ICON 2023: International Scientific Tendinopathy Symposium Consensus – the core outcome set for Achilles tendinopathy (COS-AT) using a systematic review and a Delphi study of professional participants and patients

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ABSTRACT

To develop a core outcome set for Achilles tendinopathy (COS-AT) for use in clinical trials we performed a five-step process including (1) a systematic review of available outcome measurement instruments, (2) an online survey on truth and feasibility of the available measurement instruments, (3) an assessment of the methodological quality of the selected outcome measurement instruments, (4) an online survey on the outcome measurement instruments as COS and (5) a consensus in-person meeting. Both surveys were completed by healthcare professionals and patients. The Outcome Measures in Rheumatology guidelines with a 70% threshold for consensus were followed. We identified 233 different outcome measurement instruments from 307 included studies; 177 were mapped within the International Scientific Tendinopathy Symposium Consensus core domains. 31 participants (12 patients) completed the first online survey (response rate 94%). 22/177 (12%) outcome measurement instruments were deemed truthful and feasible and their measurement properties were evaluated. 29 participants (12 patients) completed the second online survey (response rate 88%) and three outcome measurement instruments were endorsed: the Victorian Institute of Sports Assessment-Achilles questionnaire, the single-leg heel rise test and evaluating pain after activity using a Visual Analogue Scale (VAS, 0–10). 12 participants (1 patient) attended the final consensus meeting, and 1 additional outcome measurement instrument was endorsed: evaluating pain during activity/loading using a VAS (0–10). It is recommended that the identified COS-AT will be used in future clinical trials evaluating the effectiveness of an intervention. This will facilitate comparing outcomes of intervention strategies, data pooling and further progression of knowledge about AT. As COS-AT is implemented, further evidence on measurement properties of included measures and new outcome measurement instruments should lead to its review and refinement.

WHAT IS ALREADY KNOWN

⇒ Achilles tendinopathy (AT) is a tendon disorder with high impact on patients. To effectively evaluate the clinical course of AT and treatment effectiveness, reliable and valid outcome measurement instruments are necessary.A core outcome set (COS) will make evaluation of research and clinical practice more uniform and thereby facilitate comparing outcomes of intervention strategies, data pooling and further progression of knowledge about AT.There is no agreed COS for AT (COS-AT)—this limits adequate interpretation, comparison and synthesis of study results in meta-analyses.

INTRODUCTION

Achilles tendinopathy (AT) is the clinical diagnosis for load-related pain and disability localised to the

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R-JdV, KGS, PM and TSV contributed equally.

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WHAT ARE THE FINDINGS

⇒ The COS-AT consists of the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire, the single-leg heel rise test and evaluation of pain during as well as after activity/loading using a Visual Analogue Scale (0–10). These outcome measurement instruments should be used to evaluate this condition to capture the core domains disability, physical function capacity and pain on activity in clinical settings and in research trials.

⇒ It is suggested to use the COS-AT as a minimal reporting requirement—it does not prevent the use of other outcome measurement instruments (eg, VISA-A sedentary or TENDINS-A). The working group recommends considering including other outcome measurement instruments within the core domains in tendinopathy if this supports the context of the trial. These domains include patient overall rating, participation, function, psychological factors, quality of life and pain over a specific time frame.

⇒ As there have been recent challenges to the measurement properties of some of the COS-AT (eg, VISA-A), we recommend that future research focus on further evaluating its measurement properties.

HOW MIGHT IT IMPACT ON CLINICAL PRACTICE IN THE FUTURE

⇒ Using the COS-AT in the clinical setting will allow comparison of treatment outcomes between different clinical practice settings.

⇒ Adopting the COS-AT will allow for adequate meta-analysis of clinical trials, thereby providing more accurate estimates of the treatment effects for patients with AT.

Achilles tendon and affects a diverse population from sedentary individuals to elite athletes.[1] This condition frequently leads to chronic symptoms with poor quality of life and substantial healthcare consumption (median of 9 annual healthcare visits and estimated annual costs of €840 per patient with AT).[2 3] To effectively evaluate recovery of AT and treatment effectiveness, reliable and valid outcome measurement instruments are necessary.[4–6] Currently, there is considerable variation in the outcome measures used to assess interventions[5]; this can have implications for patient care, as healthcare professionals and researchers are unable to adequately interpret, compare and synthesise study results in meta-analyses.[7 8] The importance of developing a core outcome set (COS) for clinical trials is emphasised by both the Outcome Measures in Rheumatology (OMERACT)[9] and the Core Outcome Measures in Effectiveness Trials (COMET)[10] initiative. These organisations also offer detailed guidelines for the development of a COS.[10 11] For inclusion in a COS, outcome measurement instruments must be both feasible (considering cost, patient burden and availability in the clinical setting) and of sufficient quality (valid, responsive, reliable and interpretable).[9 11]

In 2018, a Delphi study was conducted at the International Scientific Tendinopathy Symposium Consensus (ICON) to establish core domains for tendinopathy.[7] Expert clinicians and researchers in tendinopathy, as well as patients with tendinopathy at different anatomical sites, identified 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.[7] The next step is to use these core domains as a guide to develop COS for each of the common tendinopathies. A COS for AT (COS-AT) is currently lacking.

The primary aim was to develop this COS-AT through a systematic search for outcome measurement instruments that map to core tendinopathy domains, methodological quality assessment and a three-round Delphi including an in-person consensus meeting. After defining the COS-AT, it should be used in future clinical trials evaluating the effectiveness of an intervention for AT.

