Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the added effect of dry cupping on therapeutic exercise in improving pain and function in patients withmedial tibial stress syndrome A randomized clinical trial

Protocol summary

Study aim

To evaluate the added effect of dry cupping plus therapeutic exercise on pain, ankle range of motion, and function

Design

A single-blind randomized controlled trial with two parallel groups. 40 participants will be randomly assigned into two groups of 20 by simple randomization. The assessor will be blinded to group allocation. The study will be conducted in Qom, Iran.

Settings and conduct

The study will be conducted at Abooreyhan Physiotherapy Clinic in Qom, Iran. Recreational runners will be recruited. After informed consent, they will be randomly allocated to control or intervention group. Both groups will receive therapeutic exercise for 4 weeks (12 sessions), and the intervention group will also receive dry cupping. Pain, ankle range of motion, and function will be measured before, after, and two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of medial tibial stress syndrome by history and clinical signs; recreational runners aged 18 to 45 years; no physical therapy for this syndrome in the last 6 months. Exclusion criteria: systemic metabolic or metastatic disease or skin infection; wound in the treatment area; bleeding disorders or anticoagulant use; pregnancy; sports other than recreational running.

Intervention groups

Control: standard therapeutic exercise including strengthening and stretching of plantar flexor muscles and ice massage, 4 weeks (12 sessions). Intervention: the same exercise plus dry cupping on the calf with a plastic cup and negative pressure matched to pain threshold, 4 weeks (12 sessions).

Main outcome variables

Pain severity; ankle dorsiflexion range of motion in weight-bearing position; ankle dorsiflexion range of motion in non-weight-bearing position; ankle plantarflexion range of motion in non-weight-bearing position; lower limb function by single leg distance hop test.

General information

Reason for update

Acronym

DCE-MTSS(از برگرفته Dry Cupping + Exercise + Medial Tibial Stress Syndrome)

IRCT registration information

IRCT registration number: **IRCT20190909044734N6**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date

2026-09-28, 1405/07/06

Registrant information

Name

Leila Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 1551

Email address

leilaabbasi.le@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-05, 1405/08/14

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the added effect of dry cupping on therapeutic exercise in improving pain and function in patients withmedial tibial stress syndrome A randomized clinical trial

Public title

Investigating the added effect of dry cupping and therapeutic exercise on improving patients with medial tibial stress syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Medial Tibial Stress Syndrome (MTSS) based on history and clinical signs Recreational runners who have not undergone physical therapy for MTSS in the last 6 months Age between 18 and 45 years Willingness and ability to participate in treatment sessions for 3 weeks

Exclusion criteria:

Presence of systemic diseases including metabolic diseases, metastatic diseases or skin infections Presence of wound in the treatment area taking anticoagulant medications History of physical therapy for MTSS in the last 6 months Participation in sports other than recreational running Pregnancy Suffering from bleeding disorders

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using the website www.randomizer.org is performed. The random allocation sequence is generated by the thesis supervisor. For allocation concealment, opaque sealed envelopes are used, which are prepared in advance according to the sample size. At the time of enrollment, one envelope is opened and the participant's group assignment is determined. The unit of randomization is individual.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blinded to the group allocation. The physiotherapist who evaluates the outcomes will not be informed about whether the patient is in the control or intervention group. Patients are instructed not to discuss their treatment with the assessing physiotherapist. Blinding of patients and therapists is not possible due to the obvious effects of cupping (such as bruising and visible marks), so the study is open-label for patients and therapists. Additionally, the vacuum gauge is covered with a shield, and both the therapist and patient cannot see the gauge reading until the patient has reported the NPRS score.

Placebo

Not used

Assignment

Parallel

Other design features

This is a randomized controlled trial (RCT) with a single-blind, parallel-group design. The intervention is conducted in ۱۲sessions over ۴ weeks. Outcome assessments are performed at three time points: baseline (before intervention), immediately after the intervention (week ۴), and two weeks after the completion of the intervention (follow-up). Due to the non-pharmacological nature of the interventions, no placebo is used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee of the School of Rehabilitation Sciences affiliated with Shiraz Unive

Street address

Shahid Douran Campus

City

Sadra City, Shiraz

Province

Fars

Postal code

7198754361

Approval date

2026-07-12, 1405/04/21

Ethics committee reference number

IR.SUMS.REHAB.REC.1405.008

Health conditions studied

1

Description of health condition studied

Medial Tibial Stress Syndrome (MTSS)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of pain in the leg during the past two week
Timepoint
Measurement of pain severity before the intervention, after the intervention, and two weeks after the end of the intervention
Method of measurement
Visual Analogue Scale for pain

2

Description
Ankle dorsiflexion range of motion in weight-bearing position
Timepoint
Measurement of ankle dorsiflexion range of motion in weight-bearing position before the intervention, after the intervention, and two weeks after the end of the intervention
Method of measurement
Goniometer

3

Description
Ankle dorsiflexion range of motion in non-weight-bearing position
Timepoint
Measurement of ankle dorsiflexion range of motion in non-weight-bearing position before the intervention, after the intervention, and two weeks after the end of the intervention
Method of measurement
Goniometer

4

Description
Ankle plantarflexion range of motion in non-weight-bearing position
Timepoint
Measurement of ankle plantarflexion range of motion in non-weight-bearing position before the intervention, after the intervention, and two weeks after the end of the intervention
Method of measurement
Goniometer

5

Description
Lower limb function based on the single leg hop test
Timepoint
Before the intervention, after the intervention and two weeks after the end of the intervention
Method of measurement
The patient hops forward as far as possible on the affected leg and lands on the same leg. The distance from the starting line to the heel is measured in centimeters. Three attempts are performed, and the best distance is recorded.

