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Effect of a common exercise programme with an individualised progression criterion based on the measurement of neuromuscular capacity versus current best practice for lower limb tendinopathies (MaLaGa trial): a protocol for a randomised clinical trial

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ABSTRACT

Introduction High-load resistance training has shown positive effects in pain and function in lower limb tendinopathies. However, some authors suggest that current exercise programmes produce an increase in tolerance to load and exercise in general but without fixing some existing issues in tendinopathy. This may indicate the need to include training aspects not currently taken into account in the current programmes. The main objective of this study will be to compare the effect of a common exercise protocol for the three predominant lower limb tendinopathies (Achilles, patellar and gluteal), based on an individualised control of the dose and training of specific aspects of the neuromuscular system versus the current best practice for each location.

Methods and analysis This study will be conducted among people with mid-portion Achilles, patellar or gluteal tendinopathy. The participants allocated to the experimental group will perform a 14-week innovative common therapeutic exercise programme. Participants allocated to the control group will carry out a 14-week exercise programme based on the best current practice for each of the studied locations. The Victorian Institute of Sports Assessment questionnaire will be considered the primary outcome. Pain, central sensitisation, fear avoidance behaviour, quality of life, treatment satisfaction, lower-limb strength and function, and high-density electromyography profile will be evaluated as secondary outcomes. Outcomes will be assessed at baseline, 7 weeks, after the intervention (week 14), 26 weeks and 52 weeks.

Ethics and dissemination The study has been approved by the Portal de Ética de la Investigación Biomédica de Andalucía Ethics Committee (1221-N-19). All participants will be informed about the purpose and content of the study and written informed consent will be completed. The results of this study will be published in a peer-reviewed journal and will be disseminated electronically and in print.

Trial registration number NCT03853122; Pre-results.

Strengths and limitations of this study

- This study protocol has been designed according to the Standard Protocol Items: Recommendations for Interventional Trials declaration.
- The single-blind, randomised controlled design of this protocol will allow this study to reach a high level of evidence.
- The design of a common exercise programme for three different sites of tendinopathy, if proven effective, can be an important advance for standardisation in clinical practice.
- The proposed new approach to exercise programmes based on the individualisation of the load and progression criteria, as well as the training of different neuromuscular characteristics, could allow a simplification of the variety of exercises of the different tendinopathies with equal or superior results.
- A possible limitation of this study may be the difficulty in comparing results from three tendinopathy locations with some differential characteristics.

BACKGROUND

Although the pathogenesis of tendinopathy has not yet been fully understood, different conceptual models have been proposed to explain this from a structural point of view, and the theory of an initial response of tendon cells to excessive loading prevails.[1 2] Likewise, there is also evidence about the presence and negative influence of psychosocial factors such as catastrophisation, distress and kinesiophobia in the outcomes and prognosis of tendinopathy.[3] Regarding treatment options, the literature published in recent decades points to progressive therapeutic exercise as the first-line treatment for lower

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limb tendinopathy.[2 4] Different mechanisms have been proposed to explain the effects of exercise programmes in tendinopathy, including local effects on tendon and muscle structure,[5 6] and central neuroplastic changes.[7]

Isolated isometric contractions have shown significant positive results on acute pain relief in patellar tendinopathy.[8 9] In addition, using isometric contractions prior to a resistance training seems to improve strength gains.[8] However, a recent study found no differences between isometric and dynamic resistance exercise on acute pain. This suggests that the specific contraction modality may not be the most relevant element, but the progressive exercise itself.[10] This approach is especially useful during the early stages of an exercise programme or during sports season to relieve symptoms in the short-time, although it is dependent on neurophysiological modulation and not seems to produce structural changes to reverse the tendinopathy itself.[10 11]

For mid-term and long-term improvement in tendinopathies, high-load resistance training has shown positive effects.[12 13] Thus, there is a marked preference for the use of isolated eccentric loading due to the enormous popularity the Alfredson protocol achieved two decades ago.[14] This popularity triggered an extensive literature and clinical practice applying this approach, predominantly in the Achilles and patellar tendinopathies.[2] Nevertheless, some systematic reviews published during the last years have observed that despite its widespread use there is a lack of evidence in favour of the isolated eccentric training and the parameters applied in this programme, and similar results have been found with other exercise approaches.[5 12 15 16] At the present time, the heavy slow resistance and the eccentric exercise training programmes have demonstrated the greatest long-term pain relief and improvement in function, not finding significant differences between both programmes.[5 13 16] Despite the absence of significant differences in function and pain, a study observed reductions of tendon abnormality and an increased collagen turnover in a group performing heavy slow resistance training and not in a group where isolated eccentric training was executed.[5] Nevertheless, the enormous popularity of the eccentric protocol and its significant simplicity have sustained an extended application of this approach.

In gluteal tendinopathy, the current evidence for training parameters is scarce. A previous study showed better global improvement of an exercise programme plus education versus a non-intervention and a corticosteroid injections group.[17] In the function, assessed with the Victorian Institute of Sports Assessment questionnaire for gluteal tendinopathy (VISA-G) at 8 weeks, significant differences were found in favour of the exercise plus education group. However, the differences between the exercise and the corticosteroids groups were not statistically significant (but clinically) at the 52-week follow-up. The programme applied in this study was a novel protocol based on conditioning stages in which different predefined exercises, frequency, volume and intensity were applied in each week. Nevertheless, in the attempt to ensure a wide variability of working areas and exercises, it resulted in a complex training protocol with a high number of exercises.

Considering all the above, it seems that although most of the programmes produce positive effects in pain and function, an optimal loading programme has not yet been described.[2] In this sense, some authors suggest that the significant differences usually found within the groups, without significant differences between groups, could indicate an increase in tolerance to load and exercise in general, but without solving some issues found in tendinopathy.[18]

This may indicate the need to include aspects not currently taken into account in the programmes. Current programmes are focused on performing very specific exercises and not individualising the neuromuscular needs and abilities of the patient. Therefore, although a certain consensus has been established about the need for working different characteristics of the neuromuscular system (pain relief, strength gaining, increase in speed and energy storage exercises and sports specific exercises),[2] most of the current methodologies work a single type of strength manifestation during the full programme, only increasing progressively the workload. Moreover, according to a previous review there is a predominant use of pain-based criteria, but the utilisation of these criteria is not supported by strong evidence.[19]

An objective individualisation of the load and progression criteria, as well as the implementation of stages, applying different speeds and loads for the training of different neuromuscular characteristics, could allow a simplification of the number of exercises performed in the three tendinopathies with equal or superior results. Thus, the development of a common programme for the three most predominant tendinopathies of the lower limb (Achilles, patellar and gluteal) could simplify its implementation by clinicians. This programme should be based on developing a personal assessment in the manner of precision medicine. Additionally, it should try to be a progressive and generalisable standard protocol that takes into account the capabilities of the individual.

