Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Neuromuscular training program for treatment of male basketball players with medial tibial stress syndrome: emphasis on attentional focus and external cues in functional movement training.

Protocol summary

Study aim
Comparison of neuromuscular exercises with external focus with therapeutic exercises on reduce pain, Improvem function, kinematic and kinetic in men basketball players with medial tibial stress syndrome

Design
Two arm parallel group randomised trial with blinded outcome assessment

Settings and conduct
Assessments are in baseline, after 6-week intervention, 3, 6, and 12 months of follow-up by a blind assessor, and variables include pain, function, muscle strength, kinematics, and kinetics. All measurements are performed in the university laboratory.

Participants/Inclusion and exclusion criteria
Inclusion criteria included those aged between 18 and 35 years with medial tibial stress syndrome for at least 3 weeks' exercise, induced pain that is located on the posteromedial border of the tibia, palpation of the posteromedial border of the tibia that produces discomfort, will be diagnosed experience sports medicine. The exclusion criteria will be having a history of tibial fracture, clinical suspicion of chronic compartment syndrome or stress fracture.

Intervention groups
In Experimental Group 1 (neuromuscular exercises with external focus) include eight types of exercises, double-leg squat, single-leg squat, lunges (walking), double-leg drop jump, single-leg standing on an unstable plate, sidestep cutting maneuver, single-leg hop for distance, vertical jump, and Countermovement jump. In Experimental Group 2 (therapeutic exercises), the exercises consisted of 3 stages of release techniques (use of foam roll with focus on lateral gastrocnemius, peroneals, and biceps femoris (short head) muscles), stretching (focusing on gastrocnemius/soleus, and biceps femoris (short head), is activation (increasing the strength of the muscles of the anterior, posterior tibialis, and medial hamstrings).

Main outcome variables
Pain, function, lower limbs muscle strength, kinematics, and kinetics

General information

Reason for update
Adding the volume of the true sample and the start and end date of the patient recruitment.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210718051938N1**
Registration date: **2021-08-01, 1400/05/10**
Registration timing: **prospective**

Last update: **2023-05-27, 1402/03/06**
Update count: **2**

Registration date
2021-08-01, 1400/05/10

Registrant information

Name
Mojtaba Jahanshahi
Name of organization / entity
Kharazmi University
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-08-09, 1400/05/18

Expected recruitment end date

2021-09-16, 1400/06/25

Actual recruitment start date

2021-08-11, 1400/05/20

Actual recruitment end date

2021-10-30, 1400/08/08

Trial completion date

empty

Scientific title

Neuromuscular training program for treatment of male basketball players with medial tibial stress syndrome: emphasis on attentional focus and external cues in functional movement training.

Public title

Effect of neuromuscular training on improving medial tibial stress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male basketball players between 18 and 35 years ages For at least 3 weeks' exercise, induced pain located on the posteromedial border of the tibia, palpation of the posteromedial border of the tibia that produces discomfort, will be diagnosed by experienced sports medicine.

Exclusion criteria:

Having a history of tibial fracture Clinical suspicion of chronic compartment syndrome or stress fracture

Age

From **18 years** old to **35 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **72**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Following the baseline examination, by using the method on the website http://randomizer.org participants are randomly assigned into the two experimental groups (neuromuscular training with an attentional focus), (therapeutic exercise), and control group. Simple randomization is used. Concealed allocation is performed using a computer generated block randomized table of numbers (1 and 2 for experimental groups and 3 for control group) created before the start of data collection by researcher who is not involved in the recruitment or treatment of patients. Then, the random numerical sequence is placed in sealed opaque envelope and processed with treatment according to the group assignment. A blinded outcome assessor who does not know the hypothesis and study methods, measures outcome at baseline, 6 weeks post-intervention, and 12 weeks follow-up.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor was blind to the process of randomization and assignment of individuals into two experimental groups and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran

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Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-06-21, 1400/03/31

Ethics committee reference number

IR.SSRC.REC.1400.053

Health conditions studied

1

Description of health condition studied

Medial tibial stress syndrome

ICD-10 code

S86.89

ICD-10 code description

Other injury of other muscles and tendons at lower leg level

Primary outcomes

1

Description

Pain

Timepoint

Baseline, 6 weeks after intervention, 3, 6, and 12 months follow up

Method of measurement

How to measure a variable is using Visual Analogue

Scale

Secondary outcomes

1

Description
Function
Timepoint
Baseline, 6 weeks after intervention, 3, 6, and 12 months follow up
Method of measurement
How to measure a variable is using vertical jump

2

Description
Muscle strength
Timepoint
Baseline, 6 weeks after intervention, 3, 6, and 12 months follow up
Method of measurement
How to measure a variable is using Biodex System isokinetic.

