

# ICON 2020—INTERNATIONAL SCIENTIFIC TENDINOPATHY SYMPOSIUM CONSENSUS: A SYSTEMATIC REVIEW OF OUTCOME MEASURES REPORTED IN CLINICAL TRIALS OF ACHILLES TENDINOPATHY

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**Abstract**

**Background** Nine core domains for tendinopathy have been identified. For Achilles tendinopathy there is large variation in outcome measures used, and how these fit into the core domains has not been investigated.

**Objective** To identify all available outcome measures used to assess the clinical phenotype of Achilles tendinopathy in prospective studies and to map the outcomes measures into predefined health-related core domains.

**Design** Systematic review.

**Data Sources** Embase, MEDLINE (Ovid), Web of Science, CINAHL, The Cochrane Library, SPORTDiscus and Google Scholar.

**Eligibility Criteria for Selecting Studies** Clinical diagnosis of Achilles tendinopathy, sample size  $\geq$  ten participants, age  $\geq$  16 years, and the study design was a randomized or non-randomized clinical trial, observational cohort, single-arm intervention, or case series.

**Results** 9376 studies were initially screened and 307 studies were finally included, totaling 13,248 participants. There were 233 (177 core domain) different outcome measures identified across all domains. For each core domain outcome measures were identified, with a range between 8 and 35 unique outcome measures utilized for each domain. The proportion of studies that included outcomes for predefined core domains ranged from 4% for the psychological factors domain to 72% for the disability domain.

**Conclusion** 233 unique outcome measures for Achilles tendinopathy were identified. Most frequently, outcome measures were used within the disability domain. Outcome measures assessing psychological factors were scarcely used. The next step in developing a core outcome set for Achilles tendinopathy is to engage patients, clinicians and researchers to reach consensus on key outcomes measures.

**Prospero Registration** CRD42020156763.

### Key points

**Achilles tendinopathy is a common condition, often persisting and disabling and impacting on quality of life.**

**Nine core domains for tendinopathy have been identified, but many different outcome measures are used to assess the impact of interventions for Achilles tendinopathy.**

**Knowledge of all available outcome measures for Achilles tendinopathy is important to decrease variability, which would enable greater synthesis and improve healthcare.**

**In our systematic review, 233 unique outcome measures for Achilles tendinopathy were identified.**

**Most frequently, outcome measures were used within the disability domain. Outcome measures assessing psychological factors were scarcely used.**

## 1 Introduction

Achilles tendinopathy is a clinical diagnosis, and the preferred term for persistent Achilles tendon pain and loss of function related to mechanical loading [1]. The incidence of Achilles tendinopathy in the general population consulting a general practitioner was reported to be two to three per 1000 registered Dutch adults [2]. Achilles tendinopathy frequently leads to chronic symptoms with a decreased quality of life [3] and substantial healthcare consumption. A significant proportion of patients with Achilles tendinopathy experience persisting symptoms for years, often resulting in decreased overall physical activity [4–6].

Standardized, reliable and valid outcome measures are essential for evaluating the severity of Achilles tendinopathy and effectiveness of treatments [7]. Currently, large variations exist in outcome measures used to assess the impact of interventions [8]. This influences patient care, because healthcare professionals and researchers are not able to adequately interpret, compare and synthesize (in meta-analyses) the results of research studies.

In the 2018 International Scientific Tendinopathy Symposium Consensus (ICON) statement, a Delphi study was conducted [8]. Expert tendinopathy clinicians and researchers as well as patients with tendinopathy (in various anatomical sites) established core domains for tendinopathy in general. This resulted in nine tendinopathy-specific core domains (patient overall rating, participation, pain on activity, disability, function, physical function capacity, quality of life, psychology, and pain over a specified time frame) [8]. The proposed next step is to develop core outcome sets for each of the common tendinopathies using the nine health-related core domains as the guide.

The overall aim of the present project is to develop and disseminate a core outcome set for assessing clinical outcomes in Achilles tendinopathy. As a first step a systematic review identifying the outcome measures previously used in clinical trials was deemed essential. Therefore, the primary aim of this systematic review was to identify all outcome measures assessing the clinical phenotype of Achilles tendinopathy used in prospective studies. The secondary aim was to map the outcome measures according to the nine core domains or determine if the outcome measures fit in any of the other domains identified in the ICON statement.

## 2 Methods

At the International Scientific Tendinopathy Symposium (ISTS) 2018 a call went out to recruit those congress participants who wanted to be involved in the Achilles tendinopathy consensus group. On the last day of the conference, a meeting was held with those who expressed interest. In addition, those at the conference were encouraged to recruit others involved in Achilles tendinopathy research or clinical practice. A steering committee was established consisting of three senior clinical researchers (KGS, PM, RJdV) from three continents. The Achilles tendinopathy consensus group's (COS-AT) member list was finalized 2 months after the ISTS 2018 meeting by asking interested members to confirm their commitment to participate in the process for developing a core outcome set for Achilles tendinopathy.

### 2.1 PROTOCOL AND REGISTRATION

The protocol for this review was registered on the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42020156763) and conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [9]. This systematic review is the first step of a large project with the aim to develop and disseminate a core outcome set for assessing clinical outcomes in Achilles tendinopathy. In the subsequent steps of this project—which are not part of this systematic review—the truth (does the outcome measure detect what it intends to measure) and feasibility (can the measure be applied easily) will be evaluated, and quality assessment of the endorsed measurements tools will be performed. In the last step a consensus meeting will be planned to reach final consensus on a core outcome set for Achilles tendinopathy. The overall project is registered in the COMET (Core Outcome Measures in Effectiveness Trials) database ([www.comet-initiative.org](http://www.comet-initiative.org)).

### 2.2 ELIGIBILITY CRITERIA

Studies were considered eligible for inclusion if meeting the following criteria: the diagnosis of Achilles tendinopathy was clinically established (as recommended in consensus [1] and guidelines [7], and imaging was not needed to establish diagnosis), a minimum total sample size of ten participants, age

of the included participants  $\geq 16$  years, and the study design was a randomized or non-randomized clinical trial, observational cohort, single-arm intervention, or case series. Studies including participants of all activity levels were eligible and there were no restrictions on the location (midportion and insertional) or duration (early-onset and chronic degenerative Achilles tendinopathy) of the condition. Only studies in English were included.

Studies were excluded according to the following criteria: the sole outcome measures were imaging parameters (as we aimed to assess the clinical phenotype of Achilles tendinopathy), the diagnosis was a full-thickness rupture of the Achilles tendon, or enthesitis with a proven inflammatory disease (e.g. rheumatoid arthritis or spondyloarthropathy), animal study or in vitro experiment, and the study design was a systematic review or prospective cohort study investigating the onset of Achilles tendinopathy (risk-factor study). Studies including participants with various tendinopathies without clear distinction of outcomes pertaining to Achilles tendinopathy were also excluded.

## 2.3 SEARCH STRATEGY

This systematic review included all articles that describe the use of outcome measures to evaluate health-related outcomes over time in patients with Achilles tendinopathy.

The literature search was performed on 1 June 2021 with the assistance of a research librarian (W.M. Bramer, Medical Library, Erasmus MC University Medical Centre Rotterdam, the Netherlands) and included studies that evaluate any type of interventions or exposure related to Achilles tendinopathy. The following databases were searched: Embase, MEDLINE (Ovid), Web of Science, CINAHL, The Cochrane Library, SPORTDiscus and Google Scholar.

The search strategy included various terms used for Achilles tendinopathy (such as tendinitis, tendinosis) and clinical trial (such as observational study, cohort analysis and clinical study). The complete search for Medline can be found in Table 1, and the complete search in all the databases in the Electronic Supplementary Material (ESM), Appendix S1.

**Table 1** Search strategy for Medline

Medline (OVID) search: 4317 references

((Tendinopathy/ OR Pathology/) AND "achilles tendon"/) OR "achilles tendon"/pa OR (((achilles OR calcaneal) AND (tendinitis\* OR tendinopath\* OR tendinosis\* OR tendonitis\* OR tendon-patholog\* OR pain\* OR injur\*)) OR achillodyn\*).ab,ti.) AND ("Observational Study"/ OR exp "Cohort Studies"/ OR "Health Surveys"/ OR exp "Epidemiologic Studies"/ OR "Case-Control Studies"/ OR "Cross-Sectional Studies"/ OR "Multicenter Study"/ OR "Comparative Study"/ OR "Clinical Study"/ OR exp "Clinical Trial"/ OR "Review"/ OR "Meta-Analysis"/ OR "Double-Blind Method"/ OR "Single-Blind Method"/ OR "Random Allocation"/ OR (random\* OR factorial\* OR crossover\* OR cross over\* OR placebo\* OR ((doubl\* OR singl\*) ADJ blind\*) OR assign\* OR allocat\* OR volunteer\* OR trial OR groups OR ((observation\* OR epidemiolog\* OR famil\* OR comparativ\* OR commun\* OR interven\*) ADJ6 (stud\* OR data OR research)) OR cohort\* OR longitudinal\* OR retrospectiv\* OR prospectiv\* OR population\* OR correlation\* OR multicenter\* OR multi-center\* OR follow-up\* OR followup\* OR clinical\* OR trial OR random\* OR review\* OR meta-analy\* OR (mixed ADJ3 method\*)).ab,ti.) NOT (news OR congres\* OR abstract\* OR book\* OR chapter\* OR dissertation abstract\*).pt. NOT (exp animals/ NOT humans/)

## 2.4 STUDY SELECTION

Two researchers (S.H. and I.S.) screened potentially relevant articles based on title and/or abstract against the inclusion criteria using Covidence systematic review software (Veritas Health Innovation,

Melbourne, Australia). In the event that consensus regarding inclusion could not be met, a third reviewer (P.M.) was consulted. Full text review was conducted by four pairs of reviewers (P.V. and M.M; A.M. and Z.H.; M.V. and K.F.; S.O. and K.S.) using a REDCap database [10]. In the event that consensus regarding inclusion could not be met between reviewer pairs, a third reviewer (S.H.) was consulted.