The main hypothesis is that it is possible to obtain equal or superior benefits in function, pain, and quality of life with a common programme for the three tendinopathies, simplifying the execution to only four movements and putting the focus of individualisation on the load progression criteria and the training of different neuromuscular characteristics.

The primary objective of this study is to compare the effect of a common exercise protocol for the three predominant lower limb tendinopathies, based on an individualised control of the dose and training of specific aspects of the neuromuscular system versus the current best practice in the treatment of each of the three studied lower limb tendinopathies.

As secondary objectives, it is proposed: (1) Develop an exercise systematisation based on the differentiation of

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stages with different aims based on the capabilities of the neuromuscular system and (2) Develop a methodology for the quantification of the intensity of the loads based on specific tests for each of the aspects of the neuromuscular system worked.

METHODS AND ANALYSIS

Trial design

This protocol (v1) describes a single-blind, parallel, randomised controlled trial (RCT) that will be conducted among people with lower limb tendinopathy, what is expected to start during the year 2021. The study has been approved by the Portal de Ética de la Investigación Biomédica de Andalucía Ethics Committee (1221-N-19). This protocol has been reported according to the Standard Protocol Items: Recommendations for Interventional Trials Declaration. The study will be published following the Consolidated Standards of Reporting Trials checklist to ensure transparent and standardised reporting of the trial.[20]

The trial adheres to the principles of the Declaration of Helsinki. All participants will be informed about the purpose and content of the study. Written informed consent will be completed from all individual participants included in the study.

Patient and public involvement

Patients will be involved in the conduct of this study. During the design stage, different inputs were received from patients with tendinopathy, which helped in the elaboration of the protocol. Once the trial has been published, participants will be informed of the results through a mail and will be sent details of the results in a study newsletter suitable for a non-specialist audience.

Participants

Recruitment details

People with mid-portion Achilles, patellar or gluteal tendinopathy will be recruited from a Spanish Health Centre.

Potential participants will be identified by one of the two medical specialists who will act as recruiters. The recruiters will identify people with at least one of the three studied lower limb tendinopathies and will establish compliance with the selection criteria described below. All subjects will be informed about the purpose and characteristics of the study, and they will be asked to be included in the study.

Eligibility criteria

Due to the specific characteristics of each of the studied tendinopathies, general and specific eligibility criteria to each region will be established.

General inclusion criteria

1. People between 18 and 65 years with a clinical diagnosis of mid-portion Achilles, patellar or gluteal tendinopathy.
2. Pain duration for at least 1 month.

General exclusion criteria

1. Corticosteroid injection in the studied tendon in the last 12 months.
2. Other injuries in the affected lower limb in the last 12 months.
3. Previous surgery for musculoskeletal causes of the affected lower limb in the last 12 months.
4. Tendinous rupture history in the affected lower limb.
5. Systemic diseases such as rheumatic arthritis or diabetes mellitus.

Specific eligibility criteria for gluteal tendinopathy

Inclusion criteria: Lateral hip pain, an intensity of pain of at least 4/10 on a 11-point numeric rating scale (0=no pain, 10=worst pain imaginable) and clinical diagnosis of gluteal tendinopathy by a doctor (with functional assessment of physiotherapy).[17]

Exclusion criteria: Low-back, sciatic or inguinal pain of an intensity greater than 2/10 on a numerical scale.[17]

Specific eligibility criteria for patellar tendinopathy

Inclusion criteria: Pain localised to the inferior pole of the patella at palpation and during jumping and landing activities, pain during testing on the single-leg decline squat,[9] and an intensity of pain of at least 3/10 on an 11-point numeric rating scale (0=no pain, 10=worst pain imaginable). Pain is localised by the patient using only one or two fingers.[2]

Exclusion criteria: Presence of a diffuse knee pain indicative of possible patellofemoral pain.[10]

Specific eligibility criteria for Achilles tendinopathy

Inclusion criteria: pain and swelling at 2–7 cm from the calcaneal insertion.[21]

Exclusion criteria: diagnosis of insertional Achilles tendinopathy.[21]

Imaging tests such as magnetic resonance or ultrasound imaging have shown only poor or moderate correlation with pain in tendinopathy.[22 23] Besides, recently in the International Scientific Tendinopathy Symposium Consensus: Clinical terminology 2019, it was agreed that imaging is not always necessary for a diagnosis of tendinopathy as it is a clinical diagnosis.[24] For this reason, only clinical diagnostic criteria will be considered for eligibility.

Concealed allocation

The allocation will be concealed by sealed opaque envelopes. For this, an assistant not involved in the study will prepare sealed and numbered consecutively opaque envelopes. Each envelope will be assigned a group randomly by a computer-generated random number list. They will be kept in a locked file cabinet only accessible to the assistant. Once the fulfilment of the selection criteria and the participation in the study are confirmed, each subject will receive an envelope sequentially and will be assigned to the corresponding group.

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Interventions

At the beginning of the programme, participants in both groups will receive individual education on basic pathophysiology of tendinopathy and the risk factors for each of the locations. Likewise, they will receive education on the identification of normal symptoms and signs and those that indicate an excess in the dose, as well as on an adequate load selection and progression.

Experimental group

The participants allocated to the experimental group will perform an innovative therapeutic exercise programme consisting of the training of different neuromuscular characteristics and a quantification and load progression based on the use of functional tests.

The programme of the experimental group will consist of 14 weeks in which 70 individualised physiotherapy sessions will be conducted, including supervised and semisupervised sessions. A minimum of 14 sessions will be conducted in a supervised face-to-face way, including seven sessions aimed at conducting control sessions for teaching and monitoring the exercises and seven sessions aimed at carrying out the tests for the quantification of the load. Thirty-seven sessions will be conducted in a semisupervised manner, performing the exercises autonomously, but with possible assistance from instructors. Additionally, participant will conduct 28 sessions of unsupervised individualised aerobic training. These sessions will be conducted with an intensity between 60% and 75% of VO^2 max, obtained using a submaximal stress test performed at baseline and at the beginning of the eighth week.