6

Description
Age
Timepoint
Before the intervention
Method of measurement
Questionnaire

7

Description
Sex
Timepoint
Before the intervention
Method of measurement
Questionnaire

8

Description
Height
Timepoint
Before the intervention
Method of measurement
Measuring tape

9

Description
Body mass index
Timepoint
Before the intervention
Method of measurement
Calculation of weight in kilograms divided by height in meters squared

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with medial tibial stress syndrome in this group receive therapeutic exercise plus dry cupping. Therapeutic exercise protocol: (1) Strengthening of plantar flexor muscles: The patient stands with the toes of the affected foot on a step, while the heel is lifted and the weight is on the forefoot. The patient holds this position for 5 seconds and then slowly returns to the starting position. The patient performs 3 sets of 15 repetitions. After reaching a score of 3 out of 10 on the Visual Analogue Scale for pain, the load is increased so that the patient performs 3 sets of 6 repetitions with maximum tolerance. (2) Stretching of plantar flexor muscles: The patient stands facing a wall with the affected leg behind, knee slightly bent, and toes

slightly inward. The heel of both feet must be completely on the ground. The patient performs 5 repetitions of 30 seconds with 10 seconds rest between sets, and moves the body backward until a stretch is felt. Then, ice massage is applied to the calf muscles for 15 minutes using an ice bag at room temperature. Dry cupping protocol: The patient lies in a side-lying or prone position with the knee and ankle in a neutral anatomical position. A plastic cupping cup with an outer diameter of 45 millimeters and a volume of 75 milliliters, equipped with a manual air evacuation applicator and a negative pressure gauge connected via a silicone tube, is applied firmly to the lower third of the line connecting the medial malleolus to the medial border of the tibia. Negative pressure inside the cup is gradually increased until the pain intensity reaches 3 out of 10 on the Numerical Pain Rating Scale, and the cup is kept in place for 5 minutes. The same procedure is immediately performed below the attachment of the gastrocnemius muscle to the Achilles tendon. The intervention is performed for 4 weeks, 3 sessions per week, for a total of 12 sessions. Each session lasts 15 minutes of exercise plus cupping.

Category

Rehabilitation

2

Description

Control group: Patients with medial tibial stress syndrome in this group receive therapeutic exercise alone. Therapeutic exercise protocol: (1) Strengthening of plantar flexor muscles: The patient stands with the toes of the affected foot on a step, while the heel is lifted and the weight is on the forefoot. The patient holds this position for 5 seconds and then slowly returns to the starting position. The patient performs 3 sets of 15 repetitions. After reaching a score of 3 out of 10 on the Visual Analogue Scale for pain, the load is increased so that the patient performs 3 sets of 6 repetitions with maximum tolerance. (2) Stretching of plantar flexor muscles: The patient stands facing a wall with the affected leg behind, knee slightly bent, and toes slightly inward. The heel of both feet must be completely on the ground. The patient performs 5 repetitions of 30 seconds with 10 seconds rest between sets, and moves the body backward until a stretch is felt. Then, ice massage is applied to the calf muscles for 15 minutes using an ice bag at room temperature. The intervention is performed for 4 weeks, 3 sessions per week, for a total of 12 sessions. Each session lasts 15 minutes of exercise.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Abooreyhan Physiotherapy Clinic

Full name of responsible person

Saeid Ghasemi Dashti

Street address

Khakfaraj, Qom, Iran

City

Qom

Province

Ghoum

Postal code

0098 993 838 9968

Phone

+98 993 838 9968

Email

saeidqasemi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

Street address

Central Building of Shiraz University of Medical Sciences, Opposite Palestine Street, Zand Street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

mohammadi@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Saeed Qasemi Dashti

Position
MSc Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Shahid Douran Campus, School of Rehabilitation Sciences, After Amir Al Momenin (PBUH) Burn Hospital, Sadra City Road
City
Shiraz
Province
Fars
Postal code
7198754361
Phone
+98 71 3212 2600
Email
saeidqasemi20@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Leila Abbasi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Shahid Douran Campus, School of Rehabilitation Sciences, After Amir Al Momenin (PBUH) Burn Hospital, Sadra City Road
City
Shiraz
Province
Fars
Postal code
7198754361
Phone
+98 71 3212 2600
Email
leilaabbasi.le@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Leila Abbasi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Shahid Douran Campus, School of Rehabilitation Sciences, After Amir Al Momenin (PBUH) Burn Hospital, Sadra City Road, Shiraz, Fars, Iran
City
Shiraz
Province
Fars
Postal code
7198754361
Phone
+98 71 3212 2600
Email
leilaabbasi.le@gmail.com

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
De-identified individual participant data, study protocol, statistical analysis plan, informed consent form, clinical study report, analysis codes, and data dictionary
When the data will become available and for how long
Access will begin 6 months after publication of the study results and will remain available for 5 years
To whom data/document is available
Researchers affiliated with academic and scientific institutions
Under which criteria data/document could be used
Data will be shared for non-commercial research purposes, including meta-analyses and secondary analyses. Requests must be submitted with a clear research proposal and signed data access agreement
From where data/document is obtainable
Leila Abbasi, School of Rehabilitation Sciences, Shiraz University of Medical Sciences, Shiraz, Iran. Email: leilaabbasi.le@gmail.com
What processes are involved for a request to access data/document
Requests are submitted via email to the principal investigator. The request is reviewed within 2 weeks. If approved, a data access agreement is signed, and the de-identified data are transferred via a secure file-sharing platform within 4 weeks
Comments