## 2.5 DATA EXTRACTION

Data extraction was completed by the same four pairs of reviewers (P.V. and M.M; A.M. and Z.H.; M.V. and K.F.; S.O. and K.S.) using a REDCap Database [10]. Disagreements between reviewers were resolved through discussion, and if consensus could not be met, a third reviewer (S.H) was consulted.

Data extraction was consistent with the minimum reporting standards described in the ICON statement [11]. We extracted first author, year of publication, study design (randomized and non-randomized trial, observational cohort, single-arm intervention, case series, other), number of participants, participant activity level (athletic, sedentary or mixed), criteria reported for establishing clinical diagnosis (patient history, clinical exam, patient-reported outcome measures/questionnaires, medical records/diagnosis codes, diagnostic imaging, other), injury location (midportion, insertional, mixed, not specified), and injury side (unilateral, bilateral, mixed, not specified). The following outcome measure data were collected: outcome measure name, definition of the outcome measure, the outcome measure method (e.g., isokinetic strength test) and/or scale (e.g., visual analogue scale or Likert scale), method for obtaining the outcome measure (patient-reported via questionnaire, patient-reported via interview, measurement taken by assessor), the best fitting core domain [8] for the outcome measure and the reference to the original publication of the outcome measure (when provided). Reviewers were offered an option of 'other' for the core domains if both reviewers agreed that an outcome measure did not fit into the established nine tendinopathy core domains. We extracted the description of the outcome measurement exactly as it was described in the article in which it was found. Outcome measures that were identical were amalgamated into a single outcome measure used in different studies, but when outcome measures were slightly different or when it was not clear whether the measurements were identical, we described them separately in the results.

In the next step the outcome measures that did not fit the core domains, and were placed in the 'other' category, were assigned to a respective candidate domain (physical activity, structure, adverse effects/events) from the ICON statement [8], or in additional Achilles tendinopathy-specific domains. For both issues, the process involved consensus between the steering group as well as confirmation from the original reviewers regarding the proposed changes.

## 2.6 RISK OF BIAS AND QUALITY ASSESSMENT

We did not perform a risk of bias or quality assessment of the included studies since the purpose of this systematic review was to identify all outcome measures used to evaluate the clinical severity in patients with Achilles tendinopathy irrespective of the type or quality of the study.

## **2.7 DATA SYNTHESIS AND ANALYSIS**

Descriptive study information and outcome measure data were combined from each reviewer pair. Outcome measures used in each study were then sub-grouped by core domain. When the core domain selection differed between the reviewer pairs for the same outcome measure, the core domain with majority selection was nominated. If there was no majority selection, a third reviewer (S.H.) was consulted. The steering group met on several occasions to adjudicate over remaining issues. Outcome measures that had been classified into multiple domains by different reviewer pairs were re-classified to the most appropriate domain according to the original ICON statement [8]. This was done by consensus and the opinion of the majority of the steering group was decisive. Analysis of the included studies included summarizing the study characteristics, the criteria for the clinical diagnosis, the measurement instruments, the number (%) of measurement instruments per domain, and how frequently each outcome measure within each domain was used (Table 2).

**Table 2** Summary of outcome measures per domain

| Name of outcome measure                                                                     | Number of studies | Measurement method | References                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------|-------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>CORE DOMAIN: patient overall rating (n = 139/307 studies (45%); 35 outcome measures)</i> |                   |                    |                                                                                                                                                                                                                                                                                                                                                               |
| Patient satisfaction (Likert; Index; NRS; VAS)                                              | 59% (83/139)      | PQ; PI             | [5, 12, 14, 19–23, 40, 58, 60, 61, 63, 68, 74, 75, 79, 86, 87, 89, 93, 96, 102, 110, 119, 122, 125, 132–134, 138, 142, 145–148, 150, 151, 153–155, 158–160, 165, 166, 169, 171, 173, 181, 185, 186, 188, 189, 193, 198, 204, 212, 223, 226, 232, 233, 235, 236, 240, 244, 250, 257, 258, 262, 267, 268, 270, 272, 273, 275, 277, 281–283, 285, 301, 304, 305] |
| Overall assessment                                                                          | 9% (12/139)       | PQ                 | [13, 15, 29, 45, 49, 57, 113, 151, 234, 241, 274, 279]                                                                                                                                                                                                                                                                                                        |
| Roles and Maudsley Score                                                                    | 7% (10/139)       | PQ                 | [50, 51, 91, 92, 116, 118, 126, 253, 295, 296]                                                                                                                                                                                                                                                                                                                |
| Global rating of change (GROC)                                                              | 5% (7/139)        | PQ                 | [44, 85, 90, 94, 95, 171, 264]                                                                                                                                                                                                                                                                                                                                |
| Improvement                                                                                 | 4% (6/139)        | PQ                 | [91, 92, 125, 253, 255, 306]                                                                                                                                                                                                                                                                                                                                  |
| Results of treatment                                                                        | 3% (4/139)        | PQ; PI             | [194, 218, 229, 269]                                                                                                                                                                                                                                                                                                                                          |
| 4-point functional scale for surgery outcome                                                | 2% (3/139)        | PQ                 | [151, 211, 215]                                                                                                                                                                                                                                                                                                                                               |
| 4-point Boyden Scale                                                                        | 2% (2/139)        | PQ                 | [216, 217]                                                                                                                                                                                                                                                                                                                                                    |
| Patient's global assessment response to therapy (PGART)                                     | 1% (2/139)        | PQ                 | [39]                                                                                                                                                                                                                                                                                                                                                          |
| Clinical global impression                                                                  | 1% (1/139)        | PQ                 | [182]                                                                                                                                                                                                                                                                                                                                                         |
| Clinical observer global assessment (COGA)                                                  | 1% (1/139)        | PI                 | [276]                                                                                                                                                                                                                                                                                                                                                         |
| Kenneth Johnson Satisfaction score                                                          | 1% (1/139)        | PQ                 | [260]                                                                                                                                                                                                                                                                                                                                                         |
| Outcome survey developed by AOFAS                                                           | 1% (1/139)        | PQ                 | [28]                                                                                                                                                                                                                                                                                                                                                          |
| Pain impact scale                                                                           | 1% (1/139)        | PQ                 | [75]                                                                                                                                                                                                                                                                                                                                                          |
| Patient global impression of change scale                                                   | 1% (1/139)        | PQ                 | [47]                                                                                                                                                                                                                                                                                                                                                          |
| Perception of Treatment Effectiveness                                                       | 1% (1/139)        | PQ                 | [47]                                                                                                                                                                                                                                                                                                                                                          |
| Perceived improvement                                                                       | 1% (1/139)        | PQ                 | [306]                                                                                                                                                                                                                                                                                                                                                         |
| Symptom resolution                                                                          | 1% (1/139)        | PQ                 | [166]                                                                                                                                                                                                                                                                                                                                                         |
| Short-form 36 Health Survey (SF-36)                                                         | 1% (1/139)        | PQ                 | [221]                                                                                                                                                                                                                                                                                                                                                         |

Table 2 (continued)

