

Core Domain Set for Tendinopathy: health domains.

Please read the following information (including ethics statement).

Project Title: Core Domain Set for Tendinopathy: an online survey and a consensus meeting.

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You are being asked to provide your response to a series of statements that concern health related domains for tendon problems. These domains when pieced together describe the impact of the condition on the individual and society as well as the underlying biology. The aim of this project is to develop a core set of domains for tendinopathy. You will respond with a Yes (agree), No (not agree), or Unsure/I do not know to a statement that will be put like this: 'Is the domain "pain" important enough to be included in a core domain set for tendinopathy?' ("pain" is an example of a number of domains that will be framed in this way in a number of statements, others are for example, activity, function, strength, ultrasound image, fear of pain, catastrophize, depression, etc). The survey will also ask if you would like to add domains or aggregate them (i.e., combine/collapse into fewer). At each statement, there is a space for you to type in your reasons for your choice and to add anything else you feel is important. We encourage you to provide as much detail as you feel important.

Your responses to these statements and your comments will be collated and provided to all participants for feedback and for discussion at the consensus meeting that will follow. At that meeting, if you are able to attend, any of the statements that did not reach at least 70% agreement (defined as: Yes (agree) was selected by more than 69% of participants) will be further discussed and there will be a second round of voting (Yes (agree) or No (not agree)). Also at that meeting, any additional domains or aggregating of domains will be discussed and voted upon. Critically, at that meeting, if you attend, you will also have the option of opting out of the process.

What are the risks of participating? There are no foreseeable risks or discomfort associated with providing the required information on the survey or with the discussions and voting at the meeting, should you attend the meeting.

Your rights as a participant: You are free to withdraw from the study at any time without providing a reason and without jeopardizing any ongoing contact with the investigators. All information provided by you and the data collected from you will be treated with utmost confidentiality and the data will be reported in a manner that does not identify your responses. You will be provided the final report on completion of the study.

University of Queensland Ethical Clearance: This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with Prof Bill Vicenzino (details above), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator: phone (3365 3924) or email (humanethics@research.uq.edu.au).

* 1. After reading the above information, select agree or disagree to participate in this survey:

- Agree / Consent
- Disagree / Not consent

Time Required to Complete Survey.

Depending on your responses to some items, there are 28 domain set items for you to consider, which will likely take at least 30 minutes to complete. The exact time is difficult to predict as it will depend on how many comments you leave at each item.

You do have the option of doing the survey in a number of parts, so that you can spread out responding to the survey over the two weeks that the survey will be open (close date: 18th August). The following points are important to understand about the survey tool being used:

- (a) When you reach and select (click on the) 'next' button, that will save the items you have responded to thus far. So the items between each 'next' button will be saved. So the 'next' button acts a bit like a save option.
- (b) When you reach and select (click on the) 'done' button, that will save and close your access to the entire survey. That is, you will not be able to return to it at that stage.
- (c) You will only be able to return to your survey by using the same device and web browser. That is, you will not be able to access the survey from a different device than that you first started completing (and clicked on the first 'next' button). The same applies for the web browser.
- (d) Only select one of the answer options (otherwise you will be directed back to the multiply selected items once you click on the next at the bottom of the page).

As a patient who has or have had tendon problems, your involvement in the survey is very important in the improvement of our understanding of tendon problems (also called tendinopathy, tendonitis, tendinosis and a range of other terms depending on the body region involved). Please provide as much information as you deem important and appropriate so that we understand what you feel and think is important about tendon problems. We will synthesize your comments and use them to guide our follow up meeting(s), before we publish a report.

Please contact Bill Vicenzino if you have any issues with completing the survey (b.vicenzino@uq.edu.au), using the email in which you received the link to this survey.

* 2. I agree to completing the survey within the next 10 days.

- Agree
- Disagree / I wish not to complete this survey

Core Domain Set for Tendinopathy: health domains.

A brief overview of the process:

Should you wish to have further information, please contact Bill Vicenzino via:

b.vicenzino@uq.edu.au

Remember that the main aim of this survey and any follow up meeting is to develop a core domain set for tendon problems (called tendinopathy herein). A tendinopathy domain set is a conceptual set of health areas that are impacted by the tendon problem. These domains when pieced together describe the impact of the condition on the individual and society as well as the underlying biology. The following text describes the process we are using to develop the core set. Please feel free to contact Bill Vicenzino on b.vicenzino@uq.edu.au (use subject: 'Core Domain Set - Patient' in your email please).