The neuromuscular resistance exercise programme will consist of five stages divided into 2, 4, 4, 2 and 2 weeks, respectively. The frequency of the neuromuscular strength training will be of 3 weekly sessions. Additionally, 2 weekly sessions of aerobic work will be done. The approximate duration of each session will be 30 min. The exercises (four exercises) will be common for the three different locations of the tendinopathies. Two of the exercises will be performed alternately in each session. During the first four stages, these exercises are based on four different positions of the feet in the leg press (feet shoulder-width apart; left foot forward; right foot forward; feet apart with 45° external rotation). These four positions are chosen because they offer greater variability in a triple extension movement (hip, knee and ankle extension) such as leg press exercise. This exercise has previously been used in patellar tendinopathy protocols,[5] but the triple extension movement could be beneficial for the function of the three tendon studied in a large number of activities of daily living. In each of the stages, load and speed parameters will be modified to influence different aspects of the neuromuscular system. During stage 5, the exercises will consist of four different jumping modalities (countermovement jump, CMJ; drop jump, DJ; DJ with dual task and repeated vertical jumps). This work will be complemented throughout the programme by 2 weekly sessions of aerobic exercise.

Aerobic exercise: Numerous studies have proven during the last decades the effect of exercise as an excellent 'polypill' that would have a positive impact on many body systems.[5] Thus, in addition to the effects that aerobic exercise may have on cardiorespiratory capacity, endurance or performance, aerobic exercise can affect the hypothalamic–pituitary–adrenal axis,[6] release exercise-induced myokines[7] or increase sensitivity to catecholamines,[8] among others potential effects. Aerobic exercise can help not only by allowing a progressive return to sports activity but also by providing a potential analgesic and recovery-accelerating effect. Although the use of a cycle ergometer makes it possible to standardise this part of the training for most people, due to the objective of this type of training it could be adapted to other forms of aerobic training such as running outdoors or on a treadmill. This would also include a possible aerobic training of the upper limbs (eg, using an upper body ergometer or generic upper limb exercises with an aerobic nature) in the early stages in those cases in which the symptoms do not allow do not allow adequate lower limb work.

Stage 1: based on isometric contractions to control symptoms and prepare the neuromuscular system for later phases. The use of isometric contractions has shown some benefits in tendinopathy such as a reduction in cortical inhibition[7 8] or immediate[8 25] and short-term[25 26] analgesia. The absence of differences between different protocols suggests that the effects may be more related to obtaining adequate intensity and time under tension than to specific exercise parameters.[25]

Stage 2: this stage includes isotonic and heavy slow resistance exercises and has been proposed by many authors with the aim of improving muscle strength and tendon stiffness.[2 27 28] The main novelty in this study is the incorporation of a methodology based on time under tension and not on the number of repetitions. Thus, the importance of ensuring sufficient time under tension lies in the fact that greater time under tension with the same volume load produces greater overall muscular fatigue[29] and a greater impact on the metabolic responses,[30] which can translate into additional neuromuscular adaptations.

Stage 3: based on strength training through exercises performed with a velocity loss of 20%. This type of training has been shown to be superior to others (velocity loss of 0%, 10% and 40%) with the greatest increases in muscle hypertrophy, avoiding the negative neuromuscular adaptations observed in work with greater velocity losses.[31]

Stage 4: based on high-load strength training. High-load resistance training has been found to be a good way to obtain maximal strength benefits.[32 33] For some decades, these increases in strength not explained solely by increases in hypertrophy have been attributed to neural adaptations.[32–35]

Stage 5: based on plyometric training, jumps and improvement of the energy storage capacity of the

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tendon. This type of training has been recommended for tendinopathy by several authors.[27 28 36 37]

In the different stages, the dose tests are designed to calculate the load needed for the appearance of fasciculations (stage 1), the inability to continue moving the load (stages 2 and 4) and a loss of speed of 20% (stage 3) on a given time, or to calculate the height maximum that can be maintained in repeated vertical jumps that can be maintained for a specified time (stage 5). In general, the working time of each series has been chosen to be less than the time calculated in the test. This fact, together with a high number of series, allows a different work in the first series, focused on accumulating volume, and in the last series, where due to neuromuscular fatigue a limit similar to that obtained in the test is reached.

Specific intervention details, as well as detailed information of each of the stages, are available in online supplemental file.

Control group

Participants allocated to the control group will carry out a 14-week therapeutic physical exercise programme. The programme will be based on the isolated eccentric training protocol described by Alfredson[14] for Achilles tendinopathy. The Alfredson's protocol modified version of Purdam *et al*[38] and the LEAP protocol of Mellor *et al*[17] will be applied for patellar and gluteal tendinopathy, respectively. The three protocols will be adapted to be carried out in 14 weeks in order to match the training of the control and intervention groups. Detailed information on the protocol and exercises used is available in online supplemental file. The control group will carry out the same number of supervised sessions as the intervention group (14 sessions), performing the remaining sessions autonomously but with the help of an instructor when necessary. Participants of both groups will keep track through an activity diary. The flow chart of the study is shown in figure 1.

Participants will be allowed to perform light and moderate physical activity as long as it does not produce an increase in symptoms both during and especially at 24 hours (Visual Analogue Scale (VAS) >50 mm). Likewise, they will be recommended to abandon those workouts