METHODS

Study protocol

At the International Scientific Tendinopathy Symposium (ISTS) 2018, an AT consensus group was formed.[5] This group worked collaboratively on prospective registration of the study protocol on the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42020156763). The project was also registered in the COMET database (www.comet-initiative.org, reference number 1323).[12]

To identify the COS for AT, we predefined five steps based on recommended methodology[9 11]: (1) a systematic review of available outcome measurement instruments, (2) an online survey (first round Delphi) on truth and feasibility, (3) assessing methodological quality of selected instruments, (4) an online survey (second round Delphi) on the COS and (5) an in-person consensus meeting (third round Delphi). The results of the first step have recently been published elsewhere.[5] The process of the complete study is described in detail below and is in line with the OMERACT guideline for Developing COS.[9]

Panel selection

The steering committee (KGS, PM and R-JdV) was formed in collaboration with the initiator of the COS development in tendinopathies (BV). The steering committee performed the recruitment and selection of the COS-AT consensus group. There was a call for potentially eligible participants during the International Scientific Tendinopathy Symposium (ISTS) in September 2018 in Groningen, the Netherlands. Some participants were also recruited afterwards via snowball methods and contacts of the steering group. The COS-AT consensus group was important for the design process and inclusion of patients throughout the project. For the Delphi parts of the process, an expert panel was selected. In the process of panel selection, our objective was to ensure a comprehensive representation of both clinicians and researchers (professional participants) and people with lived experience of having AT (referred to as patients). To achieve this, we employed a two-pronged approach.

First, to recruit patients, we enlisted the assistance of the COS-AT consensus group.[5] This group was tasked with identifying and engaging potential patients for participation. To promote diversity, we strived to constitute a patient panel that exhibited a representative distribution in terms of gender and country of residence. Anticipating a substantial time gap between the two rounds of the Delphi survey and as we required patients with AT to have current or recent (<3 months) symptoms of AT, the individuals recruited for round 1 differed from those in round 2. We anticipated a minimum number of 10 patient participants for both surveys and one for the in-person consensus meeting. On expressing their interest to participate, patients were promptly provided with a detailed email outlining the entirety of the process, along with an explicit explanation of their specific role within the panel. During all rounds, patients had equal voting rights as professional participants.

Second, in the process of the selection of professional participants, we aimed to include representatives possessing varied backgrounds (both academic and clinical) and expertise, striving to ensure an equitable and proportional distribution based on gender and country of residence. To identify suitable professional participants, we used www.expertscape.com, a website that ranks experts who are at the leading edge of knowledge and writing in peer reviewed publications within specific medical fields (search term 'Achilles tendon' with search date 1 June 2021). We contacted these selected professional participants via email, extending invitations to participate in the panel. Once professional participants expressed their interest to participate, they received an email with an explanation of the process and their exact role. Hereafter, informed consent from all participants (both patients and professional participants) was obtained.

Systematic review

Step 1: a systematic review of all available outcome measurement instruments

We set up a search strategy to identify all available outcome measurement instruments used in prospective studies including patients with AT.[5] We mapped the outcome measurement instruments into predefined health-related core domains (data have recently been published elsewhere).[7]

Consensus process

Step 2: online survey to evaluate truth and feasibility of outcome measurement instruments (first round Delphi procedure)

All original outcome measurement instruments within the core domains for tendinopathy and identified by the systematic review[5] were evaluated during an international online survey using LimeSurvey (LimeSurvey, Germany), a software package designed for safe distribution of online surveys. The description of the outcome measurement instruments from the literature was used verbatim, so the experts (patients and professional participants) could rate exactly what had been used in the literature. Within the identified outcome measurement instruments, there were instances where multiple outcome measurement instruments described similar aspects but with slight variations. For example, pain on palpation was assessed using different formats such as a yes/no responses, a 0–10 Visual Analogue Scale (VAS) and a 5-point Likert scale. To ensure a comprehensive evaluation, we separately assessed these variations in measurement and presented them exactly as they were used in the literature. The international panel consisting of the selected professional participants and patients was invited to complete the survey. The selection process of the outcome measurement instruments in this second step was initiated according to the OMERACT filters, which use truth, discrimination and feasibility as the core of the pillars for instrument selection.[9] In this step, we focused on the pillars truth (which core domain is covered and 'Is there a match with the target domain?') and feasibility ('Is the outcome measurement instrument practical to use?'). The specific outcome measurement instruments were displayed and these questions were asked for every identified outcome measurement instrument. The respondents to the survey had four response options for the specific outcome measurement instrument to be: (1) not truthful and not feasible, (2) truthful but not feasible, (3) not truthful but feasible or (4) truthful and feasible. An outcome measurement instrument was assessed in step 3 if it met the a priori decision criteria: ≥70% agree the outcome measurement instrument is both truthful and feasible.

Step 3: performing a quality assessment of the endorsed outcome measurement instruments

For this step, we only used outcome measurement instruments that were found to have content and concept match (were found to be truthful) and were feasible to use. This step consisted of a systematic review to assess the measurement properties of the selected outcome measurement instruments.

To ensure a standardised approach, we adhered to the OMERACT guideline for instrument selection in core outcome measurement sets.[9 11] This guideline uses the pillars truth (do the numeric scores make sense?) and discrimination (can it discriminate between groups of interest?). A search strategy (online supplemental file 1) was performed by a medical librarian, using a focused search that was based on (1) specific patient population of AT; (2) outcome measurement instrument names and (3) measurement properties (construct validity, test–retest reliability, responsiveness, sensitivity to change, minimum important difference and patient acceptable state). The following databases were searched for published and unpublished trials up to 17 March 2022: Embase, Medline ALL, Web of Science Core Collection, Cochrane Central Register of Controlled Trials, CINAHL and SPORTDiscus.