| Name of outcome measure                                                                       | Number of studies | Measurement method | References                                                                            |
|-----------------------------------------------------------------------------------------------|-------------------|--------------------|---------------------------------------------------------------------------------------|
| <i>Patient Overall Rating measures with no description provided or no reference available</i> | 12% (17/139)      | PQ; PI             | [45, 80, 81, 98, 124, 125, 137, 156, 160, 210, 252, 262, 273, 283, 286]               |
| "Residual Symptoms"                                                                           |                   |                    |                                                                                       |
| "Patients' Own Assessments at the Follow-up" (5 years)                                        |                   |                    |                                                                                       |
| "Patient rating"                                                                              |                   |                    |                                                                                       |
| "Likelihood on a scale from 1 to 10"                                                          |                   |                    |                                                                                       |
| "Would they have the procedure again"                                                         |                   |                    |                                                                                       |
| "Pain status and patient reports of their functional status"                                  |                   |                    |                                                                                       |
| "Return to 100%"                                                                              |                   |                    |                                                                                       |
| "Clinical outcome"                                                                            |                   |                    |                                                                                       |
| "Willingness to recommend procedure"                                                          |                   |                    |                                                                                       |
| "General recovery"                                                                            |                   |                    |                                                                                       |
| "Subjective clinical evaluation scale"                                                        |                   |                    |                                                                                       |
| "Patient impression for change of pain"                                                       |                   |                    |                                                                                       |
| "Patient impression of change for function"                                                   |                   |                    |                                                                                       |
| "Patient acceptable symptom state/instrument for satisfaction"                                |                   |                    |                                                                                       |
| "Recommendation of surgery to a close relative"                                               |                   |                    |                                                                                       |
| "Recovery time"                                                                               |                   |                    |                                                                                       |
| <i>CORE DOMAIN: participation (n = 43/307 studies (13%); 18 outcome measures)</i>             |                   |                    |                                                                                       |
| Return to sport/competition                                                                   | 42% (18/43)       | PI; PQ             | [14, 19, 22, 87, 98, 105, 121, 137, 158, 166, 191, 225, 248, 252, 270, 274, 276, 307] |
| Return to activity                                                                            |                   |                    |                                                                                       |
| Tegner score                                                                                  | 19% (8/43)        | PQ                 | [89, 159, 252, 254, 271, 272, 283, 285]                                               |
| Return to work duties                                                                         | 12% (5/43)        | PQ                 | [13, 111, 121, 205, 308]                                                              |
| Level of sports participation                                                                 | 10% (4/43)        | M                  | [169, 258, 275, 284]                                                                  |
| Ankle activity score                                                                          | 7% (3/43)         | PQ; PI             | [78, 161, 200]                                                                        |
| Decreased desired activity                                                                    | 7% (3/43)         | PQ                 | [22, 161, 293]                                                                        |
| Time to return to training/sport                                                              | 5% (2/43)         | PQ                 | [254, 277]                                                                            |
| International Physical Activity Questionnaire (IPAQ)                                          | 5% (2/43)         | PQ                 | [169, 267]                                                                            |
| Patient improvement                                                                           | 2% (1/43)         | PQ                 | [280]                                                                                 |
| Time to return to running without pain                                                        | 2% (1/43)         | PQ                 | [195]                                                                                 |
| Time to return to walking without pain                                                        | 2% (1/43)         | PI                 | [111]                                                                                 |
| Time to return to pre-injury levels                                                           | 2% (1/43)         | PI                 | [111]                                                                                 |
| Working status                                                                                | 2% (1/43)         | PQ                 | [186]                                                                                 |
| Time to return to full weight bearing                                                         | 2% (1/43)         | PQ                 | [79]                                                                                  |
| Time to maximum symptom improvement                                                           | 2% (1/43)         | PI                 | [225]                                                                                 |
| <i>Participation measures with no description provided, no reference available</i>            | 2% (1/43)         | PQ                 | [277]                                                                                 |
| "Subjective outcome on a 4-level scale"                                                       | 5% (2/43)         | PI; M              | [195, 252]                                                                            |
| "Testa et al.'s system"                                                                       |                   |                    |                                                                                       |

Table 2 (continued)

| Name of outcome measure                                                                       | Number of studies | Measurement method | References                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>CORE DOMAIN: pain on activity/loading (n = 109/307 studies (36%); 17 outcome measures)</i> |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| Pain with Activity/loading (NPRS; VAS; Likert)                                                | 87% (95/109)      | PQ; PI; M          | [6, 13, 15–17, 23, 26–29, 32, 34–37, 39, 40, 55–57, 59, 63, 64, 66, 68, 74, 78, 82, 86, 87, 89, 93–95, 97, 100, 102, 106, 107, 109, 110, 115, 118, 119, 122, 123, 125, 137–139, 141–144, 146–148, 152, 154, 165–168, 173, 174, 178, 181, 183, 188, 190, 197, 201, 222, 223, 226, 233, 234, 238, 240, 249, 251, 263, 264, 268, 272, 279, 282, 283, 286, 292, 296, 303–305, 308] |
| Pain at rest (VAS; Likert)                                                                    | 8% (9/109)        | PQ                 | [13, 16, 17, 56, 82, 137, 148, 197, 304]                                                                                                                                                                                                                                                                                                                                       |
| Pain after activity                                                                           | 2% (2/109)        | PQ                 | [48, 79]                                                                                                                                                                                                                                                                                                                                                                       |
| Blanzina score                                                                                | 2% (2/109)        | PQ                 | [121, 133]                                                                                                                                                                                                                                                                                                                                                                     |
| Nirschl pain phase rating scale                                                               | 2% (2/109)        | M                  | [251, 264]                                                                                                                                                                                                                                                                                                                                                                     |
| Achilles tendinopathy symptom assessment                                                      | 1% (1/109)        | PI                 | [52]                                                                                                                                                                                                                                                                                                                                                                           |
| Number of hops to pain                                                                        | 1% (1/109)        | M                  | [98]                                                                                                                                                                                                                                                                                                                                                                           |
| Number of single leg heel rises to pain                                                       | 1% (1/109)        | M                  | [98]                                                                                                                                                                                                                                                                                                                                                                           |
| Pain disability index                                                                         | 1% (1/109)        | PQ                 | [43]                                                                                                                                                                                                                                                                                                                                                                           |
| Patient-rated pain score                                                                      | 1% (1/109)        | M                  | [53]                                                                                                                                                                                                                                                                                                                                                                           |
| Patient-reported Outcomes measurement information system-pain interference (PROMIS-PI)        | 1% (1/109)        | PQ                 | [290]                                                                                                                                                                                                                                                                                                                                                                          |
| Pain on Activity/Loading Measures with no description provided and/or no reference available  | 6% (6/109)        | PQ; PI; M          | [14, 57, 150, 247, 274, 275]                                                                                                                                                                                                                                                                                                                                                   |
| “Spontaneous or provoked pain”                                                                |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Matched pain”                                                                                |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Rated pain”                                                                                  |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Maximum tolerable stress during walking”                                                     |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Subjective outcome”                                                                          |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Symptoms”                                                                                    |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| <i>CORE DOMAIN: function (n = 11/307 studies (4%); 10 outcome measures)</i>                   |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| Ankle activity score                                                                          | 25% (3/12)        | PQ                 | [24, 142, 187]                                                                                                                                                                                                                                                                                                                                                                 |
| Dexterity                                                                                     | 8% (1/12)         | M                  | [76]                                                                                                                                                                                                                                                                                                                                                                           |
| Function (VAS)                                                                                | 8% 1/12           | PQ                 | [86]                                                                                                                                                                                                                                                                                                                                                                           |
| Patient-reported outcomes measurement information system-physical function (PROMIS-PF)        | 8% (1/12)         | PQ                 | [290]                                                                                                                                                                                                                                                                                                                                                                          |
| Tegner score                                                                                  | 8% (1/12)         | PQ                 | [224]                                                                                                                                                                                                                                                                                                                                                                          |
| Other Function Measures with no description provided or no reference available                | 42% (5/12)        | M; PI              | [15, 122, 136, 275, 294]                                                                                                                                                                                                                                                                                                                                                       |
| “Tendon flexibility/stiffness”                                                                |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Motion analysis”                                                                             |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Numeric scale”                                                                               |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Patient survey”                                                                              |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |
| “Functional ability”                                                                          |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                |

Table 2 (continued)

| Name of outcome measure                                                                        | Number of studies | Measurement method | References                                                                    |
|------------------------------------------------------------------------------------------------|-------------------|--------------------|-------------------------------------------------------------------------------|
| <i>CORE DOMAIN: Psychological factors (n = 11/307 studies (4%); eight outcome measures)</i>    |                   |                    |                                                                               |
| Tampa scale of kinesophobia (TSK)                                                              | 36% (4/11)        | PQ                 | [4, 80, 108, 173, 309]                                                        |
| Pain catastrophizing scale (PCS)                                                               | 36% (4/11)        | PQ                 | [80, 108, 177, 309]                                                           |
| Hospital anxiety and depression scale (HADS)                                                   | 9% (1/11)         | PQ                 | [280]                                                                         |
| Patient-reported outcomes measurement information system (PROMIS) depression                   | 9% (1/11)         | PQ                 | [290]                                                                         |
| Pain anxiety symptoms scale (PASS-20)                                                          | 9% (1/11)         | PQ                 | [173]                                                                         |
| Pain Coping Inventory (PCI)                                                                    | 9% (2/11)         | PQ                 | [87, 179]                                                                     |
| Achilles Tendon Beliefs Questionnaire (ATBQ)                                                   | 9% (1/11)         | PQ                 | [173]                                                                         |
| Pain Self-Efficacy Questionnaire (PSEQ)                                                        | 9% (1/11)         | PQ                 | [171]                                                                         |
| <i>CORE DOMAIN: physical function capacity (n = 54/307 studies (17%); 31 outcome measures)</i> |                   |                    |                                                                               |
| Strength testing (non-descriptive, various muscles)                                            | 30% (16/54)       | M                  | [29, 45, 71, 100, 106, 109, 150, 152, 153, 160, 190, 201, 203, 216, 241, 302] |
| Single-leg heel rise test                                                                      | 24% (13/54)       | M                  | [48, 63, 89, 90, 107, 108, 200, 212, 216, 242, 259, 310, 311]                 |
| Isometric strength                                                                             | 9% (5/54)         | M                  | [76, 217, 269, 270, 292]                                                      |
| Functional test battery                                                                        | 9% (5/54)         | M                  | [4, 63, 64, 157, 226]                                                         |
| Ankle plantar flexion power                                                                    | 7% (4/54)         | M                  | [87, 284, 292, 311]                                                           |
| Isokinetic strength                                                                            | 7% (4/54)         | M                  | [28, 231, 232, 238]                                                           |
| Kinematic measures                                                                             | 6% (3/54)         | M                  | [263, 288, 311]                                                               |
| Kinetic measures                                                                               | 6% (3/54)         | M                  | [183, 263, 294]                                                               |
| Isometric endurance                                                                            | 4% (2/54)         | M                  | [269, 270]                                                                    |
| Surface electromyography (EMG)                                                                 | 4% (2/54)         | M                  | [152, 294]                                                                    |
| Ankle plantar flexion moment                                                                   | 2% (1/54)         | M                  | [292]                                                                         |
| Plantar flexion peak torque                                                                    | 2% (1/54)         | M                  | [80]                                                                          |
| Ankle plantar flexion rate of torque development                                               | 2% (1/54)         | M                  | [80]                                                                          |
| Plantarflexion coefficient of variation of torque                                              | 2% (1/54)         | M                  | [80]                                                                          |
| Load used in the intervention                                                                  | 2% (2/54)         | M                  | [80, 183]                                                                     |
| Return to running/sports activities                                                            | 2% (1/54)         | PQ                 | [58]                                                                          |
| Motor control performance                                                                      | 2% (1/54)         | M                  | [108][108]                                                                    |
| Ability to climb stairs                                                                        | 2% (1/54)         | M                  | [242]                                                                         |
| Ability to perform 20 heel raises                                                              | 2% (1/54)         | M                  | [188]                                                                         |
| Ability to jump                                                                                | 2% (1/54)         | M                  | [17]                                                                          |
| Reactive strength index                                                                        | 2% 1/54           | M                  | [183]                                                                         |
| Rating of perceived exertion                                                                   | 2% (2/54)         | M                  | [106, 183]                                                                    |
| Agility                                                                                        | 2% (1/54)         | M                  | [76]                                                                          |
| Plantar flexion power of the lesser toes                                                       | 2% (1/54)         | M                  | [200]                                                                         |

