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*

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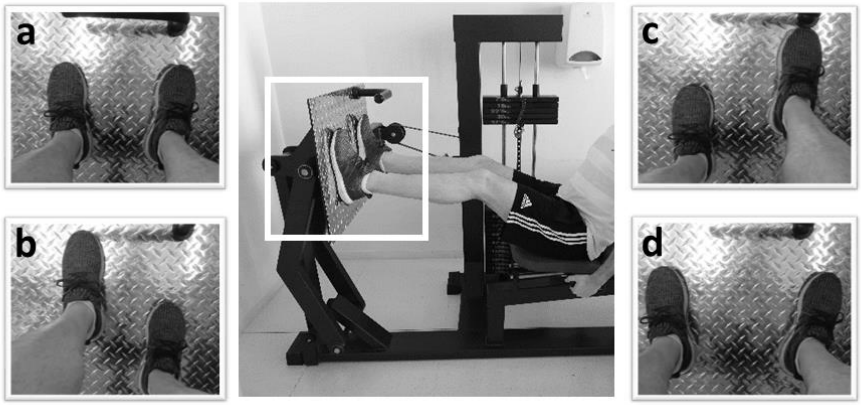
Figure 1. Foot position during the four movements of the exercises. a) Feet shoulder-width apart; b) Left foot forward; c) Right foot forward; d) Feet apart with 45° external rotation.



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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