After duplicate removal, two researchers (R-JdV and TSV) independently screened the studies based on title and abstract. Disagreements were resolved by consensus. Studies were deemed eligible if they investigated the measurement properties of the outcome measurement instruments in a population of patients with AT. The same two reviewers independently applied the eligibility criteria to the full texts, with any disagreements settled through consensus or, if necessary, with the involvement of a third reviewer (KGS). The selected studies were then grouped based on the outcome measurement instrument examined.

After this stage, the methods of the selected studies were critically appraised using the OMERACT and COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) guidelines.[13] Two researchers (IS and S-ES) with methodological expertise from the collaborating group independently assessed the methodological quality of the selected studies. Selected studies were assessed on the performance of the outcome measurement instrument (adequate/equivocal/poor) and the quality of the methods used in the particular study (good/moderate/poor). Disagreements were resolved by consensus. Studies with a high risk of bias according to this quality assessment were excluded from evidence synthesis. Subsequently, a summary of measurement properties table was made per outcome measurement instrument, based on the OMERACT guidelines. This table covered extracted data of (1) truth (target domain); (2) feasibility; (3) truth (construct validity which included hypothesis testing (convergent validity) and testing of known group differences) and (4) discrimination (test–retest reliability, responsiveness, clinical trial discrimination and thresholds of meaning) per included study. We performed a best evidence synthesis, which was based on the quality of the included studies, the number of good quality studies, the consistency across studies and the performance in each property. This resulted in a final synthesis rating that was categorised as (1) go (green), (2) cautious (amber), (3) stop (red) or (4) no data. As we expected evidence for certain outcome measurement instruments to be absent or very limited in the specific population of AT patients, we decided not to reject outcome measurement instruments with no available data on measurement properties at this stage. Where this was the case, we explicitly mentioned this limitation in the voting rounds of the Delphi process.

Step 4: an online survey on outcome measurement instruments as COS-AT (second round Delphi procedure)

The outcome measurement instruments identified during the systematic review (step 1) that were found to be feasible and within the relevant core domain for tendinopathy (step 2) and assessed for their methodological quality (step 3) were rated during an international Delphi survey. The same international panel of professional participants was invited to participate as well as a new sample (≥10) of patients with AT. For each included outcome measurement instrument, we displayed the results of steps 1 and 2 to the participants and asked whether this outcome measurement instrument should be part of the COS. The respondents to the survey had three response options: agree (yes), disagree (no) or unsure. An outcome measurement instrument was regarded as part of the COS if it met the a priori criterion decision: ≥70% agree. An outcome measurement instrument was not regarded as part of COS if ≥70% disagree. If 30%–70% agree, the outcome measurement instrument was discussed during the in-person meeting (step 5).

Step 5: defining the COS-AT during a consensus meeting at ISTS 2023 (third round Delphi procedure)

The results from the first three steps were collated and circulated to all members of the panel prior to the consensus meeting, which was held at the ISTS 2023 in Valencia (Spain) on 9 November 2023. All professional participants were asked to attend the meeting as well as several patients. At this consensus meeting, any item not already included or excluded from the outcome set (agreement between 30% and 70%), was discussed and voted on. Voting at this meeting was anonymous and recorded using specific software (Mentimeter AB, Stockholm, Sweden). The choices at this meeting were only 'agree' or 'disagree' (with the outcome measurement instrument being part of the COS). An outcome measurement instrument was endorsed if ≥70% agreed. An outcome measurement instrument with 30%–70% agreement was rated as inconclusive. These outcome measures are not definitively excluded but may be reconsidered for inclusion in the future (eg, when updating the COS-AT). An outcome measurement instrument was not endorsed if <30% agreed.

Equity, diversity and inclusion statement

The author group consisted of a representative sample of men and women and both junior and experienced researchers from a variety of disciplines and from different countries. The panel consisted of both patients and professional participants from different countries and with a representative distribution of gender and we strived for a diversity in country of residence. A challenge was to maintain the representative sample of patients throughout the process. This was especially the case for step 5, where we held an in-person meeting and were limited to the invitation of only Spanish participants, who already had the possibility to pay for healthcare services for their AT.

RESULTS

We commenced this study in September 2018, with regular meetings by the steering committee to design the study, facilitate data collection and interpretation. The project was completed in November 2023. The reasons for the long timespan of this project were related to the large workload for the steering committee, the COS-AT consensus group, patient participants and the expert panel. This high workload was mainly caused by the large amount of identified outcome measures (9376 studies), the extraction of all available 177 outcome measurement instruments and the extensive questionnaires that had to be developed and completed. This project was also performed in the era of the COVID-19 pandemic, which further delayed the process.

We contacted 68 professional participants based on the Expertscape search. 35 (51%) did not want to participate or did not respond. 33 professional participants expressed that they were available to participate in the panel. The characteristics of the professional participants and patients who completed the Delphi surveys and attended the in-person consensus meeting are displayed in table 1.

Step 1: a systematic review of all available outcome measurement instruments

The literature search was performed on 1 June 2021. In brief, there were 9376 studies identified and 307 studies were finally included.[5] 233 different outcome measurement instruments across all domains were identified, and 177 outcome measurement instruments were selected within the predefined core domains—previously reported.[7] These outcome measurement instruments were used for the next step in the COS-AT process.