Table 2 (continued)

| Name of outcome measure                                                                                          | Number of studies | Measurement method | References                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Balance                                                                                                          | 2% (1/54)         | M                  | [76]                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Calf muscle performance deficits                                                                                 | 2% (1/54)         | M                  | [197]                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Gait abnormalities at walking pace                                                                               | 2% (1/54)         | M                  | [197]                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Single hop test                                                                                                  | 2% (1/54)         | M                  | [115]                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Physical function capacity measures with no description provided or no reference available                       | 9% (5/54)         | M                  | [17, 87, 200, 241, 242]                                                                                                                                                                                                                                                                                                                                                                                                                           |
| “Walking on the tip of toes”                                                                                     |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| “Performance tests”                                                                                              |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| “Gastrocnemius and soleus flexibility”                                                                           |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| CORE DOMAIN: disability ( $n = 221/307$ studies (72%); 32 outcome measures)                                      |                   |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Victorian Institute of Sport Assessment-Achilles (VISA-A) (English; Danish; Swedish; German; Italian; Sedentary) | 64% (141/221)     | PQ                 | [3–6, 13, 19–22, 24, 25, 27, 30, 37, 39, 41, 44, 46, 47, 53, 54, 56, 58, 60, 61, 64, 65, 68–72, 75, 78–89, 91–95, 97–99, 101–104, 111, 114, 115, 120, 121, 128–130, 133, 135, 140, 143, 149, 157, 160–164, 169, 170, 172, 173, 175–177, 179, 181–183, 186, 187, 189, 191–193, 199, 207, 209, 211, 213–220, 224, 226, 237, 239, 240, 245, 246, 250, 264, 268, 271, 276, 280, 281, 284, 285, 287, 289, 291–294, 296–300, 304–306, 308–310, 312–314] |
| American Orthopaedic Foot & Ankle Society-Ankle-Hindfoot (AOFAS)                                                 | 22% (48/221)      | PQ                 | [29, 50, 51, 59, 72, 73, 91, 92, 103, 104, 111, 118, 129–132, 140, 142, 143, 146, 162, 165, 167, 184, 188, 189, 196, 198, 203, 208, 218, 221, 227, 231, 243, 244, 248, 258, 261, 265, 271, 277, 278, 282, 286, 301, 305, 315]                                                                                                                                                                                                                     |
| Foot and ankle outcome score (FAOS)                                                                              | 7% (16/221)       | PQ                 | [25, 33, 35, 36, 62, 118, 139, 140, 167, 202, 205, 228, 240, 256, 265, 267]                                                                                                                                                                                                                                                                                                                                                                       |
| Foot & ankle ability measure (FAAM)                                                                              | 2% (5/221)        | PQ                 | [90, 107, 153, 280, 311]                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Lower extremity functional scale (LEFS)                                                                          | 2% (4/221)        | PQ                 | [30, 171, 177, 200]                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Foot function index (FFI)                                                                                        | 2% (4/221)        | PQ                 | [124, 167, 208, 262]                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Achilles tendinopathy scoring system (ATSS)                                                                      | 1% (3/221)        | PQ                 | [41, 219, 220]                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Ankle osteoarthritis scale (AOS)                                                                                 | 1% (3/221)        | PQ                 | [31, 244, 259]                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Pain level and functional impairment                                                                             | 1% (3/221)        | PQ                 | [127, 247, 316]                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Functional index of lower limb activity (FILLA)                                                                  | 1% (3/221)        | PQ                 | [16, 17, 197]                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Manchester-Oxford Foot Questionnaire (MOXFQ)                                                                     | 1% (3/221)        | PQ                 | [164, 175, 178]                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Roles and Maudsley score (RMS)                                                                                   | 1% (3/221)        | PQ                 | [144, 174, 305]                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Achilles tendon rupture score                                                                                    | 1% (2/221)        | PQ                 | [225, 248]                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Maryland foot score (MFS)                                                                                        | 1% (2/221)        | PQ                 | [155, 204]                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Tegner activity scale                                                                                            | 1% (2/221)        | PQ                 | [102, 142]                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Decreased desired activity                                                                                       | 1% (2/221)        | PQ                 | [254]                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Disablement in physical activity scale (DPA)                                                                     | 1% (1/221)        | PQ                 | [264]                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Foot and Ankle Outcomes Questionnaire                                                                            | 1% (1/221)        | PQ                 | [32]                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Limitation of function                                                                                           | 1% (1/221)        | PQ                 | [14]                                                                                                                                                                                                                                                                                                                                                                                                                                              |

Table 2 (continued)

| Name of outcome measure                                                                              | Number of studies | Measurement method | References                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pain and activity Jacob and Segesser measure                                                         | 1% (1/221)        | PQ                 | [113]                                                                                                                                                                                                                                                                                                              |
| VAS foot and ankle (VAS-FA) (Thai)                                                                   | 1% 1/221          | PQ                 | [96]                                                                                                                                                                                                                                                                                                               |
| Pain Experience Scale (PES)                                                                          | 1% (1/221)        | PQ                 | [43]                                                                                                                                                                                                                                                                                                               |
| Testa's rating system                                                                                | 1% (1/221)        | PQ                 | [130]                                                                                                                                                                                                                                                                                                              |
| University of peloponnese pain; functionality and quality of life                                    | 1% (1/221)        | PQ                 | [112]                                                                                                                                                                                                                                                                                                              |
| Disability measures with no description provided, no reference available                             | 4% (9/221)        | PQ; PI             | [48, 49, 63, 77, 156, 229, 230, 240, 275]                                                                                                                                                                                                                                                                          |
| "Adapted classification of Achilles tendon disease"                                                  |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Unspecified Questionnaire"                                                                          |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Unspecified Likert scale"                                                                           |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Treatment effectiveness"                                                                            |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Modified pain and performance questionnaire"                                                        |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Achilles tendon questionnaire"                                                                      |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Ability to wear a shoe"                                                                             |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| "Dysfunction"                                                                                        |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| <i>CORE DOMAIN: quality of life (n = 24/307 studies (8%); five outcome measures)</i>                 |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| Short Form-36 Health Survey (SF-36)                                                                  | 42% (10/24)       | PQ                 | [32, 47, 54, 107, 118, 131, 142, 146, 200, 244]                                                                                                                                                                                                                                                                    |
| EuroQol 5-dimensional questionnaire (EQ-5D)                                                          | 33% (8/24)        | PQ                 | [16, 17, 80, 95, 182, 197, 240, 299, 300]                                                                                                                                                                                                                                                                          |
| Short Form-12 Health Survey (SF-12)                                                                  | 13% (3/24)        | PQ                 | [159, 208, 228]                                                                                                                                                                                                                                                                                                    |
| EQ-VAS                                                                                               | 4% (1/24)         | PQ                 | [121]                                                                                                                                                                                                                                                                                                              |
| 8-Dimension assessment of quality-of-life (AQoL-8D)                                                  | 4% (1/24)         | PQ                 | [3]                                                                                                                                                                                                                                                                                                                |
| <i>CORE DOMAIN: pain over a specified time frame (n = 94/307 studies (31%); 21 outcome measures)</i> |                   |                    |                                                                                                                                                                                                                                                                                                                    |
| Pain at follow-up (NPRS; NRS; VAS)                                                                   | 76% (71/94)       | PQ; PI             | [5, 6, 30, 33, 38, 41, 46, 50, 51, 57, 60, 61, 69–73, 75–77, 83, 90, 99, 101, 103, 114, 116, 120, 125, 126, 131, 140, 153, 160, 163, 164, 175, 182, 184, 193, 196, 199, 200, 204, 215, 218–220, 224, 225, 229, 243, 246, 256, 259, 261, 262, 266, 267, 273, 276, 278, 280, 285, 295, 300, 301, 311, 313, 315, 317] |
| Short Form-36 Health Survey (SF-36)                                                                  | 4% (4/94)         | PQ                 | [72, 165, 259, 282]                                                                                                                                                                                                                                                                                                |
| Pain at rest                                                                                         | 3% (3/94)         | PI; PQ             | [79, 111, 185]                                                                                                                                                                                                                                                                                                     |
| PainDETECT questionnaire                                                                             | 3% (4/94)         | PQ                 | [80, 87, 179, 280]                                                                                                                                                                                                                                                                                                 |
| Morning pain                                                                                         | 2% (2/94)         | VAS                | [234, 279]                                                                                                                                                                                                                                                                                                         |
| Pain over the past week                                                                              | 3% (3/94)         | PI                 | [185, 292, 315]                                                                                                                                                                                                                                                                                                    |
| Morning stiffness                                                                                    | 1% (1/94)         | M                  | [66]                                                                                                                                                                                                                                                                                                               |
| Duration of stiffness                                                                                | 1% (1/94)         | PI                 | [279]                                                                                                                                                                                                                                                                                                              |
| Pain in the last 24 h                                                                                | 1% (1/94)         | PQ                 | [44]                                                                                                                                                                                                                                                                                                               |
| American Orthopaedic Foot and Ankle Score-Pain Subscore (AOFAS)                                      | 1% (1/94)         | PQ                 | [159]                                                                                                                                                                                                                                                                                                              |
| Time course of complaints                                                                            | 1% (1/94)         | M                  | [258]                                                                                                                                                                                                                                                                                                              |
| Worst pain                                                                                           | 2% (2/94)         | PQ                 | [18, 80]                                                                                                                                                                                                                                                                                                           |