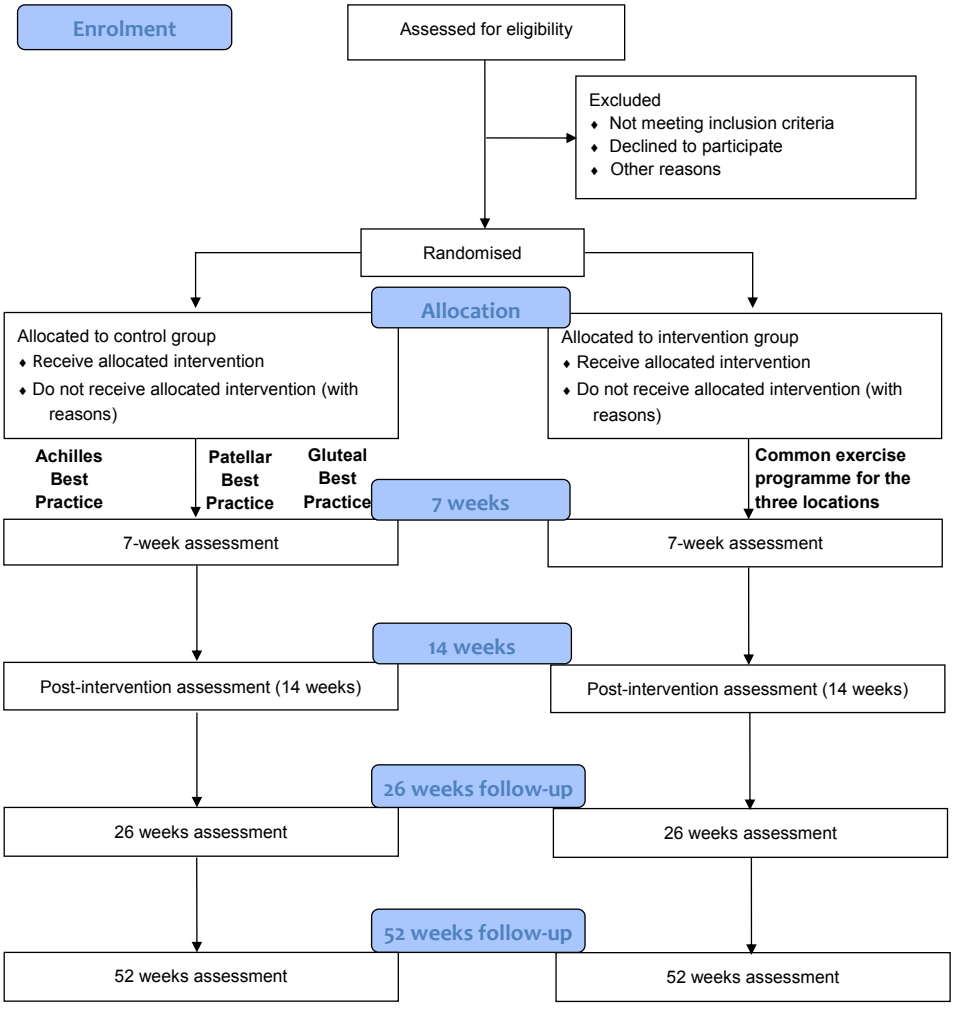

Figure 1 Flow chart of the study.

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that do not allow adequate recovery between sessions when applied together with the training programme proposed in this study.

Outcome measures

Both groups will be evaluated at the beginning, in the middle (7 weeks), and at the end of the programme, as well as in medium-term (26 weeks) and long-term (52 weeks) follow-up. The assessments and the control and resolution of possible events that may occur will be under the supervision of a researcher. The same assessor, blinded to the group allocation of the participants, will measure each outcome at each of the measurements.

Primary outcome measures

The VISA questionnaire (VISA-A, VISA-P and VISA-G for Achilles, patellar and gluteal tendinopathy, respectively)[39–41] will be considered the primary outcome and will be used to assess the effectiveness of the programme applied in each group. The VISA-A and VISA-P have been adapted and validated for the Spanish population showing satisfactory psychometric properties similar to the original English-language version.[42 43]

Secondary outcome measures

Additionally, the following secondary outcomes will be evaluated:

Visual Analogue Scale

A VAS from 0 to 100 mm will be used to record the amount of pain in the tendon at rest (VASr) and during running activity (VASa), 0 being no pain and 100 being the worst imaginable pain.[44 45] Additionally, subjects will be asked about how much time elapses when they are running until the onset of pain, in order to obtain complementary information.

Pressure pain threshold

A hand-held algometer (FPK 20, Wagner Instruments, Greenwich, USA) with a 1 cm^2 probe will be used to assess the pressure pain threshold at rest in the tendon.[46] Subjects will be positioned lying prone with the ankle in neutral position (90°) for the Achilles tendon,[47] sitting with the knee flexed to 90° for the patellar tendon,[10] and lying in the lateral decubitus position with hip joints slightly flexed for the gluteal tendon.[48] The tester will be placed perpendicular to the skin over the test area, increasing the pressure 30 kPa/s.[10] Participants will be instructed to indicate when the sensation change from comfortable pressure to slightly unpleasant pain. Test will be repeated three times with 1 min of rest between repetitions. The mean value will be used for the analysis.[10]

Örebro Musculoskeletal Pain Questionnaire

The Örebro Musculoskeletal Pain Questionnaire is a self-administered pain screening questionnaire used to identify patients with acute or subacute musculoskeletal pain who are at risk of delayed recovery. This tool aims to detect and quantify the existence of biopsychosocial aspects that may negatively affect the patient's prognosis. With a maximum punctuation of 210, a score lower than 105 points is related to low disability, a score between 105 and 130 points suggests a moderate disability, and a score higher than 130 points is related to high disability.[49] The adaptation and validation version of this questionnaire for the Spanish population has shown a rate above 0.85 on reliability in most of the variables.[50]

Central Sensitisation Inventory

The Central Sensitisation Inventory inventory will be used to identify and quantify the degree of key symptoms associated with the central sensitisation syndrome present in the included subjects.[51] The score ranges from 0 (best score) to 100 (worst score). This index has been adapted and validated to Spanish with an SE of the measurement of 2.52%.[52]

Fear Avoidance Components Scale

The Fear Avoidance Components Scale (FACS) scale is used to comprehensively assess the presence of fear avoidance beliefs and attitudes in the participants. The FACS instructions ask participants to reflect on past painful experiences and to indicate the degree to which these experiences influence on their activity. There are 20 thoughts or feelings related to fear avoidance which are scored using 6-point scales with the end points 0, completely disagree and 5, completely agree. The FACS yields a total score between 0 (best score) and 100 (worst score), and have showed a high test/retest reliability (r=0.90–0.94).[53]

EuroQol-5Dimension-5Level

The EuroQol-5Dimension-5Level (EQ-5D-5L) has been developed and validated in numerous languages and populations. This questionnaire is used to measure the health-related quality of life. This self-reported tool records the subject's perceptions of their own current overall health status assessing five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). It is applied with a short questionnaire and a VAS. Each dimension is rated in five levels from 'I have no problem with…' to 'I am unable to…'.[54] It has been validated in the Spanish population as an adequate instrument to measure perceived health.[55]

International Physical Activity Questionnaire Short Form

The International Physical Activity Questionnaire Short Form assess the type and amount of physical activity of the patients through seven questions about the physical activity performed the previous 7 days. Physical activity can be interpreted as a numerical value (reported as Median Metabolic Equivalent of Task-minutes per week) or as low, moderate or high activity levels. This form has shown acceptable measurement properties.[56]

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Treatment satisfaction

Treatment satisfaction will be assessed using a VAS, from 0 to 100 mm, with 0 being 'not at all satisfied' and 10 being 'extremely satisfied'. This tool has been shown to be less vulnerable to confounding factors and ceiling effect than asymmetric Likert scale.[57]

Lower-Limb Functional Index

The Lower-Limb Functional Index (LLFI) is an index designed for assessing the functional capacity of the lower limbs with a combination of constructs that includes body functions, body structures, activities and participation, and environmental factors. The LLFI contains 25 ideas as items and participants have to select which ones they identify with. The LLFI yields a total score (between 100, best score and 0, worst score).[58] The Spanish version of this index has been validated showing high reliability (ICC=0.96).[59]

Lower-limb strength

The lower-limb strength will be assessed with two different methods. First, the isometric strength will be assessed in a leg press machine using a s-beam load cell as performed in a previous study.[60] Additionally, isometric strength will be measured with a hand-held dynamometer following the methodology of a previous study (ankle plantarflexion for Achilles tendinopathy, knee extension for patellar tendinopathy, and hip abduction for gluteal tendinopathy).[61] In both measurements, two repetitions will be conducted and the mean value will be used for the analysis.