Step 2: online survey to evaluate truth and feasibility of outcome measurement instruments (first round Delphi procedure)

The first online survey was sent to the participants on 1 November 2021. 31 participants completed the survey (response rate 94%). 12 (39%) participants were patients and 19 (61%) were professional participants. In total, 13 (42%) participants were women and 18 (58%) man. 177 different outcome measurement instruments across all core domains were assessed. More than 70% of the participants agreed that 22 (12%) outcome measurement instruments are both truthful and feasible (table 2 and online supplemental file 2). The full results of the survey are presented in online supplemental file 3.

Step 3: performing a quality assessment of the endorsed outcome measurement instruments

We identified 4878 potentially relevant publications for assessing the quality of the endorsed outcome measurement instruments in step 3. Figure 1 shows a flow chart of the article selection process. After duplicate removal, 2119 publications were screened based on the title and abstract. Eight articles were relevant but were excluded because they were not original research articles (eg, systematic review, scoping review). 42 articles were screened in the full text. 27 articles fulfilled the eligibility criteria and were critically appraised by the methodological experts using the COSMIN criteria.[13] A summary of the methodological measurement properties, as also presented to the participants in the second round of the Delphi procedure, was made and is presented in online supplemental file 4. There were no available data on the quality of 13/22 (59%) outcome measurement instruments. The remaining nine outcome measurement instruments showed low-quality evidence of their measurement properties, with very few studies examining responsiveness (n=2), clinical trial discrimination (n=1) and thresholds of meaning (n=4). Moreover, structural validity (when assessed) was not or only partially (n=4) evaluated according to COSMIN guidelines.

Step 4: an online survey on outcome measurement instruments as COS-AT (second round Delphi procedure)

The second online survey was sent to the participants on 25 July 2023. For each included outcome measurement instrument, we displayed the results of steps 2 and 3 to the participants and asked whether this outcome measurement instrument should be part of the COS-AT. 29 participants (12 patients (41%) completed the online survey of whom 11 (38%) were women and 18 (62%)

Table 1 Characteristics of the participants completing the first and second Delphi survey

	Survey 1		Survey 2		In-person consensus meeting	
Characteristic	**PPs**	**Patients**	**PPs**	**Patients**	**PPs**	**Patients**
N	19	12	17	12	11	1
Gender: men (%)	10 (53)	8 (66)	12 (71)	6 (50)	8 (73)	1 (100)
Age: median (min-max) years	48 (29–68)	42 (28–56)	54 (30–69)	46 (29–68)	54 (32–68)	49
Role						
Clinician and researcher	13	–	14	–	10	–
Researcher/scientist only	6	–	3	–	1	–
Tendinopathy cases per month		NA		NA		
None	7		4		1	
At least 4	1		0		0	
Between 5 and 10	3		3		2	
Between 11 and 15	4		3		4	
More than 16	2		5		1	
Other*	2		2		3	
Years managing tendon problems		NA		NA		
None	1		1		0	
At least 4	2		0		0	
Between 5 and 10	2		2		0	
Between 11 and 15	1		1		3	
More than 16	12		12		8	
Other*	1		0		0	
Profession		NA		NA		
Physiotherapist	12		8		7	
Orthopaedic surgeon	3		5		2	
Sports physician	1		2		1	
General practitioner	1		1		0	
Other	1 (Biomedicine)		1 (retired orthopaedic surgeon)		1 (rheumatologist)	
Currently have a tendon problem	1	12	–	12	–	1
History of a tendon problem	9	5	–	8	–	1
Countries where participants work						
Australia	5	3	2	1	4	0
UK	3	5	2	3	2	0
USA	4	0	3	3	2	0
The Netherlands	2	0	4	2	1	0
Sweden	3	1	2	2	1	0
Italy	1	0	2	0	0	0
Canada	1	0	1	0	0	0
Belgium	0	1	0	1	0	0
Spain	0	1	0	0	0	1
Ireland	0	1	0	0	0	0
China	0	0	1	0	0	0
Denmark	0	0	0	0	1	0

*Not further specified.
NA, not applicable; PPs, professional participants.

were men. Of the 12 patients, 6 (50%) were women. The survey response rate was 88%. The results of this survey are displayed in table 3. More than 70% of the participants agreed that 3 of the 22 outcome measurement instruments should be included in the COS-AT. These outcome measurement instruments were (1) the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire,[14] (2) the single-leg heel rise test[15–17] and (3) evaluating pain after activity using a VAS (from 0 to 10, with 0 indicating no pain). There were no measurements that were excluded at this stage (ie, ≥70% disagreement). On 19 (86%) of the outcome measurement instruments, the a priori decision criteria (either ≥70% agree or disagree) were not reached (table 3). These 19 outcome measurement instruments were evaluated in step 5.

Step 5: Defining the COS-AT during a consensus meeting at ISTS 2023 (third and final round Delphi procedure)

During the ISTS 2023 in Valencia (Spain), 11 professional participants (33% of the total clinician/researcher panel) and 1 patient (man) were present. All participants received an email with detailed information about the results of steps 3 and 4. An introduction to the session was performed by the steering committee, and the 19 outcome measurement instruments not already included or excluded from the COS, were discussed and voted on. One item was endorsed, 10 were rated as inconclusive and 8 were not endorsed (online supplemental file 5). In combination with the results of step 4, a COS could be defined, comprising four outcome measurement instruments, which are displayed in table 4.