Table 2 (continued)

| Name of outcome measure                                                                        | Number of studies | Measurement method | References                                                                           |
|------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------------------------------------------------------------------------|
| Achilles tendinopathy symptom assessment                                                       | 1% (1/94)         | PI                 | [52]                                                                                 |
| Brief Pain Inventory (sf-BPI)                                                                  | 1% (1/94)         | PQ                 | [105]                                                                                |
| McGill Pain Questionnaire (sf-MPQ)                                                             | 1% (1/94)         | PQ                 | [105]                                                                                |
| Pain over time Measures with no description provided, no reference available                   | 6% (6/94)         | PQ, PI             | [5, 15, 54, 158, 191, 248]                                                           |
| “Study Specific Questionnaire”                                                                 |                   |                    |                                                                                      |
| “Subjective level and duration of pain/discomfort”                                             |                   |                    |                                                                                      |
| “Discomfort during/after injection”                                                            |                   |                    |                                                                                      |
| “Residual pain at follow-up”                                                                   |                   |                    |                                                                                      |
| “Digital pain scale”                                                                           |                   |                    |                                                                                      |
| “Opposite limb symptoms”                                                                       |                   |                    |                                                                                      |
| <i>Candidate domain: physical activity (n = 10/307 studies (3%); five outcome measures)</i>    |                   |                    |                                                                                      |
| Level of physical activity                                                                     | 50% (4/10)        | PQ                 | [3, 18, 82, 195]                                                                     |
| 7-Day physical activity recall                                                                 | 3% (3/10)         | PQ                 | [47, 80, 309]                                                                        |
| Physical activity scale (PAS)                                                                  | 10% (1/10)        | PQ                 | [4]                                                                                  |
| Level of activity                                                                              | 10% (1/10)        | PQ                 | [38]                                                                                 |
| Wallgren–Tegner activity scale                                                                 | 10% (1/10)        | PQ                 | [137]                                                                                |
| <i>Candidate domain: structure (n = 58/307 studies (19%); 21 outcome measures)</i>             |                   |                    |                                                                                      |
| Neovascularization (color doppler; power doppler)                                              | 34% (20/58)       | M                  | [20, 24, 78, 82, 87, 99, 135, 147, 148, 170, 184, 185, 191, 192, 207, 287, 308, 312] |
| Structural abnormalities (B-mode ultrasound) (tendon echogenicity; thickening; calcifications) | 29% (17/58)       | M                  | [12, 15, 28, 82, 168, 184, 192, 193, 212, 214, 216, 227, 234, 289, 291, 308, 312]    |
| Tendon thickness (B-mode ultrasound, MRI)                                                      | 24% (14/58)       | M                  | [78, 147, 148, 184, 187, 193, 196, 207, 214, 216, 234, 287, 304, 310]                |
| Structural abnormalities (magnetic resonance imaging)                                          | 10% (6/58)        | M                  | [82, 86, 152, 219, 225, 227, 286]                                                    |
| Ultrasound tissue characterization                                                             | 9% (5/58)         | M                  | [20, 24, 187, 245, 293]                                                              |
| Tendon stiffness                                                                               | 8% (4/58)         | M                  | [41, 94, 220, 291]                                                                   |
| Tendon diameter                                                                                | 7% (4/58)         | M                  | [17, 80, 197, 291]                                                                   |
| Microcirculatory assessment                                                                    | 6% (3/58)         | M                  | [33, 36, 140]                                                                        |
| Tendon oxygen saturation                                                                       | 4% (2/58)         | M                  | [35, 50]                                                                             |
| The Fowler–Philip angle                                                                        | 4% (2/58)         | M                  | [104, 224]                                                                           |
| Tendon mechanical properties (SWE; cSWE)                                                       | 4% (2/58)         | M                  | [310, 312]                                                                           |
| Post-operative tendon thickening                                                               | 2% (1/58)         | M                  | [111]                                                                                |
| Parallel pitch lines                                                                           | 2% (1/58)         | M                  | [224]                                                                                |
| Positron emission tomography (PET)                                                             | 2% (1/58)         | M                  | [152]                                                                                |
| Real-time harmonic contrast enhanced ultrasound (CEUS) Measurements                            | 2% (1/58)         | M                  | [58]                                                                                 |
| Tendon strain                                                                                  | 2% (1/58)         | M                  | [291]                                                                                |
| Thermography                                                                                   | 2% (1/58)         | M                  | [14]                                                                                 |

Table 2 (continued)

| Name of outcome measure                                                                                               | Number of studies | Measurement method | References                                             |
|-----------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|--------------------------------------------------------|
| Calcaneal pitch angle                                                                                                 | 2% (1/58)         |                    | [104]                                                  |
| Bohler's angle                                                                                                        | 2% (1/58)         |                    | [104]                                                  |
| Ultrasound characterization                                                                                           | 2% (1/58)         | M                  | [56]                                                   |
| Structure measures with no description or no reference                                                                | 2% (1/58)         | M                  | [14]                                                   |
| "Ultrasound findings"                                                                                                 |                   |                    |                                                        |
| Candidate domain: adverse effects/events (n = 6/307 studies (2%); four outcome measures)                              |                   |                    |                                                        |
| Complications                                                                                                         | 33% (2/6)         | M                  | [218, 219]                                             |
| Recalcification following surgery                                                                                     | 33% (2/6)         | M                  | [167, 286]                                             |
| Hallux specific complications                                                                                         | 17% (1/6)         | PQ                 | [259]                                                  |
| Frequency of adverse events and adherence                                                                             | 17% (1/6)         | PI                 | [47]                                                   |
| Achilles tendinopathy-related domain: range of motion (n = 13/307 studies (4%); two outcome measures)                 |                   |                    |                                                        |
| Ankle range of motion                                                                                                 | 92% (12/13)       | M                  | [17, 45, 48, 63–66, 85, 203, 242, 259, 296]            |
| 1st MTP joint range of motion                                                                                         | 8% (1/13)         | M                  | [259]                                                  |
| Achilles tendinopathy-related domain: palpation (n = 11/307 studies (4%); two outcome measures)                       |                   |                    |                                                        |
| Tenderness                                                                                                            | 45% (5/11)        | M                  | [18, 45, 53, 98, 207]                                  |
| Pain with palpation                                                                                                   | 55% (6/11)        | M                  | [37, 48, 77, 113, 234, 279]                            |
| Achilles tendinopathy-related domain: sensory modality specific pain (n = 14/307 studies (4%); five outcome measures) |                   |                    |                                                        |
| Tendon pain-pressure threshold                                                                                        | 86% (12/14)       | M                  | [13, 42, 60, 65, 90, 94, 105, 108, 177, 215, 238, 309] |
| Heat pain threshold (HPT)                                                                                             | 7% (1/14)         | M                  | [177]                                                  |
| Heat temporal summation (HTS)                                                                                         | 7% (1/14)         | M                  | [177]                                                  |
| Manually assessed tenderness score                                                                                    | 7% (1/14)         | M                  | [49]                                                   |
| Algomerty                                                                                                             | 7% (1/14)         | M                  | [218]                                                  |
| Achilles tendinopathy-related domain: clinical examination findings (n = 20/307 studies (7%); 14 outcome measures)    |                   |                    |                                                        |
| Swelling                                                                                                              | 25% (5/20)        | M, PQ              | [14, 18, 45, 137, 284]                                 |
| Calf circumference                                                                                                    | 20% (4/20)        | M                  | [197, 200, 212, 216]                                   |
| Calf diameter                                                                                                         | 5% (1/20)         | M                  | [17]                                                   |
| Interview and subjective evaluation                                                                                   | 5% (1/20)         | PI                 | [242]                                                  |
| AOFAS subscore                                                                                                        | 5% (1/20)         | PQ                 | [55]                                                   |
| Gastrocnemius peak amplitude (electromyography)                                                                       | 5% (1/20)         | M                  | [302]                                                  |
| Gastrocnemius muscle length                                                                                           | 5% (1/20)         | M                  | [203]                                                  |
| Location of pain                                                                                                      | 5% (1/20)         | M                  | [207]                                                  |