High-density electromyography

The High-density electromyography (HDEMG) profile will be calculated using non-invasive surface HDEMG in the quadriceps muscle. Participants will execute maximal isometric voluntary contractions in a leg press machine. Surface HDEMG will be recorded during 20 s. The data obtained will be analysed to extract the mean discharge rate of the motor units (in fires per second) and the recruitment and derecruitment threshold (in Nw). The HDEMG profile will only be assessed in a randomly selected subgroup of each arm.[62–65]

Other measures

Not per-protocol treatments.

Participants will be encouraged to follow the assigned interventions, trying to avoid any treatment external to the study. They will be informed of the importance of compliance with the programmes, and they will be asked to record any deviation from the protocol in a diary.

Data management

The answers obtained in the VISA questionnaire will be converted into their corresponding score for each subject. The difference in means obtained in each group between the baseline evaluation and at the end of the programme (14 weeks) will be used to determine the success of each treatment.

Sample size

The treatment effect will be evaluated by comparing success rates on the VISA measurements at follow-up between groups. With an a priori calculation based on the effect size of the LEAP study for gluteal tendinopathy (d=0.59),[17] and using an α value of 0.05 and a power of 0.8, the sample size is estimated at 44 participants per arm. Assuming losses of 15% of the sample in the follow-up measurement, the necessary sample size will be of 52 participants per group for a total sample of 104 participants.

Blinding

Due to the nature of the study, neither therapists nor subjects can be blinded. Nevertheless, the researchers responsible for the assessment and analysis of the results will be blinded to the allocation of the participants.

Statistical analysis

Statistical analyses will be conducted based on an intention-to-treat approach. A one-way analysis of variance will be carried out both at the beginning and at each of the measurement times to verify the existence of significant differences between groups. If a non-parametric distribution is found, a Kruskal-Wallis test will be carried out at each measurement time. No subgroup or additional analyses are planned a priori.

ETHICS AND DISSEMINATION

Research ethics approval

The study has been approved by the Portal de Ética de la Investigación Biomédica de Andalucía Ethics Committee (1221-N-19). The trial adheres to the principles of the Declaration of Helsinki. All participants will be informed about the purpose and content of the study. Participants will also be informed that they can withdraw their consent for participation at any time during the study without penalty. Informed consent material is available in its original language (Spanish) as online supplemental appendix S5 in online supplemental file.

Safety considerations

Any adverse effects observed during the intervention or the follow-up months will be reported by the participants and researchers. If necessary, the principal investigator will ensure that the appropriate treatment for the adverse effect produced is undertaken. Additionally, adverse effects will be reported to the ethics committee.

Protocol amendments

In the event of important changes in the protocol, they will be described in subsequent publications.

Confidentiality

All study-related and participant information will be stored in locked file cabinets in areas with limited access. Data collection and forms will be identified by

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a coded identification number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number.

Dissemination

The results of this study will be published in a relevant scientific peer-reviewed journal and will be disseminated electronically and in print.

DISCUSSION AND PERSPECTIVES

This protocol shows the methodology of an RCT designed to assess the effect of a common exercise protocol for the three predominant lower limb tendinopathies, based on an individualised control of the dose and training of specific aspects of the neuromuscular system versus the current best practice in the treatment of each of the three studied lower limb tendinopathies.

This study will provide physiotherapists directly applicable evidence about two modalities of exercise-based treatment for the management of each of the three main tendinopathies of the lower limbs. If the non-inferiority of the common experimental protocol is proved, it will provide clinicians with a tool to simplify the exercises of the exercise programmes while focusing on individualising the load progression criteria and the work of specific aspects of the neuromuscular system. Thus, this study tries to provide a progressive and generalisable standard protocol that takes into account the capabilities of the individual.

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

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SUPPLEMENTARY FILE

BMJ OPEN

Description of the exercise programmes applied on Achilles, patellar, and gluteal tendinopathy

Supplement to: *Effect of a common exercise programme with an individualised progression criterion based on the measurement of neuromuscular capacity versus current best practice for lower limb tendinopathies (MaLaGa Trial): a protocol for a randomised clinical trial*

Adrian Escriche-Escuder, Antonio I. Cuesta-Vargas, José Casaña

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APPENDIX S1. Description of the MaLaGa exercise programme

MaLaGa EXERCISE PROGRAMME

- **Duration:** 14 weeks
- **Number of sessions:** Seventhy individualised physiotherapy sessions with exercise for 14 weeks, including supervised (15) and semi-supervised (27) sessions, and 28 complementary unsupervised sessions of aerobic training.

- **NEUROMUSCULAR RESISTANCE TRAINING**
  - **Supervised sessions:** Seven individualised control exercise sessions and seven testing sessions (14/42)
  - **Semi-supervised sessions:** Twenty-seven individualised sessions of NEUROMUSCULAR RESISTANCE TRAINING (28/42)
  - **Frequency:** Three sessions per week of supervised and semi-supervised NEUROMUSCULAR RESISTANCE TRAINING (i.e.: Monday, Wednesday, and Friday)
  - **Number of exercises:** Four movements: 2 movements per session alternately. These movements are four different versions of the squat exercise in leg press (Figure 1). In each of the stages, these four variants are worked with a specific speed, number of set and repetitions, intensity, and load to produce specific neuromuscular adaptations.
  - **Volume and intensity:** It seeks to perform the maximum number of repetitions possible with a time and a load that are calculated in a previous test (excepting STAGE 4 where two repetitions are done independently of the load and capacity calculated).
  - **Load progression criteria:** Conditioning Stages-Based: five stages based on specific training objectives

- **COMPLEMENTARY AEROBIC TRAINING:** Twenty-eight unsupervised individualised sessions of AEROBIC TRAINING

- **Frequency:** Two sessions per week of unsupervised AEROBIC TRAINING (i.e.: Tuesday, and Saturday) using a cycle ergometer or running outdoors or on a treadmill.
- **Volume:** 3 sets x 8 minutes (Resting 3 minutes between sets)
- **Intensity:** 60-75% VO_2max (obtained with a submaximal stress test performed at baseline and at the beginning of the eighth week)

*****An upper body ergometer or generic upper limb exercises with an aerobic nature can be used if the symptoms (e.g. VAS >50 mm) do not allow adequate lower limb work.