Table 2 The outcome measures regarded as both truthful and feasible by the participants

Outcome measurement instrument	Truthful+feasible	NOT truthful +feasible	NOT feasible +truthful	NOT feasible and not truthful
Improvement				
A 6-point Likert scale	22 (71%)		9 (29%)	
Results of treatment				
Global Ratings of Change Scale	23 (74%)		8 (26%)	
Clinical Global Impression Scale	25 (81%)		6 (19%)	
Patient Global Impression of Change Scale	23 (74%)		8 (26%)	
Perception of treatment effectiveness	24 (77%)		7 (23%)	
Perceived improvement	22 (71%)		9 (29%)	
Return to sport/competition				
Return to sports	22 (71%)		9 (29%)	
Time to return to preinjury levels	24 (77%)		7 (23%)	
Pain during activity/loading				
A 100 mm Visual Analogue Scale (VAS)	22 (71%)		9 (29%)	
A VAS scale from 0 to 10 (0 no pain, 10 severe pain)	22 (71%)		9 (29%)	
Pain after activity				
Evaluating pain after activity using a VAS (0–10)	23 (74%)		8 (26%)	
Strength and flexibility testing				
Single-leg heel rise test	27 (87%)		4 (13%)	
Single Hop test	26 (84%)		5 (16%)	
'Gastrocnemius and soleus flexibility'	24 (77%)		7 (23%)	
Disability				
VISA-A questionnaire	26 (84%)		5 (16%)	
Foot Function Index	22 (71%)		9 (29%)	
Morning pain				
Pain first thing in the morning (VAS 0–100) (not further specified)	23 (74%)		8 (26%)	
Pain at rest				
Morning stiffness. Asking morning stiffness severity, measured on a 100 mm VAS	23 (74%)		8 (26%)	
Location of pain Identifying the site of maximum pain	24 (77%)		7 (23%)	
Ankle range of motion				
Measuring full range of motion of the ankle with a standard goniometer	23 (74%)		8 (26%)	
Adherence				
Use of co-interventions	25 (81%)		6 (19%)	
''Adherence''. A weekly online questionnaires to evaluate adherence to exercise treatment.	23 (74%)		8 (26%)	

Values are expressed as numbers (%).
VISA-A, Victorian Institute of Sports Assessment-Achilles.

Notes during the in-person consensus meeting

During the final in-person consensus meeting, several key topics emerged, underlining the perspectives of the professional participants and the patient. All participants agreed that outcome measurement instruments should be as straightforward as possible; simpler measures are deemed more reliable while those that are more extensive are often seen as having less construct validity. For example, a 0–10 VAS should be preferred over a 0–100 VAS. Additionally, there was a call for greater specificity in certain outcome measurement instruments, such as evaluating pain after activity.

A notable area of discussion revolved around the classification of certain outcome measurement instruments. For example, the use of cointerventions as outcome measurement instrument was viewed by some as essential to proper methodology, and thus not essential to a specific COS, whereas others believed it should be included in the COS-AT. Similarly, the relevance of pain location was debated. While some considered its assessment crucial in clinical diagnosis and argued it should be a part of diagnostic criteria rather than the COS-AT, others disagreed and voted for this outcome measurement instrument as part of the COS-AT.

DISCUSSION

This is the first COS for AT (COS-AT). Experts (patients and professionals) agreed on 4 outcome measurement instruments to be part of the COS-AT and 10 outcome measurement instruments were rated as inconclusive. The four agreed on outcome measurement instruments are (1) the VISA-A questionnaire, (2) the single-leg heel rise test, (3) evaluating pain after activity using a VAS (0–10) and (4) evaluating pain during activity/loading using a VAS (0–10). These outcome measurement instruments cover the domains pain on activity/loading, physical function capacity and disability, which means that the other identified core domains[7] (patient overall rating, participation, function, quality of life, psychology and pain over a specified time frame) are not covered by outcome measurement instruments of the COS-AT. It should be noted that none of the feasible and truthful outcome measurement instruments for AT reached a high-quality evidence of their measurement properties.

The in-person consensus meeting highlighted the need for more detailed specification of the evaluation of pain after activity, where clarity is lacking on the exact timing

