Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of cupping therapy with movement compared to cupping therapy on pain, lumbar range of motion, physical performance, and functional mobility in athletes with non-specific chronic low back pain

Protocol summary

Study aim

The primary aim of this study is to identify the most effective type of cupping therapy for improving chronic non-specific low back pain in athletes and to utilize the findings for better clinical decision-making.

Design

A controlled, double-blind, randomized, parallel-group clinical trial on 24 patients for randomization "www.Randomization.com" was used.

Settings and conduct

This study investigates the effects of static cupping therapy and cupping therapy combined with active movements on chronic non-specific low back pain in athletes. The study is conducted at the Physiotherapy Clinic of the Rehabilitation Faculty in Tehran. It is designed as a randomized clinical trial, with participants divided into two groups: the first group receives static cupping therapy, while the second group receives cupping therapy combined with active movements. Treatments are conducted individually in 15-minute sessions. Blinding is applied to both participants and assessors to reduce bias and increase the validity of the results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Athletes with chronic non-specific low back pain; confirmation of low back pain through diagnosis and referral to a specialist; age between 18 and 40 years; both male and female participants; pain not radiating to the lower limbs; regular exercise at least three days a week for a total of 6 hours per week.
Exclusion criteria: No lower limb injury or surgery in the past 6 months; pregnancy.

Intervention groups

Static cupping therapy and cupping therapy with active movements.

Main outcome variables

Pain intensity; lumbar range of motion; physical function; functional mobility; overall perception of treatment effect.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241029063539N1**
Registration date: **2024-12-02, 1403/09/12**
Registration timing: **prospective**

Last update: **2024-12-02, 1403/09/12**
Update count: **0**

Registration date

2024-12-02, 1403/09/12

Registrant information

Name

Arezoo Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-09, 1403/09/19

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of cupping therapy with movement compared to cupping therapy on pain, lumbar range of motion, physical performance, and functional mobility in athletes with non-specific chronic low back pain

Public title

Effects of cupping therapy with movement in athletes with non-specific chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Athletes with non-specific chronic low back pain Confirmation of low back pain diagnosis by a specialist physician Age between 18 and 40 years Both male and female genders Pain does not radiate to the lower limbs Duration of low back pain exceeds 3 months No contraindications for cupping therapy (e.g., blood clotting disorders, any skin issues, fractured areas, etc.) Engaging in regular exercise at least three days per week, totaling 6 hours per week The average pain intensity, based on the Numeric Rating Scale (NRS), must be equal to or greater than 30 millimeters. No lower limb injuries or surgeries in the past 6 months

Exclusion criteria:

Absence from more than one session in the therapy sessions Pregnancy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be grouped using a random allocation method with blocks of four (www.Randomization.com). This allocation will be performed by an individual outside the research team prior to the start of the study to prevent bias. Participants will be divided into two groups: 1. Group 1: Static cupping therapy (without active movements) 2. Group 2: Cupping therapy with active movements Based on the sample size, a number of opaque envelopes will be prepared. Each generated random sequence will be recorded on a card, and the cards will be sequentially placed inside the envelopes. To maintain the random sequence, the envelopes will be numbered externally in the same order. Finally, the envelopes will be sealed and placed in a box in sequence. At the time of participant enrollment, one envelope will be opened in order based on the sequence of eligible participants entering the study, revealing the assigned group for that participant.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants: Patients are randomly assigned to one of two intervention groups: the static cupping therapy group or the cupping therapy group with active movements. However, they are informed that they will only undergo cupping therapy. Participants are not made aware of the specific type of intervention they receive, and no explanation is provided regarding the differences between the two treatments (static and with active movements). This approach aims to prevent bias in patients' expectations and experiences. Evaluator: In addition to the participants, the evaluator is also blinded to the group to which each participant is assigned. This means the evaluator only conducts assessments and evaluates the tests included in the study, without any knowledge of the participant's group allocation. This process helps to prevent bias in the evaluation results. By employing these blinding methods, the validity and accuracy of the study's results are enhanced, allowing for a better assessment of the actual effects of the interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, Enghelab St., Shemiran Intersection, Corner of Safi Alishah St., Faculty of Rehabilitation