In preparation for this survey, we conducted a systematic review of publications of randomised clinical/control trials for tendinopathy in Pubmed over the past 2 decades. 122 randomised clinical trials were identified and potential domains for this Delphi consensus process were extracted and tabulated. The numbers of studies reporting each domain (expressed as a %) as well as some examples of the types of outcome measures used for each of these domains are provided with each question in this survey. This information is provided as context, to assist in your considerations of each domain. The outcomes that are provided are what has been reported - please remember their inclusion is not a validation of their veracity as an outcome measure for tendinopathy.

Please note that the domain set we are striving for is one that:

- (a) contains generic health domains that will be used across all tendons;
- (b) is the minimal recommended set;
- (c) will be reviewed at a time to be agreed (recommendation: approximately 10 years, or as new information comes to light);
- (d) will serve as the basis to formulate a Core Outcome Set for Tendinopathy (see following).

The next stage after we agree upon a Core Domain Set for Tendinopathy will be:

- (a) To establish tendon-specific interest groups that will work on reviewing the evidence (systematically) on relevant outcome measures, including evaluating the validity and feasibility of these measures.
- (b) To undertake a Delphi process (survey and consensus meeting post-Groningen) on the basis of the findings from (a) so as to agree upon a set of outcome measures that will be recommended for use in future clinical trials, cohort studies and eventually clinical practice.
- (c) To ideally establish these tendon-specific interest groups at Groningen ISTS meeting, so that they can work on outcome measures for the following ISTS meeting.

The OMERACT Handbook was used as a basis for this process, and is a good resource should you wish to further contribute to the process (Boers et al (2016) The OMERACT Handbook: Available from: <http://www.omeract.org/pdf>.)

Core Domain Set for Tendinopathy: health domains.

* 3. Is the domain 'Disability*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 75 papers (122; 62%).

**The types of outcome measures that are used by authors for this domain are: (a) all patient rated (completed by the patient); (b) ask a series of questions about how the tendon problem affects a range of activities (e.g., day to day activities, sport, recreation) to score disability (or the limits to function/doing things); and (c) give one number to represent the patient's problem. Some of the measures that are used are VISA-A,-P,-G; Disability of the Arm, Shoulder and Hand (DASH and quickDASH); Patient Rated Tennis Elbow Evaluation (PRTEE); Foot and Ankle Outcome Score (FAOS); Western Ontario and McMaster University OA Index (WOMAC); Roles Maudsley Score.*

Only select one option

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 4. Is the domain 'Pain on Activity or Loading*' important enough to be included in a core domain set for tendinopathy? This domain was reported on 60 occasions in 45 papers (37%), as some authors used multiple loading tests (e.g.; often the hop, jump and squat).

**The types of outcome measures used by authors for this domain were usually a 10cm line (Visual Analogue Scale) and a 11 point Numerical Rating Scales (0 to 10) by which the participant (patients or controls) reported the level of pain on certain tasks that are known to aggravate tendons. Some example of tasks are hopping, jumping, squatting, gripping, lifting.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 5. Is the domain 'patient perception of condition status*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 37 papers (30 %).

**Two examples of the types of outcome measures reported by authors were: global rating of change (e.g., are you better, same or worse than immediately before treatment), and patient perception of status of condition (e.g., is your current condition satisfactory, when you take your general functioning and current pain into consideration).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 6. Is the domain 'structure*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 36 papers (30 %), as 51 different measures or 42% of all domains extracted.

**The types of outcome measures reported were: MRI, US (grey scale, Doppler), and Xray.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 7. Is the domain 'Pain', without any further specification*, important enough to be included in a core domain set for tendinopathy? This domain was reported in 36 papers (30 %).

**The unique feature of this domain (Pain) is that the authors only state they reported pain of the participants. That is, they did not specify if it was under loading (e.g., activity, hop or walk) or specific circumstances (e.g., first step) or in a particular time frame or at a specific time (e.g., morning). So this item in this survey is asking you to consider if pain should be further specified, as in some of the other items in this survey.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 8. Is the domain 'Clinical examination findings', reported as a composite (combination) of a number of different clinical tests*, important enough to be included in a core domain set for tendinopathy? This domain was reported in 28 papers (/122; 23%).

