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The efficacy of heavy slow resistance training combined with ultrasound therapy in patellar tendinopathy

Submission date
24/01/2024

Recruitment status
No longer recruiting

Registration date
17/02/2024

Overall study status
Completed

Last Edited
14/10/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Patellar tendinopathy (PT) is a common chronic sports injury that occurs in sports such as basketball, volleyball, and others with high demands for jumping, causing significant distress to athletes. Currently, there are few studies on combination therapy for PT. This study aimed to investigate the efficacy of high-intensity low-speed resistance training (HSR) training combined with high-dose therapeutic ultrasound (TUS) for treating PT in young individuals, aiming to explore a highly efficient intervention method for improving PT.

Who can participate?
Students aged 18-35 years old from Wuhan Sports University diagnosed with distal PT following physical examination and imaging

What does the study involve?
Participants will be recruited and randomly assigned to three groups: a combined HSR and high-dose TUS treatment group, an HSR training group, and a high-dose TUS treatment group. The intervention lasts for 8 weeks. Questionnaires and horizontal jumping distance will be used for inter-group data comparison and analysis. Lower extremity extensor muscle strength will also be recorded using the Maximum Isometric Muscle Strength Test system. Musculoskeletal ultrasound is used to measure patellar tendon thickness and blood flow. The kinematic characteristics of the participants will also be analyzed. Additionally, a follow-up at week 16 will be conducted using further questionnaires.

What are the possible benefits and risks of participating?
There is potential for significant improvement in symptoms of PT pain, reduction in patellar tendon thickness, decreased blood flow within the patellar tendon, increased lower extremity stability, and enhanced muscle strength of the lower extremity. This study may offer an effective treatment option for other patients with similar conditions, potentially alleviating their symptoms, reducing healthcare expenses, and lessening the burden on both families and communities. All equipment and devices used for data collection will be sterilized, and the loading protocol of the study will be individualized based on each subject's cardiorespiratory

capacity. Furthermore, all intervention methods are safe and do not pose any adverse effects on the participants' health.

During the intervention process, subjects may experience difficulties in tolerating the exercise load and may exhibit symptoms such as panic or chest tightness. Nonetheless, all interventions will be conducted under the supervision of trained professionals, who can promptly address any discomfort.

Where is the study run from?
Wuhan Sports University Sports Rehabilitation Center (China)

When is the study starting and how long is it expected to run for?
July 2022 to May 2023

Who is funding the study?
Wuhan Sports University

Who is the main contact?
Mr Fengliu Xiao,17857500763@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2023025

Study information

Scientific Title

Comprehensive assessment of heavy slow resistance training and high-dose therapeutic ultrasound in managing patellar tendinopathy

Study objectives
To observe the efficacy of 8 weeks of HSR training combined with high-dose therapeutic ultrasound in patients with PT, and to provide a safe and effective exercise prescription for the clinic to promote patients' recovery

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/07/2022, Medical Ethics Committee of Wuhan Institute of Physical Education (Wu Han Sports University, NO.46, Luoyu Road, Hong Shan District, Wuhan, 430070, China; +86 027-87191823; wtdzb@whsu.edu.cn), ref: 2023025

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Options of treatment in junior people with patellar tendinopathy

Interventions
This study is designed as a single-blind randomized controlled trial. The objective is to assess the effectiveness of heavy slow resistance (HSR) therapy in combination with high-dose therapeutic ultrasound (TUS) and combined therapy for patellar tendinopathy by comparing pre- and post-intervention data. Rigorous experimental protocols are implemented, limiting the study to the Sports Intervention Center of Wuhan Institute of Physical Education, employing a consistent experimental site, and enlisting a highly trained therapist.

College students with patellar tendinopathy will be recruited from Wuhan Sports University and randomly divided into three groups: an HSR training group, a comparative TUS treatment group and a combined group. The imaging physicians are blinded. A random assignment program of concealment was used: opaque envelopes with a certain sequence. Subjects were evenly distributed into three groups in numerical order.

In the HSR training group, participants undergo three training sessions per week, each comprising three exercises: deep squat, leg press, and Bulgarian deep squat. These exercises are performed bilaterally on the body, with a 2-minute rest between each set. The repetitions/load intensity follows a progressive pattern: 12RM in the first to the second week, 10RM in the third to the fourth week, 8RM in the fifth to the sixth week, and 6RM in the sixth to the eighth week.