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Approval date

2024-10-29, 1403/08/08

Ethics committee reference number

IR.TUMS.FNM.REC.1403.134

Health conditions studied

1

Description of health condition studied
Non-specific chronic low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Intensity of Pain: Pain is an unpleasant sensory experience that occurs in association with actual or potential tissue damage. The level of this unpleasant experience is considered the intensity of pain. In this study, pain intensity refers to the average score obtained from the Visual Analog Scale (VAS) for pain over the past 24 hours.
Timepoint
Measuring pain intensity was conducted in the first session, the last session, and one week after the end of the intervention in each group: active movement cupping therapy and cupping therapy without active movement.
Method of measurement
Visual Analog Scale (VAS)

2

Description
Lumbar Range of Motion: This refers to the extent of movement at each joint, which depends on the bony structure and the physiological characteristics of the surrounding connective tissue. The range of motion in the lumbar spine for forward flexion, backward extension, and lateral bending is typically 40-50, 15-20, and 20 degrees, respectively.
Timepoint
Measurement of trunk range of motion was conducted in the first session, the last session, and one week after the end of the intervention in each group: active movement cupping therapy and cupping therapy without active movement.
Method of measurement
Inclinometer device

Secondary outcomes

1

Description
Physical Function: The ability to perform activities requiring physical effort, ranging from self-care (activities of daily living) to more complex tasks that require a combination of skills, is often defined by social aspects or participation in a social environment.
Timepoint
The time points for measuring physical function can be the first session, the last session, and one week after the end of the intervention in each group: active movement cupping therapy and cupping therapy without active movement.
Method of measurement
The Athlete Disability Index (ADI) questionnaire.

2

Description
Functional Mobility: This refers to an individual's physiological ability to move independently and safely in various environments in order to perform functional activities or tasks and to participate in daily activities at home, in the workplace, and in the community.
Timepoint
The time points for measuring functional mobility can be the first session, the last session, and one week after the end of the intervention in each group: active movement cupping therapy and cupping therapy without active movement.
Method of measurement
Single-legged hop Test.

3

Description
Overall Effect Perception Scale:This is a direct scale that addresses the patient's personal perception since the intervention was performed.
Timepoint
The time point for measuring the Overall Effect Perception Scale can be one week after the end of the intervention in each group: active movement cupping therapy and cupping therapy without active movement.
Method of measurement
In this study, the individual's perception of the treatment effect is assessed using an 11-point scale, scoring from -5 (much worse than at the start of treatment), through a neutral score of 0, to +5, which indicates significant improvement compared to the start of treatment.

Intervention groups

1

Description
Intervention Group 1: Static Cupping Therapy. In the static cupping therapy treatment method, participants in the first group receive treatment individually while lying prone (on their stomachs). The cups are placed on the lower back, parallel to the spine, covering the area from L1 to L5, with a distance of 3 to 5 centimeters between them. The negative pressure inside the cups is approximately 300 millibar. In the cupping therapy with active movement technique, oil or gel is used to reduce friction and facilitate the movement of the cups on the skin. The treatment in the first group lasts for 15 minutes and is combined with standard exercises for chronic non-specific low back pain.
Category
Rehabilitation

2

Description
Intervention Group 2: Cupping Therapy with Active Movements. This intervention is similar to the previous one in terms of duration and method, but it is combined with additional active exercises. Participants in this group receive 15 minutes of cupping therapy and, in addition, perform other active exercises. These exercises include seated forward bends, cat-camel movement, seated side bends, seated spinal twists, and child pose.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy Clinic - School of Rehabilitation

Full name of responsible person
Dr. Arsalan Ghorbanpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Noureddin Nakhostin Ansari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
A portion of the data, such as information related to the primary outcome or similar details, can be shared.
When the data will become available and for how long
The access period begins 6 months after the publication of the results.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Data from this clinical trial will be available for use in another study with the permission of the study investigator.
From where data/document is obtainable
Nakhostin@sina.tums.ac.ir
What processes are involved for a request to access data/document
Correspondence should be addressed to Dr. Nakhostin Ansari: Nakhostin@sina.tums.ac.ir
Comments