Table 2 (continued)

| Name of outcome measure                                               | Number of studies | Measurement method | References                        |
|-----------------------------------------------------------------------|-------------------|--------------------|-----------------------------------|
| <i>Clinical examination findings with no description or reference</i> | 32% (7/22)        | M                  | [39, 45, 182, 221, 231, 241, 242] |
| “Clinical parameters”                                                 |                   |                    |                                   |
| “Current pain”                                                        |                   |                    |                                   |
| “Clinical examination”                                                |                   |                    |                                   |
| “Physical examination”                                                |                   |                    |                                   |
| “Interview and subjective evaluation”                                 |                   |                    |                                   |
| “Intensity of clinical parameters”                                    |                   |                    |                                   |
| <i>DOMAIN: other (n = 4/307 study (1%); three outcome measures)</i>   |                   |                    |                                   |
| Use of cointerventions                                                | 50% (2/4)         | PI                 | [47, 87]                          |
| Adherence                                                             | 25% (1/4)         | PQ                 | [87]                              |
| Drug compliance                                                       | 50% (1/4)         | PQ                 | [94]                              |

Each row represents one outcome measure. In cases where outcome measures had the same/similar names but were measured differently they were considered as different outcome measures  
*PQ* patient-reported via questionnaire, *PI* patient-reported via interview, *M* measurement taken by assessor, *NPRS* Numerical Pain Rating Scale, *VAS* Visual Analog Scale

## 3 Results

### 3.1 IDENTIFICATION OF STUDIES

The search and inclusion process is summarized in Fig. 1. The initial search resulted in 9376 records after duplicates were digitally removed. Additionally, 41 records were manually removed because of duplicate findings, leaving 9335 potentially eligible studies. The abstract and title screening resulted in 8855 studies being excluded. Full text review was performed for 480 studies. Following full text review, 307 studies were included for data extraction.

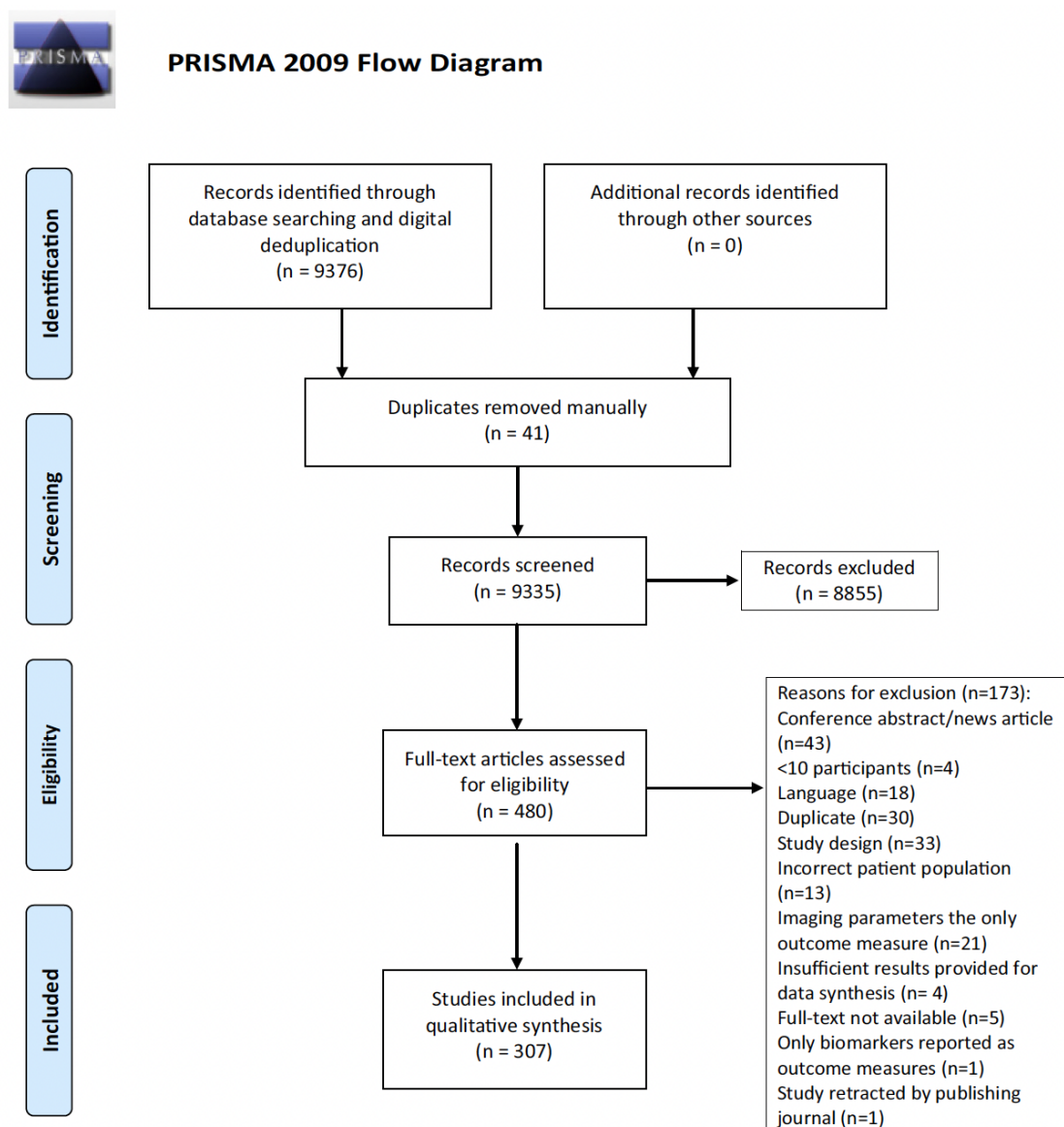


Fig.1 PRISMA flow diagram of study selection process

### 3.2 CHARACTERISTICS OF THE INCLUDED STUDIES

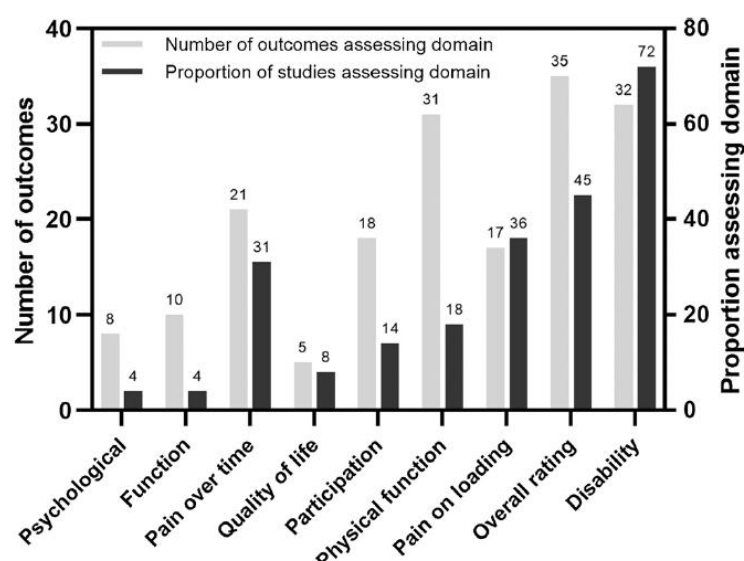
Included studies were published between 1984 and 2020 (median [interquartile range (IQR)], 2014 [2008–2018]), consisting of 29% (89/307) randomized trials [5, 12–98], 6% (17/307) non-randomized trials [99–116], 26% (81/307) single cohort [3, 4, 6, 117–188], 33% (101/307) case series [189–287], 3% (8/307) case–control studies [128, 288–294], and 4% (11/307) pilot or feasibility trials [295–303]. Included studies had a median (range) of 36 (22–58) participants, totaling 13,248 participants included in this systematic review. Participants were identified as athletic in 23% (70/307), sedentary in 3% (9/307), or both athletic and sedentary participants in 25% (76/307) of the studies, while 50% (152/307) of the studies did not provide any information on participant activity level. Achilles tendinopathy location was described in 84% (257/307) of the studies, of which 19% (58/307) included insertional, 48% (146/307) included midportion, and 17% (53/307) reported including both locations. Tendinopathy side was reported as unilateral and bilateral in 40% (122/307) of the studies, unilateral tendinopathy in 22% (67/307), only bilateral tendinopathy in two studies, and 38% (116/307) did not specify.

### 3.3 DESCRIPTIVE ANALYSIS OF CRITERIA FOR CLINICAL DIAGNOSIS

Clinical diagnostic criteria were categorized as patient history ( $n = 219$ ), clinical exam ( $n = 233$ ), patient-reported outcome measures/questionnaires ( $n = 23$ ) and medical records/diagnosis codes ( $n = 27$ ), with additional diagnostic imaging to confirm diagnosis in 160 studies. Seventy-four percent (226/307) of the studies reported using more than one criterion for the diagnosis. The most common criteria combined patient history, clinical exam, and diagnostic imaging (MRI, ultrasound, x-ray, or a combination) to confirm diagnosis in 28% (86/307), followed by 23% (72/307) of the studies that cited patient history and clinical exam without diagnostic imaging. Two studies stated diagnosis was confirmed during surgery and one study cited “self-reported symptoms”. No details were provided for clinical diagnosis in 8% (24/307) of the studies.