**This domain covers measures that report a single number/score for a combination of clinical tests (e.g., combine the test results of range of motion, strength, palpation into one score). Some examples of these measures/scores are: University of California-Los Angeles (UCLA); Constant score; Liverpool elbow score.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 9. Is the domain 'Pain over 24 hours' important enough to be included in a core domain set for tendinopathy? This domain was reported in 23 papers (19 %).

**The measures used here include asking the participant (patients or controls) to rate their pain over a specified time frame(s) (e.g., last week, last 24 hours, in the morning, at night) on a 10cm line (Visual Analogue Scale) or out of 10 (Numerical Rating Scale).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 10. Is the domain 'Quality of Life*' important enough to be included in a core domain set for tendinopathy? This domain was reported by 21 authors (17%).

**The types of outcome measures reported: EQ-5D, AQoL, SF-36, international Hip Outcome Tool (iHOT-33), SF-36, Western Ontario Rotator Cuff Index (WORC), Foot & Ankle Outcome Score (FAOS).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

- * 11. Is the domain 'strength*' important enough to be included in a core domain set for tendinopathy?
This domain was reported in 19 papers (16 %).

**Strength being measured by an instrument such as: a dynamometers or force transducers.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 12. Is the domain 'range of motion*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 19 papers (16%).

**This was usually measured with a special instrument (goniometer, inclinometer, or dynamometer), but also visually in a few reports. Note that this is a sole domain here. In another domain ('clinical examination findings') it is included in a combined score.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

Core Domain Set for Tendinopathy: health domains (continued).

* 13. Is the domain 'palpation* (pain or tenderness)' important enough to be included in a core domain set for tendinopathy? This domain was reported in 11 papers (9 %).

**The clinician presses on the tendon with a thumb or finger and elicits pain (or not in controls) and the participant (patient or control) reports this pain or tenderness in a variety of ways (e.g., on a 10cm line, out of a 11 point rating scale (0 to 10), bespoke nominal/ordinal scales, or in some cases not stated in the paper).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 14. Is the domain 'Pain elicited with clinician applied stress test*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 9 papers (7 %).

**Clinicians applied a special stress or orthopaedic test and the participant (patient or control) report the intensity of pain they feel on a 10cm line or 11 point scale. This is not the participant doing the test as would be the case when they hop or jump or squat in the domain item 'pain on activity or loading' above.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 15. Is the domain 'adverse effects/events*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 9 papers (7 %).

*Adverse effects/events are any event that occurs to the participant (patient or control) while in the study (or being followed clinically). They need not be related to a treatment for the tendinopathy or to the study in particular, but just any event that is adverse to the health of the individual.

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 16. Is the domain 'economic impact: costs*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 4 papers (3 %).

**This is usually measured from medical/health records, questionnaires, diaries, or interviews.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 17. Is the domain 'sensory-modality specific pain*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 8 papers (7 %).

**The amount of a stimulus (such as pressure, heat, cold) that elicits pain is measured with an instrument (an algometer) for this domain. So it is not the level of pain that is the focus but how much stimulus elicits the pain, and the stimulus is a sensory one.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 18. Is the domain 'function*' important enough to be included in a core domain set for tendinopathy?
This domain was reported in 8 papers (7 %).

**This domain is specifically about the participant rating their level of function in one score (e.g., Patient Specific Function Scale, wherein 100% is full function and 0% is unable to use the limb such as in a sling for the arm and not weight bearing on a leg). It does not ask about the pain, just about the function.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 19. Is the domain 'physical function*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 6 papers (5 %).

**The types of measures used for this domain were: distance jumped, height hopped, number of single heel raises. That is, how much of a task the participant (patient or control) was willing to perform.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 20. Is the domain 'psychological impact*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 3 papers (2.5 %), accounting for 5% of all domains extracted.

**The types of outcome measures were: pain catastrophizing scale, pain self efficacy, anxiety and depression scales .*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 21. Is the domain 'sport participation*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 3 papers (2.5 %).

**The sorts of measures used here were: the time to return to sport, the level of sport achieved, and a range of different scales of participation in sport (e.g., social or elite level).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 22. Is the domain 'medication use' important enough to be included in a core domain set for tendinopathy? This domain was reported in 3 papers (2.5 %).

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 23. Is the domain 'work participation*' important enough to be included in a core domain set for tendinopathy? This domain was reported in 2 papers (2 %).

**This domain relates to things like how long to return to work, the level of work (how strenuous for the particular tendon).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 24. Is the domain 'physical activity*' important enough to be included in a core domain set for tendinopathy? This domain was reported in at least 5 papers (4%).

