

BMJ Open Progression criteria in loading exercise programmes in lower limb tendinopathy: a protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Lower limb tendinopathies have high rates of incidence and prevalence. Their symptomatology affects the functional capacity of people to exercise and work, being an important cause of economic and social burden. The evidence from the last decades points to therapeutic exercise as the first-line treatment in tendinopathies due to its good short-term and long-term clinical outcomes. However, there is no consensus about how the load progression should be managed throughout the therapeutic exercise programmes.

Methods and analysis This systematic review will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The present protocol has been registered in the International Prospective Register of Systematic Reviews (PROSPERO). The search will be performed through PubMed and Scopus by two reviewers, including references, from inception to 31 August 2019. It will include randomised controlled trials that: included patients with Achilles, patellar or gluteal tendinopathy; assessed pain, function or performance; and included at least one group where progressive physical exercise was administered as monotherapy. The quality of the studies included will be assessed using the Physiotherapy Evidence Database scale. The Grading of Recommendations, Assessment, Development and Evaluation Working Group approach will be used to assess the quality of the evidence. A meta-analysis will be performed if there is sufficient homogeneity across the interventions and outcomes measures to ensure pooling.

Ethics and dissemination Ethical approval is not necessary for this systematic review protocol. Regardless of its nature, the results obtained in this study will be published in a peer-reviewed journal and presented at a relevant conference.

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BACKGROUND

Lower limb tendinopathies have a general incidence and prevalence of 11.83 and 10.52 cases per 1000 person-years, respectively.¹ In the case of sports, prevalence rates increase up to 45% in patellar tendinopathy in elite male volleyball players.² Therefore, the high rates of prevalence and persistence have an

Strengths and limitations of this study

- This systematic review is anticipated to be the first systematic review that expressly and comprehensively identifies, assesses and summarises the evidence regarding load progression criteria in lower limb tendinopathy.
- This systematic review protocol has been designed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols guidelines.
- The participation of a third independent reviewer in case of disagreements will reduce the risk of observer bias.
- A possible limitation of this systematic review may be the non-inclusion of studies in which the effect of exercise programmes was studied without a control group.
- Some heterogeneity is expected in the design of the included studies that could make quantitative analysis difficult.

impact on the functional capacity to exercise and work, causing an economic and social burden.

Regarding management, traditional passive treatments, such as corticosteroids injections,^{3 4} transverse friction⁵ or therapeutic ultrasound,⁵ have shown short-term effects in some cases but have not been maintained in long-term follow-up. Other passive therapies, such as heel brace,⁶ shockwave^{7 8} or platelet-rich plasma,⁹ are usually assessed in a combined treatment with exercise but there exists a lack of evidence in studies where these modalities of treatment work as monotherapy.

On the opposite side, the evidence from the last three decades points to therapeutic exercise as the first-line treatment in tendinopathies due to its good short-term and long-term clinical outcomes and the non-existence of adverse effects.^{3-5 10} In this regard, different modalities of therapeutic exercise, such as



isolated eccentric, combined eccentric and concentric, isometric or heavy slow resistance training, had shown positive outcomes on pain and function when controlled with placebo,¹¹ surgery,¹² passive treatment⁵ or other modalities of exercise groups.^{13 14}

In the context of the pathological model of the tendinopathy proposed by Cook and Purdam,¹⁵ tendon pathology is considered as a bidirectional continuum and divided into three theoretical stages: reactive tendinopathy, tendon dysrepair and degenerative tendinopathy. In this model, adding or removing load would be the primary stimulus that would produce an advance or retreat within the continuum. From this approach, it is necessary to correctly handle the progression of the load for an appropriate progress within the continuum. Different methods have been used for this purpose by clinicians and researchers. However, there are no clear objective criteria for how this progression should be managed throughout the therapeutic exercise programmes.

Some authors have considered that a high risk of injury in athletes is more related to an inappropriate monitoring and progression of the load than to the use of high loads.¹⁶ In this regard, the use of the 10% rule is widespread among those who prescribe or practice exercise in the field of sports medicine or physical training. This rule suggests that an increase above 10% compared with the previous week's load would considerably increase the risk of suffering an injury while lower increments of the load would be safer. However, the current evidence is insufficient to make this claim. While in team sports, such as rugby, increases greater than 10%, and above all, 50%, significantly increased the risk of injury,¹⁶ in beginning runners, it seems that although an increase of 30% of the load does considerably increase the risk of injury, an increase of 20%–25% was well-tolerated.¹⁷ In any case, we must interpret this method as a guide and not as a rule, differentiating the context and the level of preparation of the subject, and look for other, more objective methods and criteria.