ORGANIZATION OF THE NEUROMUSCULAR RESISTANCE EXERCISE PROGRAMME

- The programme is divided into 5 STAGES.
- Each STAGE is divided into 2 or 4 weeks:
  - **STAGE 1:** 2 weeks
  - **STAGE 2:** 4 weeks
  - **STAGE 3:** 4 weeks
  - **STAGE 4:** 2 weeks
  - **STAGE 5:** 2 weeks
- Each STAGE is preceded by **TESTS** for each of the four movements to individualise timing and load of exercises
  - **STAGE 1 (FASCICULATIONS TEST):** isometric tests of fasciculations and compensations
  - **STAGE 2 (LOAD FOR A PREVIOSLY ESTABLISHED TIME):** tests for calculate the maximum load that allows working for 45 seconds
  - **STAGE 3 (SPEED LOSS TRESHOLD):** tests for calculate the load for experiencing a speed loss threshold of at least 20% at 45 seconds
  - **STAGE 4 (LOAD FOR WORKING FOR A VERY SHORT TIME):** tests to calculate the load that you can mobilize for 4 but not for 8 seconds
  - **STAGE 5 (LOAD FOR MINIMUM CONTACT IN JUMP TESTS:** tests to calculate the height with which the contact time is lower during a Drop Jump (DJ).

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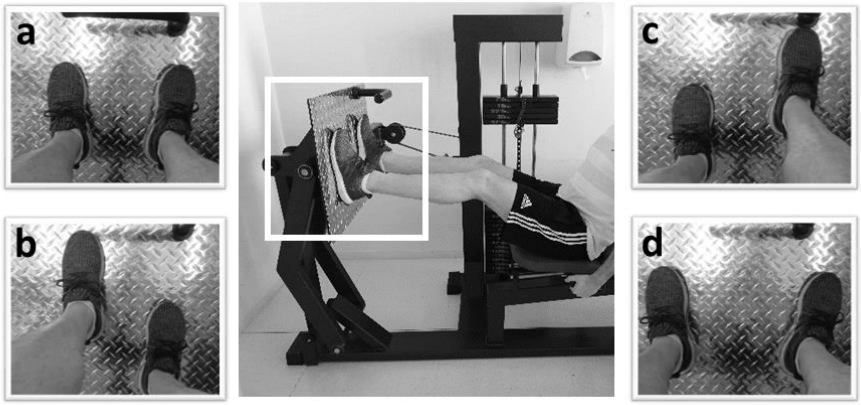
Figure 1. Foot position during the four movements of the exercises. a) Feet shoulder-width apart; b) Left foot forward; c) Right foot forward; d) Feet apart with 45° external rotation.



STAGE 1

TEST 1: isometric (60° knee flexion) test of fasciculations and compensations in leg press machine. The load is maintained isometrically. Test is stopped when fasciculations or compensations appear. Using three attempts (resting 3 minutes between repetitions), the purpose is obtaining the weight with which the fasciculations appear at approximately 45 seconds. The first attempt is used to approach the load with values below the assumed limit (i.e.: load that produces fasciculations or compensations after 60 seconds). The second one is used to approach the load with values above the assumed limit (i.e.: load that produces fasciculations or compensations before 35 seconds). The last attempt is used to try an accurate approach to the load, with a value that should be between the first two attempts. Test is repeated for each of the four movements in the leg press machine.

Microcycle 1: Principal component (PC): isometric (60°) with the load obtained in the Test 1 for each movement. Although the appearance of earlier fasciculations is likely in the last series, the exercise remains until the conclusion of the 45 seconds.

Volume: 5 sets x 45 seconds (resting 1 minute between sets)

TEST 2: repetition of the Test 1 for each of the four movements.

Microcycle 2: PC: isometric with the load obtained in the Test 2. Although the appearance of earlier fasciculations is likely in the last series, the exercise remains until the conclusion of the 45 seconds.

Volume: 5 sets x 45 seconds (resting 1 minute between sets)

STAGE 2

TEST 3: maximum load per time. Using three attempts (resting 3 minutes between repetitions), the purpose is to calculate the maximum load that allows to perform the exercise for 45 seconds (or approximately 12RM). The first attempt is used to approach the load with values below the assumed limit (i.e.: load that allows to perform the exercise for 60 seconds). The second one is used to approach the load with values above the assumed limit (i.e.: load that does not allow to perform the exercise more than 35 seconds). The last attempt is used to try an accurate approach to the load, with a value that should be between the first two attempts.

Microcycle 3: PC: maximum isotonic contractions for a pre-established time.

4*30 seconds (with the load obtained in the Test 3 for 45 seconds) R2 minutes between sets

Microcycle 4: PC: maximum isotonic contractions for a pre-established time.

4*30 seconds (with the load obtained in the Test 3 for 45 seconds) R2 minutes between sets

Microcycle 5: PC: maximum isotonic contractions for a pre-established time.

6*30 seconds (with the load obtained in the Test 3 for 45 seconds) R2 minutes between sets

Microcycle 6: PC: maximum isotonic contractions for a pre-established time.

6*30 seconds (with the load obtained in the Test 3 for 45 seconds) R2 minutes between sets

STAGE 3

TEST 4: Load for speed loss threshold (45 seconds): Using three attempts (resting 3 minutes between repetitions), the purpose is to calculate the load that patient can mobilize for approximately 45 seconds before experiencing a speed loss of at least 20% [1]. The first attempt is used to approach the load with values below the assumed limit (i.e.: load that produces a speed loss of 20% after 60 seconds). The second one is used to approach the load with values above the assumed limit (i.e.: load that produces a speed loss of 20% before 35 seconds). The last attempt is used to try an accurate approach to the load, with a value that should be between the first two attempts.

Microcycle 7: PC: neural impulses

4*15 seconds [2] (with the load obtained in the **Test 4**) R2 minutes between sets

Microcycle 8: PC: neural impulses

4*15 seconds [2] (with the load obtained in the **Test 4**)

R2 minutes between sets

TEST 5: Repetition of the test 4.

Microcycle 9: PC: neural impulses

4*15 seconds [2] (with the load obtained in the **Test 5**)

R2 minutes between sets

Microcycle 10: PC: neural impulses

4*15 seconds [2] (with the load obtained in the **Test 5**)

R2 minutes between sets

STAGE 4

TEST 6: Using three attempts (resting 3 minutes between repetitions), the purpose is to calculate the load that you can mobilize for 4 but not for 8 seconds. The first attempt is used to approach the load with values below the assumed limit (i.e.: load that allows perform the exercise more than 8 seconds). The second one is used to approach the load with values above the assumed limit (i.e.: load that does not allow to perform the exercise more than 3 seconds). The last attempt is used to try an accurate approach to the load, with a value that should be between the first two attempts.

Microcycle 11: PC: neuromuscular junction

6*2 reps (load obtained from the Test 6)

R2 minutes between sets

Microcycle 12: PC: neuromuscular junction

6*2 reps (load obtained from the Test 6)

R2 minutes between sets

STAGE 5

TEST 7: Using three attempts (resting 3 minutes between repetitions), the purpose is to calculate the height with which the contact time is lower during a Drop Jump (DJ). A contact mat is used for this calculation.