For the TUS group, high-energy dose Transcutaneous Ultrasound (TUS) using the Ultrasound Unit US-700 from Japan is specifically applied to the patellar tendon region. The subject's patellar tendon maintains full contact with the conductor of the high-energy dose TUS, with gel

serving as the conductor. Throughout the procedure, the subject is in a supine position, with a cushion supporting the knee for immobilization, and the knee slightly flexed at approximately 20°. In cases of bilateral symptoms, the knee with the most severe symptoms receives treatment with a high-energy dose TUS, set at 1MHz for 10 minutes in a continuous mode.

For the combined group, participants undergo high-energy dose TUS immediately after completing the training session. The parameters, time, setup, position of the subjects, and materials used for high-energy dose TUS are identical to those in the TUS group.

Intervention Type
Mixed

Primary outcome(s)
1. Improvement in subjects with patellar tendinopathy (PT) measured using the Victorian Institute of Sport Assessment Scale for Patellar Tendinopathy (VISA-P) questionnaire scores at baseline, 8 weeks and 16 weeks
2. Pain in subjects with PT measured using Visual Analogue Score (VAS) scores at baseline and 8 weeks

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline and 8 weeks:
1. Improvement in balance in subjects with patellar tendinopathy (PT) measured using the Y-Balance Test (YBT)
2. Quadriceps flexibility measured using the Modified Tomas Test
3. Improvement in strength and jumping ability measured using appropriate testing equipment
4. Patellar tendon thickness and blood flow in the tendon measured using a musculoskeletal ultrasound detector

Completion date
30/05/2023

Eligibility

Key inclusion criteria
1. Subjects with a Victorian Institute of Sport Assessment-Patella (VISA-P) questionnaire score of <80 out of 100
2. History of patellar tendon pain related to training or competition
3. Structural changes in the patellar tendon on grey-scale ultrasound and/or increased tendon vascular distribution on energy Doppler
4. Significant tenderness on palpation near the end of the patellar tendon and pain limited to the inferior level of the patella
5. Pain aggravated by squatting or jumping. Ultrasonography was performed by a 15-year-experienced sonographer and was positive for the presence of patellar tendon structural changes and/or hypoechoic changes and/or thickening of the patellar tendon (anterior-posterior diameter >6 mm) and/or increased intra-tendinous Doppler flow

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Duration of pain less than three months
2. Acute knee or patellar tendon injury with a history of knee surgery in the past year
3. Presence of inflammatory arthropathy with the use of potentially affecting patellar tendon medications (e.g., quinolones) in the past year
4. Use of corticosteroids for topical injections in the past month
5. History of past patellar tendon rupture
6. Inability to perform an exercise program or participate in other treatment programs
7. Inability to perform an exercise program or participate in other treatment programs, and other coexisting lesions identified by physical examination or ultrasound/MRI
8. Exercise program, or participation in another treatment program, physical examination or ultrasound/MRI findings of other coexisting knee pathology
9. Inability to undergo high-energy dose ultrasound therapy or indications that ultrasound is contraindicated such as (active tuberculosis, bleeding tendency, severe cardiac disease, malignant tumors, venous thrombosis, and pregnant women)

Date of first enrolment
01/08/2022

Date of final enrolment
15/03/2023

Locations

Countries of recruitment
China

Study participating centre
Wuhan Sports University Sports Rehabilitation Center
NO.46, Luoyu Road, Hong Shan District
WUHAN
China
430070

Sponsor information

Organisation
Wuhan Sports University

ROR
https://ror.org/004je0088

Funder(s)

Funder type
University/education

Funder Name
Wuhan Sports University

Alternative Name(s)
, , Wǔhàn Tǐyù Xuéyuàn, WSU, WHSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be stored in a publically available repository, https://db.yaozh.com/cpg

• The type of data stored: Electronic data
• The process for requesting access (if non-publicly available)
• Timing for availability: Data will be available after the study is published
• Whether consent from participants was required and obtained: Consent had been obtained from the participants

• Comments on data anonymization: Data has been anonymized
• Any ethical or legal restrictions: No ethical or legal restrictions
• Any additional comments: No additional comments

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/10/2024	14/10/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes