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Blood flow restriction training in tennis elbow (lateral epicondylitis)

Submission date
24/10/2019

Recruitment status
No longer recruiting

Registration date
20/01/2020

Overall study status
Completed

Last Edited
13/12/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with lateral elbow epicondylitis (or tennis elbow) are treated with physiotherapy. The use of specific exercises is a common and effective intervention for the safest and fastest recovery. The use of additional specific exercises with blood flow restriction at the extremities has been suggested to deliver significant results, faster and with less pain. However, it is not yet known whether they are more effective in lateral elbow tendinopathy. Therefore, the aim of this study is to assess the effectiveness of these exercises in patients with external elbow tendinopathy.

Who can participate?
Patients aged 18-50 with external elbow tendinopathy lasting for more than two weeks

What does the study involve?
Patients are divided into two groups. One group does exercises with blood flow restriction and the other without restriction. Sessions are held twice a week and the process takes a total of 6 weeks. Participants undergo an additional re-evaluation visit after 12 weeks.

What are the possible benefits and risks of participating?
Although there is no additional benefit to participation, this study aims to significantly improve the care of patients with lateral elbow tendinopathy in the immediate future. Participation is voluntary and non-participation will not affect the quality of the treatment services received. Participants are free to leave the study at any time without having to explain the reasons. Contraindications and risks to participation are minimal and common to any form of active treatment. Applying the exercises can rarely cause local reactions such as muscle discomfort, tenderness or numbness for 24-48 hours due to pressure in the area. The feeling is like the muscle soreness one experiences when returning to exercise after a long absence. Personal data collected will be kept strictly confidential by the principal investigator. Research staff and therapists will only know the necessary details. The information will be encrypted so that it cannot be identified.

Where is the study run from?
University of West Attica (Greece)

When is the study starting and how long is it expected to run for?
March 2019 to December 2021 (updated 23/03/2021, previously: March 2021)

Who is funding the study?
University of West Attica (Greece)

Who is the main contact?
1. Stefanos Karanasios PhD Cand, MSc, PT
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2. Prof. Georgios Gioftsos
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20191023SK

Study information

Scientific Title
The effects of low load resistance training with blood flow restriction in patients with lateral elbow tendinopathy: a randomized controlled trial

Acronym
Blood Flow Restriction (BFR), Lateral Elbow Tendinopathy (LET)

Study objectives
Low load resistance exercises with blood flow restriction are more effective in increasing strength, reducing pain and improving function compared to usual exercises in patients with lateral elbow tendinopathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/06/2020, Research Ethics Committee University Of West Attica (UNIWA, Egaleo Park Campus, Agiou Spiridonos 28, 12243 Egaleo, Athens, Greece; +30 (0)2105387294; ethics@uniwa.gr), ref: 36898 / 03-06-2020

Study design
Single-center triple-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Lateral elbow tendinopathy (tennis elbow)

Interventions
Participants will be randomized with an appropriate software https://www.randomizer.org/ to either a blood flow restriction exercise programme or a placebo blood flow restriction exercise programme. A concealed allocation will be applied. Assessor, therapists and patients will be blinded.

Both groups of patients will be treated with a usual exercise programme in lateral elbow tendinopathy. One group will use blood flow restriction and the other group placebo blood flow restriction (cuffs without air inflated). The exercise programmes will be held in physiotherapy sessions (twice a week) for 6 weeks. Also, all patients will be treated with soft tissue massage and the same appropriate advice and a home exercise programme.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Pain-free grip strength: the mean value (kg) of three efforts presented as a ratio of the maximum grip strength of the unaffected side will be included A Jamar hand dynamometer is used. Measured at baseline, 6 and 12 weeks follow-up
2. Pain and functional disability measured using the patient-rated tennis elbow (PRTEE) questionnaire at baseline, 6 weeks and 12 weeks follow-up.
3. Pain measured using the visual analogue score (NRPS) at baseline, 6 and 12 weeks

Secondary outcome measures
1. Tendon thickness, neovascularity, presence of spurs, calcification and/or tears in the common extensor tendon (lateral epicondyle) measured using diagnostic ultrasound imaging at baseline, 6 and 12 weeks follow-up
2. Isometric strength of elbow flexors and extensors measured using Bio Fet force evaluation system (mean of three efforts of the maximum isometric contraction) at baseline, 6 and 12 weeks follow-up
3. Self-perceived recovery measured using 6-point Global Rating Of Change (GROC) scale at 6 and 12 weeks follow-up

Overall study start date
01/03/2019

Completion date
30/12/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/07/2020:
1. Men and women 18-50 years old diagnosed with LET
2. Symptoms for over 2 weeks
3. Pain provoked by palpation on the lateral epicondyle
4. Positive: Cohen's test, Maudsley test, Mill's test
5. A decrease in pain grip strength >5% in elbow extension compared to flexion

Previous inclusion criteria:
1. Men and women 18-50 years old diagnosed with LET
2. Symptoms for over 2 weeks
3. Pain provoked by palpation on the lateral epicondyle
4. Positive: Cohen's test, Maudsley test, Mill's test
5. Pain grip strength ratio >5% on unhealthy side compared to the healthy one

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Shoulder tendinopathy
2. Cervical radiculopathy
3. Rheumatoid arthritis
4. Neurological deficit
5. Radial nerve entrapment
6. Past treatment for the elbow before entering the study
7. Professional athletes
8. Lateral elbow tendinopathy of the same side in the last 3 years
9. Serious cardiovascular diseases
10. Venous deficiency
11. History of heart surgery
12. Cancer history
13. Breast surgery
14. Orthopaedic surgeries during the last 6 months
15. Thrombosis
16. Body mass Index ≥ 30
17. Crohn syndrome
18. Family or personal history of pulmonary embolism

Date of first enrolment
01/02/2020

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Greece

Study participating centre
Physio Kifisia
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Sponsor information

Organisation
University of West Attica

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Sponsor type
University/education

Website
https://www.uniwa.gr/en/home-page/

Funder(s)

Funder type
University/education

Funder Name
University of West Attica

Results and Publications

Publication and dissemination plan
A study protocol is not currently available online. At the end of data analysis, the results of the study will be published in international congress and electronic scientific journals.

Intention to publish date
24/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Stefanos Karanasios (physio.manual@gmail.com). Type of data: row data of primary and secondary outcome measures. Availability: from 31/03/2021. Access criteria: systematic reviews and meta-analysis, quantitative synthesis for studies in the same scope of interest, peer review reasons. Mechanisms: upon request. Consent from participants is obtained according to GDPR data protection.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			27/03/2020	No	No