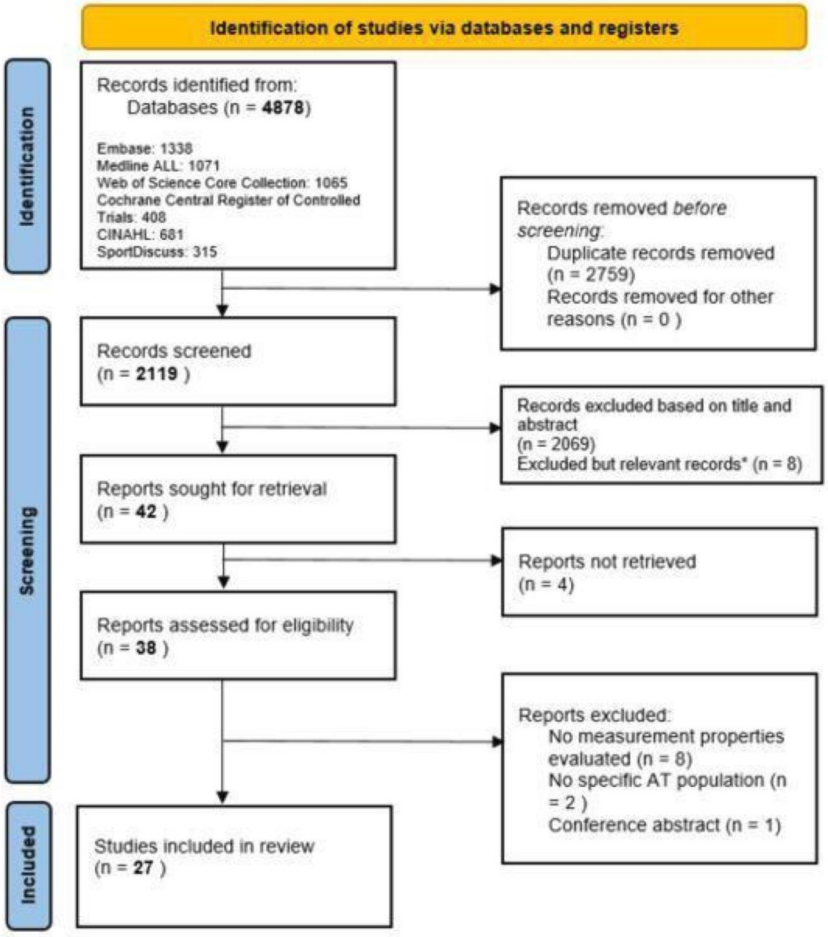

Figure 1 Flow chart of the article selection process for the research question related to the quality of the outcome measurement instruments. AT, Achilles tendinopathy. ∗Systemetic reviews or meta-analysis evaluating measurement properties with a population of Achilles tendinopathy patients.

of measurement. When this outcome measurement instrument is used in clinical trials, it should be explicitly stated when it is measured (eg, an hour after activity or a day after activity) and what 'activity' exactly entails (eg, walking or running). While current pain assessments in the COS-AT use the VAS, we suggest the Numerical Rating Scale can also be used as a potentially more practical alternative, as the panel considered both measures largely interchangeable when used consistently on a 0–10 scale. It is possible to use a 0–100 scale if this is deemed more appropriate in certain contexts. In that case, the scores could be converted for meta-analysis.

The single-leg heel rise test is regularly employed to assess the strength-endurance of the plantar flexors. The test generally involves the maximum number of repetitive concentric–eccentric plantar flexor muscle actions but is variably described in literature.[18] The number of maximum repetitions is the most frequently reported outcome measure when performing this test. It is worth noting that other parameters might be extracted from this test and also assessed using an application: unable/able, work (joule), cm above the ground (measured from the heel).[19] While it is unsure from the current study which specific outcome measure would be the best to use and which test method is most optimal, it is worth noticing that this heterogeneity exists for this outcome measure.

During the meeting, there was also considerable debate as to whether the use of cointerventions and the location of pain should be part of the COS-AT. Voting results showed 64% being opposed to their inclusion. On reviewing these results, we believe it is crucial to emphasise that both measures are significant for sound methodology and diagnostic assessment respectively. However, their suitability as part of the COS-AT warrants further consideration and a considerable degree of reservation.

It also became clear that high-quality studies into all different measurement properties of the outcome measures are lacking. Only limited evidence was available for the majority of the endorsed measurement instruments. Especially on construct validity—with inclusion of structural validity and cross-cultural adaptation, which are not assessed in the current study following OMERACT guidelines—and responsiveness, clinical trial discrimination and thresholds of meaning more research is needed.

Clinical and research implications

The development of the COS-AT carries significant clinical and research implications. The introduction of standardised outcome measurement instruments, as derived in this study, offers several potential benefits. The COS-AT will enhance the ability to conduct meaningful meta-analyses in the future, providing a more robust foundation for advancing our understanding of interventions for AT. The adequate evaluation and comparison of interventions will facilitate

Table 3 Summary of the results of the second round Delphi survey

		Should this measurement instrument be part of the core outcome set for Achilles tendinopathy?			
Outcome measurement instrument	**Domain**	**Yes (%)**	**No (%)**	**Unsure (%)**	**Endorsement**
A 6-point Likert scale	Patient overall rating	9 (31)	16 (55.2)	4 (13.8)	Inconclusive
Global Ratings of Change Scale	Patient overall rating	14 (48.3)	13 (44.8)	2 (6.9)	Inconclusive
Clinical Global Impression	Patient overall rating	19 (65.5)	7 (24.1)	3 (10.4)	Inconclusive
Patient Global Impression of Change Scale	Patient overall rating	9 (31)	17 (58.6)	3 (10.4)	Inconclusive
Perception of Treatment Effectiveness	Patient overall rating	11 (37.9)	14 (48.3)	4 (13.8)	Inconclusive
Perceived improvement	Patient overall rating	5 (17.2)	20 (69)	4 (13.8)	Inconclusive
Return to sports	Participation	18 (62.1)	7 (24.1)	4 (13.8)	Inconclusive
Time to return to preinjury levels	Participation	18 (62.1)	9 (31)	2 (6.9)	Inconclusive
A 100 mm Visual Analogue Scale (VAS)	Pain on activity/loading	20 (69)	6 (20.6)	3 (10.4)	Inconclusive
A VAS from 0 to 10	Pain on activity/loading	20 (69)	6 (20.6)	3 (10.4)	Inconclusive
Evaluating pain after activity using a VAS (0–10)	Pain on activity/loading	21 (72.4)	6 (20.7)	2 (6.9)	Endorsed
Single-leg heel rise test	Physical function capacity	22 (75.9)	4 (13.8)	3 (10.4)	Endorsed
Single Hop Test	Physical function capacity	17 (58.6)	8 (27.6)	4 (13.8)	Inconclusive
Gastrocnemius and soleus flexibility	Physical function capacity	13 (44.8)	13 (44.8)	3 (10.4)	Inconclusive
VISA-A questionnaire	Disability	25 (86.2)	0	4 (13.8)	Endorsed
Foot Function Index	Disability	8 (27.6)	18 (62.1)	3 (10.3)	Inconclusive
Pain first thing in the morning (VAS 0–100)	Pain over a specified time frame	15 (51.7)	9 (31)	5 (17.3)	Inconclusive
Morning stiffness severity (VAS 0–100)	Pain over a specified time frame	17 (58.6)	9 (31)	3 (10.4)	Inconclusive
Location of pain	Pain over a specified time frame	19 (65.5)	10 (34.5)	0	Inconclusive
Measuring full range of motion of the ankle	Range of motion	10 (34.5)	16 (55.2)	3 (10.3)	Inconclusive
Use of cointerventions	Other	19 (65.5)	8 (27.6)	2 (6.9)	Inconclusive
Adherence	Other	18 (62.1)	9 (31)	2 (6.9)	Inconclusive

