis, strain and ruptures to nearby muscles or fascia will be excluded. Seminal papers outside the timeframe used in this study will be included if considered relevant for the scope of this review. Studies in English will be included but there will be no restrictions regarding type of setting.

Information sources

9) Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage

Literature search strategies will be developed using MeSH terms and truncated free text words that relate to AT. We will search for studies published from December 1st, 2009 and onwards in PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL) and Cumulative Index to Nursing and Allied Health Literature (CINAHL).

Search strategy

10) Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated

The literature search strategies will be designed in collaboration with a librarian with expertise in designing such strategies for systematic reviews. A draft of the search strategy used in PubMed is presented below.

Search	Add to builder	Query	Items found	Time
#8	Add	Search ((((((Achilles AND Tendi*)) OR (calcane* AND Tendi*)) OR (Triceps surae AND Tendon)) OR achillodynia) OR ((Achilles) AND tendon AND Pain)) Filters: Publication date from 1999/01/01 to 2019/12/31; Humans	2368	06:50:38
#7	Add	Search ((((((Achilles AND Tendi*)) OR (calcane* AND Tendi*)) OR (Triceps surae AND Tendon)) OR achillodynia) OR ((Achilles) AND tendon AND Pain)) Filters: Publication date from 1999/01/01 to 2019/12/31	3096	06:50:13
#6	Add	Search ((((((Achilles AND Tendi*)) OR (calcane* AND Tendi*)) OR (Triceps surae AND Tendon)) OR achillodynia) OR ((Achilles) AND tendon AND Pain))	3873	06:50:01
#5	Add	Search (Achilles) AND tendon AND Pain	1511	06:41:43
#4	Add	Search achillodynia	77	06:41:35
#3	Add	Search Triceps surae AND Tendon	550	06:41:29
#2	Add	Search calcane* AND Tendi*	381	06:41:20
#1	Add	Search Achilles AND Tendi*	2496	06:41:11

Study records:

Data management

11a) Describe the mechanism(s) that will be used to manage records and data throughout the review

We will upload search results to Excel, an internet-based software that was chosen by Cochrane as the standard production platform for Cochrane Reviews, and use this for the screening, data extraction, and diagnostic validity assessment (16). The studies retrieved from the search will be divided in thirds and screening will be performed independently in three pairs. If any disagreement should occur between one pair (e.g. KL and HR) another author from one of the other pairs (e.g. MLP) will be consulted and will have final decision of inclusion or exclusion. After extraction, data will be exported to Microsoft Excel.

Selection process

11b) State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)

KL will independently screen the titles and abstracts of the studies that are retrieved from the search. We will then obtain full-text versions of studies that appear to be eligible based on our inclusion criteria. We will also obtain full-text versions if there is uncertainty of eligibility based on the title and abstract screening. Full-text versions will be divided into the three groups, independently screened and final inclusion will be determined subsequently. Any disagreements will be discussed and if consensus cannot be reached, a third author from one the other groups, will be consulted who will have the final decision of inclusion or exclusion.

Data collection process

11c) Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators

Members from each group will extract data independently. Any disagreements within one of the groups that cannot be resolved by discussion will be decided by one author from one of the other groups. We will develop data extraction forms prior to data extraction; however,

these may be subject to change depending on the number of sub-classifications that may emerge during extraction of eligibility criteria. We will contact study authors to resolve any uncertainties. If no response is obtained within 21 days, a reminder will be forwarded with an additional 14 days.

Data items

12) List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications

We will extract the terminology used to describe the condition, study design, experimental interventions and type of control used, participant eligibility criteria, as well as the following participant demographic and clinical characteristics; age, BMI (height and weight will be extracted to calculate this if BMI is not reported), symptom duration, pain intensity, and activity level. Individual studies may have multiple groups. In these cases, we will combine the groups and report a weighted mean and SD. If studies report the median and range, we will estimate the mean and SD (17). Both studies on mid-portion tendinopathy and insertional tendinopathy will be included, but they will be analysed and reported separately. Dependent on numbers of papers we will either report both disorders in the same manuscript or report in two separate papers.

Outcomes and prioritization

13) List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale

N/A

Risk of bias in individual studies

14) Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis

Due to the objectives of this review, we will not perform a risk of bias assessment.

Data synthesis

15a) Describe criteria under which study data will be quantitatively synthesised

N/A

15b) If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I², Kendall's τ)

Because we want to include the entire population of individuals with AT that have been studied (i.e. we aim to capture all studies) there will be inferential statistical analyses. Data will be presented using descriptive statistics (mean and Standard Deviation (SD)) and individual study data will be presented in scatterplots. Based on how the participant eligibility criteria were used, studies will be sub-grouped, and the mean (SD) in specific sub-groups will be reported. If a study did not use, for example, mean pain over the last week as a criterion but still reported participants' mean pain over the last week, this study will be sub-grouped into a "No criterion" sub-group. We will compare the means between sub-groups to assess if there is an association between the choice and definition of a participant eligibility criterion and the corresponding clinical characteristic and/or demographic characteristic of participants. We will only sub-group studies based on criteria that are directly related to the demographic or clinical characteristic reported.

15c) Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)

Sub-group analyses will be used to explore possible sources of heterogeneity, based on study type (questionnaire or clinical study) and study setting (primary, secondary or tertiary care settings).

15d) If quantitative synthesis is not appropriate, describe the type of summary planned

Participant eligibility criteria will be sub-classified in a tentative process where overarching themes and sub-themes emerge as data are extracted. For example, "Pain" is likely to be an overarching theme but there are many criteria that relate to pain (e.g. palpation pain, first step pain in the morning, mean pain over a specific time period or worst pain over a specific time period). We will pool studies if they use criteria that would result in the same characteristic (e.g. age will be same if age ≥ 18 is an inclusion criterion or age < 18 is an exclusion criterion). After data have been extracted and overarching themes and sub-themes have been chosen, all authors will decide by consensus if there was a high variability in the participant eligibility criteria used and if some criteria were irrational.

Meta-bias(es)

16) Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)

N/A

Saturday 20.04.2020

Confidence in cumulative evidence

17) Describe how the strength of the body of evidence will be assessed (such as GRADE)

N/A

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