TEST 8: Using three attempts (resting 3 minutes between repetitions), the purpose is to calculate the maximum jump height that can be kept jumping for 60 seconds. The first attempt is used to approach the height jump with values below the assumed limit (i.e.: load that allows perform the exercise more than 60 seconds). The second one is used to approach the load with values above the assumed limit (i.e.: load that does not allow to perform the exercise more than 50 seconds). The last attempt is used to try an accurate approach to the load, with a value that should be between the first two attempts. A contact mat is used for this calculation.

Microcycle 13: PC: neuromuscular junction

3*3 Counter Movement Jump (maximum height)

R2 minutes between sets

4*4 DJ (height obtained from the Test 7)

R2 minutes between sets

Dual task: 4*4 DJ during a dual task (simultaneous performance of a cognitive activity consisting of the subtraction of 2 units at a random number between 0 and 100) (height obtained from the Test 7)

R2 minutes between sets

Repeated Vertical Jumps: 3*40 seconds (The purpose is to perform the highest number of jumps with the height jump obtained in Test 8. Execution: With hands placed on the hips, the subjects squats down until the knees are bent at 90 degrees. Then, jumps vertically as high as possible, and lands back on the mat with both feet at the same time, bending the knees and repeating the jumping action)

R2 minutes between sets

Microcycle 14: PC: neuromuscular junction

3*3 Counter Movement Jump (maximum height)

R2 minutes between sets

4*4 DJ (height obtained from the Test 7)

R2 minutes between sets

Dual task: 4*4 DJ during a dual task (simultaneous performance of a cognitive activity consisting of the subtraction of 2 units at a random number between 0 and 100) (height obtained from the Test 7)

R2 minutes between sets

Repeated Vertical Jumps: 3*40 seconds (The purpose is to perform the highest number of jumps with the height jump obtained in Test 8. Execution: With hands placed on the hips, the subjects squats down until the knees are bent at 90 degrees. Then, jumps vertically as high as possible, and lands back on the mat with both feet at the same time, bending the knees and repeating the jumping action)

R2 minutes between sets

APPENDIX S2. Description of the control exercise programme for Achilles tendinopathy

Based on the isolated eccentric training protocol [3]

Volume: 3 sets x 15 repetitions

Frequency: Twice daily, seven days a week

Load: Weight that allows performing the exercise with a mild or moderate feeling of pain or discomfort.

Progression load criterion: Pain-based criterion: When the pain sensation decreases, the weight will be increased using a weighted backpack.

Exercises: two exercises: unilateral heel raises with bent knee and unilateral heel raises with straight knee

Duration: 14 weeks

APPENDIX S3. Description of the control exercise programme for patellar tendinopathy

Based on the unilateral isolated eccentric training protocol [4]

Volume: 3 sets x 15 repetitions

Frequency: Twice daily, seven days a week

Load: Weight that allows performing the exercise with a mild or moderate feeling of pain or discomfort.

Progression load criterion: Pain-based criterion: When the pain sensation decreases, the weight will be increased using a weighted backpack.

Exercise: Eccentric single leg squat on a 25˚decline board

Duration: 14 weeks

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APPENDIX S4. Description of the control exercise programme for gluteal tendinopathy

Exercise programme based on the LEAP protocol [5]

Volume, frequency, load, and exercises: Table 1

Progression load criterion: Conditioning Stage-Based criteria: Volume, frequency, load, and exercises are modified in each stage.

Duration: Fourteen weeks (the original LEAP protocol has a duration of 8 weeks)

Table 1 Exercise Dosage and Progressions (adapted from Mellor et al. (2016) [6])

Stage	Exercise	Effort	Speed	Reps	Sets	Freq
Weeks 1-2 – Familiarisation	*Low load activations*	Light	Slow onset	10	1–2	BD
	Static Abduction:		Hold 5–10 s			
	In supine lying	Light	Slow onset	3–5	1	BD
	In standing		Hold 5–15 s			
	Pelvic Control during Functional Loading:					daily
	Bridging	Light	Moderate	10	1	daily
	Double Leg Bridging					
	Functional Strengthening:	Light-SWH	Slow	10	1	
	Double leg squats					
	Abductor Loading via *Frontal Plane Movement:*	Light	Moderate	10 each	1	daily
	Sidestepping					
Weeks 3-4 – Early Loading & Movement Optimisation	*Low load activations*	Maintain as per weeks 1-2				
	Static Abduction:					
	Pelvic Control during Functional Loading:					
	Bridging:					
	Double leg bridging	Light	Slow	10	1	daily
	Single leg biased ex:	SWH	Slow	5	1	
	Offset bridging					
	Functional Strengthening:					
	Double leg squats	Light	Slow	10	1	daily
	Single leg biased ex:	SWH	Slow	5	1	
	Offset squat					
	Abductor Loading via *Frontal Plane Movement:*	Light	Moderate	15 each	1	daily
	Sidestepping					
Week 5–14 – Graduated Loading	*Low load activations*	Maintain as per week 1-2				
	Static Abduction:					
	Pelvic Control during Functional Loading:					
	Bridging:	Light	Slow	5	1	
		daily Double leg bridging				
	Single leg biased ex	SWH – Hard		5–10	2	
		daily Functional Strengthening:				
	Double leg squats	Light	Slow	5	1	
	Single leg biased ex	SWH - Hard		5–10	2	

	Abductor Loading via *Frontal Plane Movement:*					daily
	Sidestepping	Light	Moderate	10 each	1	
	Band Sideslides	SWH- Hard		5–10 each	1–2	
Week 5–14 – Graduated Loading; Sliding platform with spring resistance						
Warm up	*Abductor Loading* via *Frontal Plane Movement:*					
	Bilateral Abduction:					Twice weekly
	In upright	Light	Moderate	5 each way	1	
	In minisquat	Light	Moderate	5 each way	1	
Higher level loading	*Abductor Loading* via *Frontal Plane Movement:*					Twice weekly
	Bilateral Abduction:					
	In upright	SWH-VH	Slow	5–10 each way	1	
	In minisquat	SWH-VH	Slow	5–10 each way	1	
	Pelvic Control during Functional Loading:	Light - SWH	Moderate	5–10	1–2	Twice weekly
	Scooter					

Repetitions (Reps); Frequency (Freq); Effort based on Borg Scale (Borg, [30]); Somewhat Hard (SWH); Very Hard (VH); Speed: Slow = 3 s each movement phase – up/down/in/out; Moderate = 2 s each movement phase; Bi-daily (BD)

APPENDIX S5. Informed consent model (original language)

Consentimiento informado – Información al paciente

Título del protocolo: **Programa común de Ejercicio Físico Terapéutico con dosificación individual frente a la mejor práctica actual en tendinopatías de miembros inferiores: ensayo clínico aleatorizado**

Investigador principal: Dr. Antonio I. Cuesta Vargas

Sede donde se recoge los datos del estudio: Facultad de Ciencias de la Salud, Universidad de Málaga
Arquitecto Francisco Peñalosa, 3, 29071 Málaga

Nombre y edad del paciente:

Antes de proceder a la firma de este consentimiento informado, lea atentamente la información que a continuación se le facilita y realice las preguntas que considere oportunas. Una vez comprendido todos los apartados del estudio, y si desea participar, se le pedirá que firme el presente consentimiento, del cual, se le entregará una copia firmada y fechada.

