Testing how light resistance exercises with blood flow restriction can help treat tennis elbow: a controlled study

Submission date 08/01/2025	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 14/01/2025	Overall study status Completed	 Statistical analysis plan Results
Last Edited 10/01/2025	Condition category Musculoskeletal Diseases	[] Individual participant data[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Blood flow restriction (BFR) training is a specialized exercise method that has gained attention for its ability to enhance the effects of resistance training, even when performed with low weights or resistance. This makes it particularly useful for individuals who are unable to engage in high-intensity resistance training, such as those with certain clinical conditions or musculoskeletal injuries. Traditional high-intensity strength training can be challenging and sometimes risky for these populations, leading to potential complications or prolonged recovery periods. Lateral epicondylitis, commonly known as tennis elbow, is a condition characterized by pain and tenderness on the outer part of the elbow, typically resulting from overuse of the forearm muscles. It is a common musculoskeletal injury that can significantly affect daily activities and overall quality of life. Patients with lateral epicondylitis often require rehabilitation programs to manage pain and restore function. This study aims to explore the potential benefits of incorporating BFR into a low-intensity therapeutic exercise program specifically designed for patients with lateral epicondylitis. Over 4 weeks, the study seeks to determine whether BFR could improve recovery outcomes, reduce pain, and enhance muscle strength more effectively than standard low-intensity.

Who can participate?

Patients who have been diagnosed with lateral epicondylitis for more than one month

What does the study involve?

Participants will be asked to engage in a therapeutic exercise program that incorporates BFR. The program will be conducted over 4 weeks, with participants attending sessions three times per week. Each session involved low-intensity resistance exercises targeting the muscles of the forearm and upper arm, which are typically affected in lateral epicondylitis. Participants perform the prescribed exercises under the supervision of trained therapists

What are the possible benefits and risks of participating?

Participating in this study offered several potential benefits. First and foremost, the inclusion of BFR in the rehabilitation program is expected to enhance the training effects compared to

standard low-intensity exercises. This means that participants might experience better muscle strength and quicker recovery with less overall effort. However, it is important to note that while BFR has shown promise in enhancing training effects, it might not necessarily lead to better outcomes for every participant.

Where is the study run from?

The study was conducted at a hospital located in southern Taiwan, which provided a clinical setting equipped with the necessary facilities and staff to conduct the rehabilitation program.

When is the study starting and how long is it expected to run for? March 2022 to December 2022

Who is funding the study? Ministry of Science and Technology, Taiwan

Who is the main contact? 1. Chong-Qing Wu, altl0411@hotmail.com 2. Lan-Yuen Guo, yuen@kmu.edu.tw

Contact information

Type(s) Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers B11102

Study information

Scientific Title

Investigating the clinical efficacy of low-intensity resistance training combined with blood flow restriction in the management of lateral epicondylitis: a randomized parallel study

Study objectives

For patients with musculoskeletal injuries, low-intensity training could provide specific benefits of exercise effect than the traditional physical therapy

Ethics approval required Ethics approval required

Ethics approval(s)

Approved 22/04/2022, Pingtung Christian Hospital Institutional Review Board (No. 60, Ta-Lian Road, Pingtung, 900, Taiwan; +886 8 7368686; 03549@ptch.org.tw), ref: IRB707B

Study design Randomized controlled parallel design study

Primary study design Interventional

Secondary study design Randomised parallel trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Therapeutic exercise for lateral epicondylitis

Interventions

This is a randomized controlled parallel design study that evaluates participants diagnosed with lateral epicondylitis. Participants will be randomly assigned to either the experimental group with low-intensity resistance with blood flow restriction training (LR-BFR) or the control group with low-intensity resistance training only using a lottery system. Both groups will receive 4 weeks of intervention. Participants attend three sessions per week, making a total of 12 sessions throughout the study. Each session lasted approximately 30 to 45 minutes.

Intervention Type

Behavioural

Primary outcome measure

The following primary outcome measures are assessed before and after the training period:

- 1. Pain measured using a Visual Analogue Scale (VAS)
- 2. Tenderness threshold measured using an algometer

3. Pain-free grip strength (PFGS) measured using a dynamometer

Secondary outcome measures

Pain and disability associated with lateral epicondylitis measured using the Patient-Rated Tennis Elbow Assessment (PRTEE) before and after the training period

Overall study start date

01/03/2022

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Participants between the ages of 30 and 60 years who were diagnosed with lateral epicondylitis by a physician

2. Unilateral elbow pain persisting for more than 1 month

3. No significant improvement in pain around the lateral epicondyle of the humerus within 4 weeks despite medication/physical therapy

Participant type(s)

Patient

Age group Adult

Lower age limit 30 Years

Upper age limit 60 Years **Sex** Both

Target number of participants 60

Total final enrolment

12

Key exclusion criteria

1. History of elbow trauma, ligament injury, fracture, tumor, or surgery

2. Diagnosed or treated for cervical radiculopathy or systemic arthritis

3. Presence of cardiovascular disease (eg, heart disease, varicose veins, peripheral arterial disease, Raynaud's syndrome, etc.)

4. Administration of corticosteroid injections, proliferation therapy, or similar medications within the past 3 months

5. Bilateral elbow pain

6. Previous experience with blood flow restriction training

Date of first enrolment

22/04/2022

Date of final enrolment

31/08/2022

Locations

Countries of recruitment

Taiwan

Study participating centre Ministry of Health and Welfare Pingtung Hospital No. 270, Ziyou Road, Pingtung City, Taiwan Pingtung County Taiwan 90054

Sponsor information

Organisation Pingtung Hospital

Sponsor details

Department of Rehabilitation, Ministry of Health and Welfare Pingtung Hospital No. 270, Ziyou Road

Pingtung City Taiwan 900027 +886 8-7363011#2126 rehab@pntn.mohw.gov.tw

Sponsor type University/education

Website https://www.pntn.mohw.gov.tw/english/

ROR https://ror.org/039f5ga37

Funder(s)

Funder type Government

Funder Name Ministry of Science and Technology, Taiwan

Alternative Name(s) Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type Government organisation

Funding Body Subtype National government

Location Taiwan

Results and Publications

Publication and dissemination plan Planned publication in a peer-reviewed journal

Intention to publish date 30/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Chong-Qing Wu, altl0411@hotmail.com and Lan-Yuen Guo, yuen@kmu.edu. tw

• The type of data that will be shared: Statistical analysis results derived from participant-level data will be shared

• Timing for availability: after research publication

• Whether consent from participants was required and obtained: Consent for data sharing was obtained from participants as part of the informed consent process during recruitment.

• Comments on data anonymization: All shared data will be fully anonymized to protect participant confidentiality

• Any ethical or legal restrictions: Data sharing is subject to approval from the ethics committee and will comply with institutional policies and applicable legal regulations. Access to data will be granted only for non-commercial research purposes and under a data-sharing agreement

• Any additional comments: The data will be shared upon reasonable request, provided that the requestor submits a clear research proposal outlining the intended use of the data and agrees to comply with ethical and legal guidelines for data use. Additional supporting documents, such as the study protocol, will also be available upon request

IPD sharing plan summary

Available on request