VISA-A, Victorian Institute of Sports Assessment-Achilles.

evidence-based decision-making for professional participants in the future. This could lead to more effective and personalised treatment strategies, ultimately improving patient care and outcomes. It is strongly recommended that the selected COS-AT will be used in future research, although this does not preclude the use of other outcome measurement instruments. For example, if an intervention is aimed to improve or evaluate psychosocial factors in AT patients it is still appropriate to include an outcome measurement instrument that covers this specific domain (along with the COS-AT).

It is crucial to recognise that the implementation of the COS-AT may face certain barriers. Researchers and clinicians accustomed to using a variety of outcome measurement instruments may require time to adapt to this standardised approach.[20 21] Lack of awareness and familiarity of the recommended COS-AT could also potentially form a barrier to effective implementation.[22] Another barrier might be that other more general health-related outcome measurement instruments are considered important in specific clinical settings. Adding disease-specific outcome measurement

Table 4 Endorsed outcome measurement instruments for the core outcome set for Achilles tendinopathy

Outcome measurement instrument	**Domain**	**Endorsement (rate of agreement)**	**Methodological measurement properties (quality of data)**
VISA-A questionnaire	Disability	Endorsed in second Delphi round (86%)	**Moderate** More research is needed on responsiveness and clinical trial discrimination.
Single-leg heel rise test*	Physical function capacity	Endorsed in second Delphi round (76%)	**Low/limited** More research is needed on construct validity, test–retest reliability, responsiveness, clinical trial discrimination and thresholds of meaning
Evaluating pain after activity using a VAS (0–10)	Pain on activity/loading	Endorsed in second Delphi round (72%)	**Low/limited** More research is needed on construct validity, test–retest reliability, responsiveness, clinical trial discrimination and thresholds of meaning.
Evaluating pain during activity/loading using a VAS (0–10)	Pain on activity/loading	Endorsed after in-person consensus meeting (75%)	**Low/limited** More research is needed on construct validity, test–retest reliability, responsiveness, clinical trial discrimination and thresholds of meaning.

*Testing calf muscle strength by asking the patient to perform a maximum number of single leg heel raises. (Unable/able, number of heel raises, work (joule), cm above the ground (measured from the heel)).
VAS, Visual Analog Scale; VISA-A, Victorian Institute of Sports Assessment-Achilles;

Feature box

The International Scientific Tendinopathy Symposium Consensus (ICON) group Achilles recommends that:

⇒ Clinical trials should include the agreed core outcome set for Achilles tendinopathy (COS-AT) as a minimum so that future meta-analyses will be able to better estimate treatment effects.

⇒ This COS-AT should be used alongside clinical trial reporting guidelines (eg, CONSORT and ICON PART-T) in reporting clinical trials.

⇒ Further evaluation of the COS-AT measurement instrument measurement properties is warranted—for example, for validity, reliability, responsiveness and feasibility—as recommended in the OMERACT and COnsensus-based Standards for the selection of health Measurement Instruments guidelines.

⇒ New outcome measurement instruments should be further developed covering the core domains of patient overall rating, participation, function, quality of life, psychology and pain over a specified time frame.

⇒ The COS-AT represents the minimal reporting requirement but should not prevent the use of other outcome measurement instruments in trials or clinical practice.

instruments to this set might not be feasible. To facilitate effective implementation of the COS-AT, researchers and clinicians need to be informed about the benefits of the COS-AT and why they are relevant to patients.[21] Another facilitator of implementation of the COS-AT is the use of an international panel with both professional participants and patients in the consensus process.[20 21] It should be noted that the exclusion of an outcome measurement instrument from the COS-AT does not diminish their relevance. Such measures can still be important in the clinical setting of individual healthcare providers or patients and adding other (disease) specific items may be context-driven decisions (eg, using an outcome measure to assess psychological factors in a trial on the effectiveness of a psychological intervention for AT).