Justificación del estudio

Objetivos del estudio:

- Comparar el efecto de un programa de entrenamiento experimental, basado en el control de la dosis y el trabajo de adaptaciones neuromusculares específicas, frente a la mejor práctica actual consistente en un programa de ejercicio terapéutico.

Importancia:

- El principal beneficio que persigue el presente estudio es comprobar el efecto de la dosificación del ejercicio de manera individualizada y el trabajo de adaptaciones neuromusculares específicas, en el contexto de un programa de ejercicios protocolizado, en la mejoría a corto y, sobre todo, a largo plazo, de las tendinopatías del miembro inferior.

Implicaciones para el paciente

- La participación es totalmente voluntaria.
- El paciente puede retirarse del estudio cuando así lo manifieste, dando las explicaciones que considere oportunas, sin ser cuestionadas y sin que esto repercuta en sus cuidados médicos.
- Todos los datos carácter personal, obtenidos en este estudio son confidenciales y se tratarán conforme a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.
- La información obtenida se utilizará exclusivamente para los fines específicos de este estudio.

Procedimiento de recogida de datos y programa de intervención

Si decide aceptar participar en el estudio, se le realizarán algunas preguntas sobre usted, sus hábitos y sus antecedentes médicos. Se realizarán en la primera sesión evaluaciones a través de tests funcionales realizados por un fisioterapeuta, se rellenarán una serie de cuestionarios y se recogerán pruebas de imagen a través de una técnica totalmente inocua como es la ecografía. Estas pruebas se repetirán a las 7, 14, 26 y 52 semanas.

Una vez realizada la evaluación inicial, se iniciará una intervención de 14 semanas de ejercicio, orientadas a la recuperación de la tendinopatía de miembro inferior que usted padece, consistente en la realización de uno de los dos programas de ejercicio terapéutico estudiados, siguiendo las indicaciones del fisioterapeuta.

Contraindicaciones

Las contraindicaciones aquí descritas han sido consideradas previamente a la realización del presente estudio para incluirle a usted dentro del mismo, pero le informamos de las mismas por si se hubiera presentado alguna de ellas y usted no nos lo hubiese comunicado anteriormente:

- Inyección de corticoides en el tendón estudiado en los últimos 12 meses.
- Otras lesiones en la pierna afecta en los últimos 12 meses.
- Cirugía previa por causas musculoesqueléticas de la pierna afecta en los últimos 12 meses.
- Antecedentes de ruptura tendinosa en el lado afecto.
- Artritis reumatoide o diabetes mellitus.
- Enfermedades psiquiátricas graves.
- Deterioro cognitivo severo.
- Incapacidad psíquica para comprender los test.
- Patologías sistémicas agudas.
- Tumor.
- Infarto de miocardio reciente.
- Enfermedades infecciosas.
- Embarazo.

Al firmar este documento, usted afirma que se encuentra en perfectas condiciones para la ejecución de todos los ejercicios propuestos. Usted antes de comenzar el estudio e incluso antes de firmar el presente documento, puede formular cuantas preguntas estime oportunas.

Aclaraciones

- Su decisión de participar en el estudio es completamente voluntaria.
- No habrá ninguna consecuencia desfavorable para usted, en caso de no aceptar la invitación.
- Si decide participar en el estudio puede retirarse en el momento que lo desee, aun cuando el investigador responsable no se lo solicite, informando las razones de su decisión la cual será respetada en su integridad.
- No tendrá que hacer gasto alguno durante el estudio.
- No recibirá pago por su participación.
- En el transcurso del estudio usted podrá solicitar información actualizada sobre el mismo, al investigador responsable.
- Todos los datos y resultados obtenidos y emanados del presente estudio estarán destinados sólo y exclusivamente a investigación.
- La información obtenida en este estudio, utilizada para la identificación de cada paciente, será mantenida con estricta confidencialidad por el grupo de investigadores.
- Si considera que no hay dudas ni preguntas acerca de su participación, puede, si así lo desea, firmar la Carta de Consentimiento Informado anexa a este documento.

  Sus datos serán tratados de acuerdo a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos y Garantía de los Derechos Digitales.

Declaración del consentimiento informado

Yo,

he leído y comprendido la información previamente descrita y mis preguntas han sido respondidas. He sido informado y entiendo que los datos e imágenes obtenidas en el estudio pueden ser publicados o difundidos con fines científicos, manteniendo mi anonimato en todo momento. Por ello, acepto participar en el presente estudio de investigación. Comprendo que mi participación es voluntaria; que puedo retirarme del estudio: cuando quiera, sin tener que dar explicaciones y sin que esto repercuta en mis cuidados y atención sanitaria

Recibiré una copia firmada y fechada del presente consentimiento.

Firma del participante:	Fecha:
Nombre y firma del testigo (sólo si corresponde):	Fecha:

D. Antonio I. Cuesta Vargas, como investigador principales de este estudio, o alguno de sus colaboradores, declara que:

Yo, , con cargo de en el presente estudio, he explicado al Sr(a) arriba firmante, la naturaleza y los propósitos de la investigación, así como le he expuesto los riesgos y beneficios que implica la participación. He respondido las preguntas del paciente y he solicitado si tiene alguna duda. Acepto que he leído y conozco la normativa correspondiente para realizar investigación con seres humanos y me acojo a ella.

Una vez concluidas y aclaradas todas las dudas y consultas, se procede a firmar el presente documento:

Fecha:

Firma del investigador:

Carta de revocación del consentimiento

Título del protocolo: **Programa común de Ejercicio Físico Terapéutico con dosificación individual frente a la mejor práctica actual en tendinopatías de miembros inferiores: ensayo clínico aleatorizado**

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Nombre y edad del paciente:

Por este conducto deseo informar mi decisión de retirarme de este protocolo de investigación por las siguientes razones:

Firma del participante:

Fecha:

Nombre y firma del testigo (sólo si corresponde):

Fecha:

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