**This is about the participant (patient or control) rating overall physical activity regardless of pain or the tendinopathy.*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 25. Is the domain 'participation*' important enough to be included in a core domain set for tendinopathy?
This domain was reported in 1 paper, but it had 4 scales (3% of all scales).

**This was measured by asking participants (patients and controls) what their level of activity was with family and at home, recreation, running or other physical activity, and social activities, using a 10cm line (0cm = no limitation, 100cm = complete limitation).*

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

* 26. Is the domain 'discontinue treatment (drop out)*' important enough to be included in a core domain set for tendinopathy?

This was not extracted from the reviewed reports and is included here for consideration.

Yes / Agree

Unsure / I do not know

No / Disagree

Please provide your reason(s) for your response:

Core Domain Set for Tendinopathy: health domains.

This a list of the domains that you have thus far considered in this survey are:

Disability
Pain on activity/loading
Patient perception of condition status
Structure
Pain without context specified
Clinician examination findings as a combined score
Pain over a 24 hour period
Quality of life
Strength (muscle)
Range of motion
Palpation
Pain with clinician applied stress
Adverse effects
Economic impact
Sensory modality tests
Function
Physical Function
Psychological impact
Sport participation
Medication use
Work participation
Physical activity level
Participation (life)
Discontinue treatment

* 27. Are there any other domains that you consider important enough to be included in a core domain set for tendinopathy?

Yes

Unsure / I do not know

No

Please provide your reason(s) for your response, particularly if you consider domain(s) should be included:

* 28. Are there any domains that you consider are NOT important enough to be included in a core domain set for tendinopathy? That is, they should be removed from this list of domains.

Yes

Unsure / I do not know

No

Please provide your reason(s) for your response, particularly if you consider domain(s) should be included:

* 29. Should any of the domains listed above be aggregated (combined into one or fewer domains) before being included in a core domain set for tendinopathy?

Yes

Unsure / I do not know

No

Please provide your reason(s) for your response, particularly which domain(s) should be aggregated:

* 30. Should any of the domains listed above be further split up or divided into two or more domains before being included in a core domain set for tendinopathy?

Yes

Unsure / I do not know

No

Please provide your reason(s) for your response, particularly which domain(s) should be aggregated:

Please provide the following details

This will enable a good description of the group who established the Core Domain Set for Tendinopathy. It will not identify you as an individual in any reporting.

* 31. What is your sex?

Female

Male

* 32. What is your current age in years?

* 33. Select which of the following best describes your role in the field of tendinopathy:

Clinician only

Clinician and Researcher

Researcher/Scientist only

Neither a clinician nor a researcher/scientist (e.g., you are a patient participant)

Other (please specify)

* 34. On average, how many cases of tendinopathy would you see in a normal month?

None (I am a patient participant and do not treat or research tendinopathy)

Between 5 and 10

None, but I am a clinician or scientist

Between 11 and 15

At least 4

More than 16

Other (please specify)

* 35. How many years of experience have you in managing tendon problems?

None (I am a patient participant and do not treat or research tendinopathy)

Between 5 and 10 years

None, but I am a clinician or scientist

Between 11 and 15 years

At least 4 years

More than 16 years

Other (please specify)

* 36. What is your health care profession (e.g., sports physician, physiotherapist, rheumatologist, surgeon)? Type NA if you are a patient participant and not a health care practitioner.

37. What is your highest level of academic qualification?

Undergraduate Diploma/Certificate

PhD

Bachelor

Clinical Doctorate

Master

None of these

Other (please specify, e.g., if you have a medical speciality or another degree)

* 38. Do you currently have a tendon problem?

Yes

No

This space is for you to provide more detail:

* 39. Have you had a tendinopathy in the past (that is not currently a problem)?

Yes

No

This space is for you to provide more detail:

* 40. Which country do you work in?

* 41. Which country do you live in?

Thank you for making the effort to contribute to this process.

One or two more questions and you are done...

42. Please leave any further comments or detail you would like to provide for this process:

Many thanks for taking the time to complete this survey. A report of the data from this survey will be available early in September for your comment/consideration.

Professor Bill Vicenzino

on behalf of the committee:

Dr Ebonie Rio

Dr Sean McAuliffe

Dr Adam Weir

Professor Alexander Scott

Professor Johannes (Hans) Zwerver (Chair)