Strengths and limitations

A strength of the consensus process for selecting the COS-AT is that we prospectively registered the protocol and engaged a diverse group of participants, with various professions and nationalities, each possessing expertise in providing healthcare or performing research within the field of tendinopathy. We used Expertscape to identify professional participants, which may not fully capture the diversity of clinical experiences and perspectives, particularly from pure clinicians. However, a majority of the professional participants reported regularly seeing patients with tendinopathy, ensuring a strong clinical focus within the panel. It is important to acknowledge that there was limited representation of professional participants and patients from regions other than the UK, USA, Australia and Europe and only 1 patient and 11 professional participants were present at the final consensus meeting. This consensus meeting was the main phase where dissenting opinions (as described in the notes during the final meeting) could be discussed. Due to the limited representation, dissenting opinions might not have been fully captured. However, our participant pool for both surveys comprised a representative sample, with more than 10 patients having AT and more than 30 health professionals. We did not collect detailed information on patients' pain, disability and physical activity levels to avoid questionnaire fatigue, which may affect the representativeness of the patient sample. While there are no specific OMERACT criteria for the attendance rate of an in-person meeting, we feel this is a limitation of this process, due to the international nature of the design and the planned meeting during a specific conference. Next to this it, may have been a challenging place for the only patient participant to speak out, although we made several efforts to lower this barrier (eg, sufficient time for translation, checking their understanding via the translator and directly asking for his thoughts on the outcome measures). In the future, a larger and more representative panel of patients could be included in this last step by performing an online meeting. While we did not choose this because of the limitations of online meetings (loss of non-verbal communication, technical issues, reduced engagement, time zone challenges and impersonal interaction), this should be reconsidered when the COS-AT is updated. However, the majority of the endorsed COS-AT was already established in step 4 of the process by 29 experts (12 patients). One additional outcome measurement instrument was added after discussion during the in-person meeting. This collective effort ensures that the resulting COS-AT contains outcome measurement instruments holding genuine significance for patients with AT. Additionally, the consensus process was carried out without external funding influence. This independence strengthens the integrity of our COS-AT development. The prospective registration of the protocol is also a strength of this consensus process.

There were several limitations in the development of the COS-AT. One notable challenge was the limited or low-quality evidence for many of the identified outcome measurement instruments. This may introduce uncertainty in the reliability and validity of the selected COS components. For example, the VISA-A has been criticised in terms of its measurement properties.[23 24] This might not be clearly noticeable in the quality assessment table (online supplemental file 4) we used in the process. This table was based on the OMERACT guidelines, and as a result, structural validity and cross-cultural adaptation were not assessed while COSMIN guidelines include these as part of construct validity. Especially regarding structural validity, most studies did not determine this aspect of validity and when it was reported, it was not done using a unidimensional structure. This could implicate that the quality of the endorsed COS-AT is actually lower when assessed using the COSMIN guidelines. The ongoing inclusion of the VISA-A in the COS-AT (as for any other outcome measure) should be considered against those reviews, and in light of further evaluation of its measurement properties. However, a notable strength of the VISA-A is that it has been cross-culturally adapted and validated in a broad spectrum of languages.[25–31] Another reason why it is currently useful to include the VISA-A questionnaire (as well as VAS related to loading) in the COS-AT is the fact that most previous clinical studies used these outcome measurement instruments.[5 7 8] With the aim of improving the ability to synthesise data for meta-analyses in the future, it is likely of benefit that future clinical trials can also be statistically compared against previous ones. An additional limitation is

that notes were made by a single person during the in-person meeting. Recording and qualitatively analysing and reporting the discussion may have reduced this source of bias.

Another possible limitation is that we have not included recently developed outcome measurement instruments—as our evidence search census date was March 2021. For example, the TENDINopathy Severity Assessment–Achilles (TENDINS-A) has been recently developed from interviews with patients and clinicians having adequate content validity,[32] as well as excellent reliability and structural validity.[33] The VISA-A has also been recently developed for sedentary individuals and might be included in the future.[34] Our scan of the literature since the census date has not identified any other outcome measurement instruments that would have likely changed the outcome of our COS-AT. When new measurement instruments become available the COS-AT will need to be reviewed and if deemed appropriate it would need a revision with the current COS-AT as foundation.

What comes next?

Future research should focus on evaluating the measurement properties of specific outcome measurement instruments, which have limited evidence but were included in the COS-AT. Furthermore, the COS-AT currently does not cover several core domains in tendinopathy, including patient overall rating, participation, function, psychological factors, quality of life and pain over a specific time frame.[7] Future research should focus on assessing the reliability and validity of outcome measurement instruments within these core domains or to develop new instruments. Measurement properties of recently developed outcome measures (such as the VISA-A sedentary[34] or TENDINS-A)[32] should also be evaluated, and these measures should be validated cross-culturally to determine their potential inclusion in the COS-AT. Valid imaging outcomes could be developed for use alongside the COS-AT but were not included in this process as imaging was not included as core domain. The COS-AT should be updated in the future to potentially include new measures and incorporate the latest methodological evidence.

Knowledge dissemination plays a crucial role in ensuring the widespread adoption of the COS-AT within research and clinical practice.[35] Efforts should be directed towards effectively communicating the importance of this COS-AT, hereby enhancing its integration into clinical practice guidelines, and facilitating its use in future clinical trials. Continuous engagement with relevant stakeholders, such as professional participants and patients, is important to ensure that the COS-AT will be used widely, ultimately advancing the standardisation and quality of care for individuals with AT.

CONCLUSION

This is the first extensive five-step process to develop a COS for AT (COS-AT). The COS for clinical trials of AT consists of four outcome measurement instruments that are (1) the VISA-A questionnaire, (2) the single-leg heel rise test, (3) evaluating pain after activity using a VAS (0–10) and (4) evaluating pain during activity/loading using a VAS (0–10). Patients and professional participants agreed on these four outcome measurement instruments to be part of the COS-AT.

While the selected COS-AT provides a structured approach for evaluating interventions for AT, it is important to acknowledge the current limitations in the measurement properties of these instruments. It is recommended that the selected COS-AT will be used as a minimum reporting requirement in future clinical trials evaluating the effectiveness of an intervention for AT. Researchers should remain open to incorporating additional or alternative outcome measurement instruments as new evidence and tools become available. Using the COS-AT in conjunction with emerging outcome measures could help to build a comprehensive evidence base to ultimately improve future patient care for patients with AT.

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