### 3.4 SYNTHESIS OF RESULTS

The summary of the outcome measures identified is reported in Table 2 (more detail is provided in ESM, Appendix S2). Below, we present the outcome measures as mapped under the core domains. Figure 2 provides an overview of the number of studies and outcome measures per core domain.



**Fig. 2** Overview of the number of studies and outcome measures per core domain

## 3.5 CORE DOMAINS

### 3.5.1 PATIENT OVERALL RATING

Measurement instruments related to patient overall rating were reported in 45% (139/307) of the studies (Table 2; Fig. 2) [5, 12–15, 19–23, 28, 29, 39–41, 44, 45, 47, 49–51, 57, 58, 60, 61, 63, 68, 74, 75, 79–81, 85–87, 89–96, 98, 102, 110, 113, 116, 118, 119, 122, 124–126, 132–134, 137, 138, 142, 145–148, 150, 151, 153–156, 158–160, 165, 166, 169, 171, 173, 176, 181, 182, 186, 188, 189, 193, 194, 198, 204, 210–212, 215–219, 221, 223, 226, 229, 232–236, 240, 241, 244, 250, 252, 253, 255–258, 260, 262, 264, 268–270, 272–277, 279, 281–283, 285, 295, 296, 301, 304–306, 308]. Patient satisfaction was the most frequently reported measurement instrument (83 studies) [5, 12, 14, 19–23, 40, 58, 60, 61, 63, 68, 74, 75, 79, 86, 87, 89, 93, 96, 102, 110, 119, 122, 125, 132–134, 138, 142, 145–148, 150, 151, 153–155, 158–160, 165, 166, 169, 171, 173, 181, 185, 186, 188, 189, 193, 198, 204, 212, 223, 226, 232, 233, 235, 236, 240, 244, 250, 257, 258, 262, 267, 268, 270, 272, 273, 275, 277, 281–283, 285, 301, 304, 305], followed by an overall assessment (12 studies) [13, 15, 29, 45, 49, 57, 113, 151, 234, 241, 274, 279].

### 3.5.2 PARTICIPATION

Participation was assessed using 18 measurement instruments from 13% (43/307) of all studies (Table 2; Fig. 2). This core domain included measures relating to return to activity, including sports (18 studies) [14, 19, 22, 87, 98, 105, 121, 137, 158, 166, 191, 225, 248, 252, 270, 274, 276, 307], general activity (eight studies) [89, 159, 252, 254, 271, 272, 283, 285] and work duties (four studies) [169, 258, 275, 284]. The most commonly reported measurement instrument was the Tegner Score (five studies) [13, 111, 121, 205, 308].

### 3.5.3 PAIN ON ACTIVITY/LOADING

Pain on activity/loading was evaluated by 17 outcome measures from 36% (109/307) of all studies (Table 2; Fig. 2). The Numerical Pain Rating Scale (NPRS), Visual Analogue Scale (VAS) and Likert scales were used for assessing the pain on activity/loading in 95 studies.

### 3.5.4 FUNCTION

Function was assessed by nine measurement instruments from 4% (11/307) of all studies (Table 2; Fig. 2) [15, 24, 76, 122, 136, 142, 187, 224, 275, 290, 294]. The Ankle Activity Score was reported most frequently ( $n = 3$ ) [24, 142, 187].

### 3.5.5 PSYCHOLOGICAL FACTORS

Psychological factors were evaluated in 4% (11/307) of all studies (Table 2; Fig. 2) [4, 80, 87, 108, 171, 173, 179, 280, 290, 309]. The Tampa Scale of Kinesiophobia was the most frequently reported (45%) of all measures [4, 80, 108, 173, 309].

### 3.5.6 PHYSICAL FUNCTION CAPACITY

Physical function capacity was assessed by 31 measurement instruments from 17% (54/307) of all studies, with strength being the most frequent measurement [4, 17, 28, 29, 43, 45, 48, 58, 63, 64, 71, 76, 89, 100, 106, 109, 115, 150, 152, 153, 157, 160, 188, 190, 197, 200, 201, 203, 212, 216, 217, 226, 231, 232, 238, 241, 242, 259, 263, 269, 270, 288, 292, 294, 302, 311]. Strength was measured using various methods (e.g., plantar flexion torque, isometric, isokinetic) (Table 2; Fig. 2) [28, 29, 45, 71, 76, 100, 109, 150, 152, 153, 160, 190, 201, 203, 216, 217, 231, 232, 238, 241, 269, 270, 292, 302, 311]. The single leg heel rise test was the most frequently reported specific test (13 studies) [48, 63, 89, 90, 107, 108, 200, 212, 216, 242, 259, 310, 311]. Other outcome measures included measures of ability to walk, jump and balance.

### 3.5.7 DISABILITY

Disability was evaluated by 32 measurement instruments from 72% (221/307) of all studies (Table 2; Fig. 2).

The most common outcome measure used was the Victorian Institute of Sports Assessment - Achilles (VISA-A) questionnaire (141 studies) [3–6, 13, 19–22, 24, 25, 27, 30, 37, 39, 41, 44, 46, 47, 53, 54, 56, 58, 60, 61, 64, 65, 68–72, 75, 78–89, 91–95, 97–99, 101–104, 111, 114, 115, 120, 121, 128–130, 133, 135, 140, 143, 149, 157, 160–164, 169, 170, 172, 173, 175–177, 179, 181–183, 186, 187, 189, 191–193, 199, 207, 209, 211, 213–220, 224, 226, 237, 239, 240, 245, 246, 250, 264, 268, 271, 276, 280, 281, 284, 285, 287, 289, 291–294, 296–300, 304–306, 308–310, 312–314].

There were five language versions of the VISA-A used in addition to English and one modified version for sedentary individuals [3, 4, 64, 89, 149, 162, 185, 287].

### 3.5.8 QUALITY OF LIFE

Quality of life was assessed by five questionnaires from 8% (24/307) of all studies (Table 2; Fig. 2) [3, 16, 17, 32, 47, 54, 80, 95, 107, 118, 121, 131, 142, 146, 159, 182, 197, 200, 208, 228, 240, 244, 299, 300]. SF-36 was the most frequently reported (ten studies) [32, 47, 54, 107, 118, 131, 142, 146, 200, 244] followed by EQ-5D (nine studies) [16, 17, 80, 95, 182, 197, 240, 299, 300].

### 3.5.9 PAIN OVER A SPECIFIED TIME FRAME

Pain over a specified time frame was evaluated in 21 measurement instruments from 31% (94/307) of all studies (Table 2; Fig. 2). The most common outcome measure used for this domain (in 71 studies) included various measures of pain (e.g., NPRS, Numerical Rating Scale (NRS), VAS) to assess pain at a specific time (e.g., last 24 h, morning, duration of complaints) [5, 6, 30, 33, 38, 41, 46, 50, 51, 57, 60, 61, 69–73, 75–77, 83, 90, 99, 101, 103, 114, 116, 120, 125, 126, 131, 140, 153, 160, 163, 164, 175, 182, 184, 193, 196, 199, 200, 204, 215, 218–220, 224, 225, 229, 243, 246, 256, 259, 261, 262, 266, 267, 273, 276, 278, 280, 285, 295, 300, 301, 311, 313, 315, 317].

## 3.6 CANDIDATE DOMAINS

The ICON 2019 consensus statement identified candidate domains that were strongly debated and believed to be relevant to tendinopathy but failed to reach  $\geq 70\%$  agreement by a small margin [8]. Outcome measures extracted in this review related to three candidate domains (physical activity, structure, adverse effects/events).

### 3.6.1 PHYSICAL ACTIVITY

The candidate domain physical activity was defined as overall physical activity levels including self-report and measures with wearable sensors. The steering committee of this study identified five outcome measures from 3% (10/307) of studies that were deemed more suitable for this candidate domain than one of the core domains (Table 2) [3, 4, 18, 38, 47, 80, 82, 137, 195]. These outcome measures were originally placed in the core domains participation, function and patient overall rating by reviewers. 'Level of physical activity' was moved from participation for two studies and from function for two studies. '7-Day Physical Activity Recall' was moved from participation for two studies and function for one study. The 'Physical Activity Scale' was moved from participation. 'Level of activity' was moved from patient overall rating. 'Wallgren-Tegner Activity Scale' was moved from participation.

### 3.6.2 STRUCTURE

Structure was reported in 19% (58/307) of the studies, with neovascularization being the most frequently reported measurement instrument (20 studies) (Table 2; Fig. 2) [20, 24, 78, 82, 87, 99, 135, 147, 148, 170, 184, 185, 191, 192, 207, 287, 308, 312]. Structure was reported using 21 various outcome measures of tendon morphological, vascular and mechanical properties using diagnostic ultrasound, MRI and other imaging technologies. All measures relating to structure were originally placed in the 'other' core domain by the reviewers.

### 3.6.3 ADVERSE EFFECTS/EVENTS

Adverse events were reported as outcomes in 2% (6/307) of all studies [47, 167, 218, 219, 259, 286]. 'Complications' and 'Recalcification following surgery' were each moved from the category 'other' for two studies, respectively. 'Hallux specific complications' was moved from function. 'Frequency of adverse events' and 'adherence' were moved from the 'other' core domain.