3

Description
Kinematic
Timepoint
Baseline, 6 weeks after intervention, 3, 6, and 12 months follow up
Method of measurement
How to measure a variable is using Visual3D software (C-motion Inc, Germantown).

4

Description
Kinetic, Tibia acceleration and Time to Stabilization
Timepoint
Baseline, 6 weeks after intervention, 3, 6, and 12 months follow up
Method of measurement
How to measure a variable is using Two three-axis force plates (AMTI model) in vertical, anterior-posterior, and medial-lateral.

Intervention groups

1

Description
First intervention group: Benjaminse et al. (2015) training protocol will be used for the first intervention group. These exercises include eight different types of exercises, in each of which the feedback and verbal training appropriate to that exercise is given to the subjects before the exercise and also during the exercise. People will receive the necessary feedback during practice and will perform well. Feedback exercises include eight types of exercises,double-leg squat, single-leg squat, lunges (walking), double-leg drop jump, single-leg standing on an unstable plate, sidestep cutting maneuver, single-leg hop for distance, vertical jump, and Countermovement jump. During the exercises, the feedback instructions verbally and visually, using learning strategies, applied external attention to the subjects, and influenced their movements during the exercise. For example, in order to perform single-leg squat movements, subjects are asked to stand in front of a conical obstacle and slowly bend their legs in the direction of the cone while descending and bending their knees, focusing on the cone. External focus).
Category
Rehabilitation

2

Description
Second intervention group: Second intervention group: Exercises include 3 stages of release, stretching, and activation techniques. The subject is asked to participate in the main exercise program after warm-up, which includes release, stretching, and activation exercises. In the first phase, people will use release exercises using a foam roll focusing on the lateral gastrocnemius, peroneals, and biceps femoris (short head) muscles. Exercises with two high intensities (maximum pain tolerance) are performed in 30 seconds or low intensity (minimum pain tolerance) in 90 seconds. Stretching phase exercises are performed focusing on the gastrocnemius/soleus, and biceps femoris (short head). The intensity and volume of the exercises include 3 sets of 30 seconds. The third phase, the activation phase, will focus on increasing the strength of the anterior, posterior tibialis, and medial hamstring muscles. These exercises are performed with 10 to 15 repetitions and each repetition includes 1 to 2 seconds, maintaining isometric contraction at the end of the range of motion and 4 seconds maintaining extroverted contraction.
Category
Rehabilitation

3

Description
Control group: The control group will not receive any intervention and will perform their routine (basketball) exercises.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharazmi University Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
No governmental fund has been received for this study, and it is conducted by researchers.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only data related to demographic and outcomes information is shared.
When the data will become available and for how long
After publishing the article / articles extracted from the study.
To whom data/document is available
The data can be displayed and shared at the reasonable request of the Iranian Clinical Trial Registration Center, journals and university individuals / researchers who are conducting research and scientific activities in this field.
Under which criteria data/document could be used
Data analysis and use of documents can only be done provided that their results are presented in systematic review articles conducted by researchers and academic researchers. Necessary conditions for sending data and documents include: 1. Sending an email (preferably with valid university addresses) to one of the researchers of the study. 2. A brief and logical explanation of how to use the data or documents. 3. Ensuring the registration of the protocol Systematic review studies that have requested access to data or documentation.
From where data/document is obtainable
Through requesting from Mojtaba Jahanshahi: Mojtaba-jahanshahi@yahoo.com Amir Letafatkar: letafatkaramir@yahoo.com Robert baker: rb415@comcast.net Michael Fredericson: mfred2@stanford.edu
What processes are involved for a request to access data/document
The applicant can request details from the researchers within 7 to 14 days using the message sent by email.
Comments