Another commonly used load progression criterion is the pain intensity measured with a numerical rating scale. Most of the protocols traditionally used in tendinopathies, such as those based on the models proposed by Alfredson *et al*,¹⁸ Stanish *et al*,¹⁹ or Silbernagel *et al*,²⁰ use pain or discomfort during exercises to determine the load. The Alfredson's protocol describes the need to gradually increase the load through external weights when pain or discomfort during execution diminishes.¹⁸ The Stanish's protocol indicates that the appropriate load should be such that pain, or discomfort, is experienced in the last set of 10 repetitions.¹⁹ In the same way, in the Silbernagel's protocol, pain is allowed to reach 5 on the visual analogue scale.²⁰ Although changes in rating pain scales have been analysed and related to their clinical importance in some studies,²¹ there is a lack of evidence about their relationship with optimal load levels in exercise programmes. A variation in the training volume throughout the weeks, using

temporary stages, has also been used in some exercise programmes.

Many studies have compared the effectiveness of different exercise programmes on tendinopathies. In the same way, several studies have analysed the effect of different symptom management strategies in similar exercise programmes (eg, pain allowed or not allowed during exercises performing).^{22 23} Additionally, a recent narrative review about tendinopathy has analysed different issues, such as pathoetiology, risk factors, prevention, diagnosis or management.²⁴ Nevertheless, the choice of one of the existing load progression criteria as the most appropriate is controversial since the studies are usually focused on comparing different types of exercise and not different progression criteria, requiring an additional analysis of this topic.

In an effort to reduce the heterogeneity, this review will only focus on the three predominant tendinopathies of the lower extremities (Achilles, patellar and gluteal). In these tendinopathies, despite the differences in their anatomy and diagnosis, there seem to be many similarities in the approach to their treatment by exercise.

Thus, the aim of this systematic review will be to summarise and analyse the existing literature about what criteria of progression are used in loading exercise programmes in the tendinopathies of the lower extremities and its effectiveness.

METHODS

This systematic review will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.²⁵ The present protocol has been registered in the International Prospective Register of Systematic Reviews.

Eligibility criteria

Those randomised clinical trials that meet the following selection criteria will be included:

- Participants: Subjects with patellar, midportion Achilles (studies where the location of the painful area was not specified or where both locations were analysed as a whole will be included, considering the predominant incidence of non-insertional Achilles tendinopathies) or gluteal tendinopathy; aged at least 16 years.
- Interventions: Progressive exercise programmes, at least one group where physical exercise was administered as monotherapy. Physical exercise has been defined as a subcategory of physical activity consisting of planned, structured and repetitive movement performed with the purpose of the improvement or maintenance of physical performance or health.²⁶ Thus, any voluntary action of the neuromuscular system will be considered as physical exercise, including: aerobic exercise; strengthening exercise; plyometrics; active, self-assisted or guided-imagery exercise; active, passive or self-assisted stretching exercises; other similar forms of exercise; or a combination of these.

- c. Control interventions: No-intervention, sham or other experimental groups.
- d. Outcomes: Studies where, at least, pain, function or performance outcomes are measured.
- e. No date or language restrictions will be applied.

Exclusion criteria: (a) studies including subjects with previous tendon surgical treatment and (b) studies in which the exercise was not applied as monotherapy in any of the groups or where the control group conducted a supplemented modality of the exercise performed in the intervention group.

Data sources and searches

Two reviewers will search PubMed and Scopus databases, including references, from inception to 31 August 2019. The following search term combinations will be used: ('patellar tendin*' OR 'jumper's knee' OR 'lander's knee' OR 'Achilles tendin*' OR 'midportion Achilles tendin*' OR 'gluteal tendin*' OR 'greater trochanteric bursitis' OR 'greater trochanteric pain syndrome' OR 'lower limb tendinopathy' OR 'tendinopathy') AND ('exercise' OR 'strength' OR 'training' OR 'resistance' OR 'loading' OR 'progressive' OR 'physical activity' OR 'eccentric'). Search will be extended to 'title, keywords and abstract' in Scopus, while it will be extended to 'all fields' in PubMed to expand the possibilities of finding potentially includable articles that are badly indexed. Online supplementary file has available extended information about the searches that will be executed in both search engines. Additionally, a manual search in the references of different articles will be performed by one reviewer searching for studies that could have been left out of the general search or that were not indexed in the databases used. All references will be imported into Mendeley Reference Manager and duplicates will be removed.