## 3.7 ACHILLES TENDINOPATHY SPECIFIC DOMAINS

Four domains that did not achieve the threshold for core or candidate domain status (< 70% agreement) for tendinopathy in the ICON 2019 consensus meeting were identified as relevant for Achilles tendinopathy by the steering group. More than 48 studies had outcome measures relating to this specific domain. These domains were range of motion, palpation, sensory modality specific pain, and clinical examination findings (Table 2). The outcome measures assigned to these non-core domains were originally assigned to other domains by reviewers and then moved after consensus between reviewers and the steering committee. 'Ankle range of motion' was reported in 4% (13/307) of the studies [17, 45, 48, 63–66, 85, 203, 242, 259, 296] and one study [259] reported first metatarsophalangeal joint range of motion. 'Pain and or tenderness with palpation' was reported in 4% (11/307) of the studies [18, 37, 45, 48, 53, 77, 98, 113, 207, 234, 279], and 'Sensory modality specific pain' was reported in 4% (14/307) of the studies [13, 42, 49, 60, 65, 90, 94, 105, 108, 177, 215, 218, 238, 309].

'Clinical examination findings' included various measures such as swelling (five studies) [14, 18, 45, 137, 284] and calf circumference (four studies) [197, 200, 212, 216].

## 3.8 RECLASSIFIED OUTCOME MEASURES

Seven strength outcome measures were moved to physical function capacity domain after consensus between reviewers and the steering committee (Table 2). Isometric plantar flexion strength in one study was moved from the 'other' category and from the 'function' category for another study. Isokinetic strength in one study was moved from 'other'. Plantar flexion peak torque was moved from 'other' for one study. Plantar flexion force was moved from 'other' for one study, plantar flexion strength was moved from 'function' for two studies and the three were amalgamated with 'nondescriptive strength testing'.

# 4 Discussion

The aim of this large systematic review was to synthesize all available outcome measures reported in prospective studies investigating Achilles tendinopathy and categorize them according to core tendinopathy domains identified by the ICON working group [8]. We identified 307 eligible studies, which included a total of 10,981 participants. The proportion of studies that included outcomes for core domains ranged from 4% for the psychological factors domain to 72% for the disability domain.

In fact, aside from disability, all other domains were represented in 45% or less of the studies. There were between five and 35 unique outcome measures utilized for each core domain and 177 different outcome measures across all core domains. Commonly used outcome measures are the VISA-A questionnaire (64% of the studies in the disability domain), pain with activity/loading (87% of the studies in the pain on activity/loading domain), patient satisfaction (59% of the studies in the patient overall rating core domain), and pain at follow-up (77% of the studies in the pain over a specified time frame domain). Seventy-four studies (24%) reported outcome measures related to candidate domains or tendinopathy and 58 studies (19%) reported outcome measures considered relevant to the Achilles tendinopathy-specific domains.

#### **4.1 WHY ARE THESE FINDINGS RELEVANT?**

As evidenced by the findings of this review, researchers commonly utilize different outcomes to assess the same domain. We even identified multiple outcome measures that described a similar measurement, but in a slightly different way. This poses challenges for both researchers and clinicians. A barrier to pooling in meta-analyses is the existing heterogeneity in outcome measure reporting for a specific domain, and this limits efforts to synthesize current evidence to inform future research and guide evidence-based practice. As such, the use of disparate outcomes measures is recognized as a problem that contributes to research waste [318]. To address this issue there are emerging global efforts to develop core outcome sets that are agreed by stakeholders (clinicians, patients, and researchers). Leading the way in this area is the COMET (Core Outcome Measures in Effectiveness Trials) Initiative ([www.comet-initiative.org](http://www.comet-initiative.org)). This group has both published a handbook [319] for the process of developing a core outcome set and developed a COMET database. Our ICON Achilles tendinopathy group seeks to achieve agreed-upon core domains and outcomes for Achilles tendinopathy and our study is prospectively registered on the COMET database. We report the first step of this process in this systematic review. This first step provides a relevant overview for researchers and clinicians working with Achilles tendinopathy patients. It also contains the necessary information that will form the basis of forming the core outcome set.

#### **4.2 RELEVANCE OF THE NON-CORE DOMAINS**

Among the non-core domains, the most frequently assessed was structure (19% of studies). This is noteworthy because the structure domain narrowly missed the threshold for inclusion as a core domain for tendinopathy in general, achieving 69% agreement [8]. There is currently limited evidence supporting the change in structure outcomes following interventions [293, 320, 321] and the prognostic value of structure outcomes [181, 310]. In response, an ICON sub-group was formed to further guide, synthesize and develop outcome measures within the tendinopathy structure domain. Other non-core (physical activity, adverse events) and Achilles tendinopathy-specific domains (range of motion, palpation, sensory modality specific to pain and clinical examination such as calf circumference) were assessed by a minority of studies (0.6% to 7%). It is important to allow stakeholders to decide whether the new domains identified are worthy of inclusion as core for Achilles tendinopathy (a function of the planned Delphi process—see Sect. 4.5).

### **4.3 WHAT DOES THIS MEAN FOR RESEARCHERS AND CLINICIANS?**

This systematic review provides a full overview of all available outcome measures for Achilles tendinopathy. This can aid researchers and clinicians in selecting the most appropriate outcome measures for their specific aim. As per the ICON consensus group statement [8], it is recommended that core domains are used in research and clinical practice, although this does not prevent the use of other domains, if relevant. For example, if an intervention that is aimed at improving range of motion is being evaluated, it may be appropriate to include this as an outcome. We also caution against using an outcome measure solely because it is commonly assessed in the literature without critically appraising its clinimetric properties (part of the next steps in developing a core outcome set for Achilles tendinopathy).

### **4.4 STRENGTHS AND LIMITATIONS**

Our review is strengthened by the thorough search strategy in multiple databases, and study selection and data-extraction processes conducted by teams of two independent team members. The extensive reviewer team have no conflicts of interest that may impact on the validity of our review. There are some limitations that should be highlighted. We did not include all study designs, such as small studies with a sample size of less than ten and case studies. Given we included 307 studies spanning a 37-year period we do not believe this would have substantially altered our review findings. A potential source of bias is the steering group's adjudication over disagreement between pairs of reviewers in assigning outcomes to domains. To minimize this bias, we have been transparent in outlining the process we followed, and we involved the original reviewers in all consensus decisions. The mapping of the outcome measures to the domains will also be revisited in the next stage of the consensus for COS for Achilles tendinopathy. A limitation is that we included a huge diversity in study populations and diagnostic criteria. Although imaging is not recommended as an essential diagnostic tool [1], there is ongoing debate about the diagnostic criteria for Achilles tendinopathy [322]. It could be argued that we have not included a homogenous population of people with Achilles tendinopathy, but this does not detract from our aim of identifying all available outcomes measures utilized for this condition. Finally, we have reported imaging outcomes that were identified in our yield but this is not likely to be a complete list as we excluded studies that only reported imaging outcomes.

### **4.5 FUTURE DIRECTIONS**

The diversity in outcome measures identified in this review confirms the need to develop a core outcome set for Achilles tendinopathy, to facilitate data pooling and inform practice in the near future. The next step in the process of developing this core outcome set is to engage key stakeholders, including patients, clinicians and researchers, to reach consensus regarding the outcome measures (from the measures identified in this review), that should be used in research and practice. This consensus process will involve a Delphi study with online survey and face-to-face meeting components. Another critical component prior to recommending a core outcome set is to perform a critical appraisal of the clinimetrics of the proposed outcome measures.

## 5 Conclusions

In this systematic review 233 outcome measures assessing the clinical phenotype of Achilles tendinopathy were identified and mapped into domains. Each core outcome domain was represented by between 4% (psychological factors domain) to 72% (disability domain) of studies. There were between eight and 35 unique outcome measures utilized for each core domain. The next step in developing a core outcome set for Achilles tendinopathy is to engage key stakeholders, including patients, clinicians and researchers, to reach consensus on key outcomes measures.

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## Declarations

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**Competing interests** Karin Grävare Silbernagel, Peter Malliaras, Robert-Jan de Vos, Shawn Hanlon, Mitchel Molenaar, Hakan Alfredson, Inge van den Akker-Scheek, Jarrod Antflick, Mathijs van Ark, Kenneth Färnqvist, Zubair Haleem, Jean-Francois Kaux, Paul Kirwan, Bhavesh Kumar, Trevor Lewis, Adrian Mallows, Lorenzo Masci, Dylan Morrissey, Myles Murphy, Richard Newsham-West, Richard Norris, Seth O'Neill, Koen Peers, Igor Sancho, Kayla Seymore, Patrick Vallance, Arco van der Vlist and Bill Vicenzino declare that they have no conflicts of interest relevant to the content of this review.

**Availability of data and material** Upon reasonable request.

**Code availability** Not applicable.

**Author contributions** BV devised the systematic review idea. KS, PM, RN-W and RJDV originally designed the systematic review and all authors were subsequently involved in refining its design. AV and RJDV performed the literature search with assistance from the librarian. SH and IS screened trials for inclusion. SH, MM, PV, AM, ZH, MV, KF, SO and KS performed data-extraction. SH and MM analyzed the data. KS, PM and RJDV interpreted the results of the data-analyses. SH, MM, KS, PM and RJDV drafted the manuscript. KS, PM and RJDV are study guarantors. All authors reviewed the final manuscript and agreed to be accountable for all aspects of the work and approved the final manuscript for submission. The corresponding author attests that all listed authors meet authorship criteria.

**Ethics approval** Not applicable.

**Transparency declaration** The article's guarantors affirm that the article is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

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