Study selection

After eliminating duplicates, search results will be screened by title and abstract by two independent authors. When the information available in the title and abstract is not sufficient to decide, the researchers will retrieve the full-text. The full-text of these potentially eligible studies will be independently screened by two reviewers to identify those that potentially meet the inclusion criteria outlined in section Eligibility criteria. Any disagreement between them over the eligibility of particular studies will be resolved through discussion with a third reviewer.

Outcomes

To achieve the stated objective, the primary outcome of this systematic review will be load progression criteria.

The secondary outcomes will be clinical outcomes, such as the Victorian Institute of Sport Assessment (VISA) questionnaire (VISA-A, VISA-P and VISA-G for Achilles, patellar and gluteal tendinopathies, respectively) and pain measured with scales or questionnaires, and performance outcomes, such as strength or jumping tests.

Data extraction and quality assessment

For the data extraction, full-text of the included studies will be retrieved and independently assessed by two reviewers. An extraction form will be used to obtain data from the selected studies for assessment of study quality and evidence synthesis. Extracted information will include: study setting; study population; participant demographics and baseline characteristics; details of the intervention and control conditions; load progression criteria of the exercise programmes; recruitment and study completion rates; outcomes and times of measurement; Cohen's *d* effect size; percentage of change; and information for assessment of the risk of bias. Discrepancies will be identified and resolved through discussion, and a third reviewer will be involved when consensus is not reached.

With respect to the effect size, it will be distinguished in five levels²⁷:

- a. Cohen's $d < 0.2$ will be considered a trivial effect size.
- b. Cohen's $d \geq 0.2$ will be considered a small effect size.
- c. Cohen's $d \geq 0.5$ will be considered a moderate effect size.
- d. Cohen's $d \geq 0.8$ will be considered a large effect size.
- e. Cohen's $d \geq 1.3$ will be considered a very large effect size.

To assess the quality of the included studies and the existence of potential bias in the trials, two separate reviewers will independently evaluate each study using the Physiotherapy Evidence Database (PEDro) scale.²⁸ Each trial report will be given a total PEDro score ranging from 0 to 10. Studies scoring 7–10 will be considered methodologically to be of high quality, studies ranging from 5 to 6 will be considered methodologically to be of fair quality, while those studies that score below 5 will be felt to be of poor quality. Therefore, we will only include articles which score 5 or higher on the PEDro scale.

Data synthesis

Some heterogeneity is expected in the design, interventions and outcome measures of the studies. We will use a narrative synthesis to report the data. If possible, the progression criteria will be grouped into categories of sufficient homogeneity in their applied management strategies. Additionally, it is intended to compare the influence of the progression criteria (individually and in their respective categories) on the effects produced by the different exercise programmes. This is intended to be done by comparing them to other progression criteria in similar or different exercise programmes analysing clinical and performance outcomes.

We will consider a meta-analysis if there are two or more studies of sufficient homogeneity across the outcomes measures to ensure pooling. Heterogeneity will be analysed using the I^2 statistic.^{29 30} A value of $>25\%$ will be considered a sign of low heterogeneity, $>50\%$ a sign of moderate heterogeneity and $>75\%$ a sign of high heterogeneity.^{29 30} If possible, subgroup analysis will be

developed and publication bias will be assessed using a funnel plot graph.

Quality of the evidence

The quality of the body of evidence will be independently rated by two reviewers using the Grading of Recommendations Assessment, Development and Evaluation approach.³¹ Five aspects will be analysed: risk of bias, inconsistency of effect, indirectness, imprecision and publication bias for the main outcomes. Hence, the quality of the evidence will be rated as high, moderate, low or very low.

Patient and public involvement

No patients will be involved in this systematic review.

DISCUSSION

The current evidence points to progressive exercise programmes as the first-line treatment in tendinopathies.^{3 4} However, there is a lack of consensus about the appropriate load progression criteria among the different protocols and methodologies of exercise that are commonly applied.

This systematic review will clarify the evidence about which load progression criterion is more appropriate in loading exercise programmes in lower limb tendinopathies. This knowledge will improve the management of dose and load progression in tendinopathies, which could mean a crucial step in improving the efficiency of current exercise programmes.

If changes or amendments are produced to the present protocol, these will be reported in all generated publications.

Ethics and dissemination

Informed consent is not necessary for this systematic review protocol. Regardless of its nature, the results obtained in this study will be published in a peer-reviewed journal and presented at a relevant conference.

Contributors All the authors met the criteria recommended by the International Committee of Medical Journal Editors. All the authors made substantial contributions to the conception and design, piloted the inclusion criteria and provided direction on the data extraction and analysis. AE-E and AIC-V formulated the idea for the study. AE-E drafted the article. AIC-V and JC critically revised the draft for important intellectual content. All the authors agreed on the final version.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval is not necessary for this systematic review protocol.

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