Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effectiveness of cupping therapy in patients with chronic nonspecific low back pain: a randomized sham-controlled trial

Protocol summary

Study aim
Investigating the effect of cupping therapy in patients with CNLBP

Design
This study is a two-arm, double-blind, randomized controlled trial with parallel groups. Patients are allocated to the intervention or control group randomly utilizing the permuted block randomization method.

Settings and conduct
Participants will be randomly assigned to intervention or control groups using permuted randomization. A third-party will create a random treatment list and place it in sequentially numbered envelopes. The envelopes will be given to participants after their primary assessment. The study will take place at IUMS.

Participants/Inclusion and exclusion criteria
Inclusion criteria: CNLBP for at least three months, pain intensity between 3 to 6 based on the numeric pain rating scale, body mass index between 19 to 23, no contraindications for therapeutic exercise and electrotherapy Exclusion criteria: Comorbidities, spinal deformities, serious pathological symptoms, patient dissatisfaction, absence from more than three consecutive sessions, receiving physiotherapy, analgesics, or procedural interventions in the past 4 weeks, prior use of cupping therapy, neurological, vestibular, visual, or auditory disorders

Intervention groups
In the intervention group, the patient lies in a supine position, and the entire lumbar area is covered with body oil. Then, two 5 cm diameter cups are placed on both sides of the spinal column. Moderate negative pressure is manually generated between the cups and the skin, following which the cups are moved along the spine. This process lasts for three minutes. In the control group, patients also lie in a supine position, and two 5 cm diameter cups are placed on the lumbar area and kept stationary for one minute. Additionally, both groups undergo routine physiotherapy, including electrotherapy and stability exercises.

Main outcome variables
Pain and functional disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130409012953N5**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date
2023-12-18, 1402/09/27

Registrant information

Name
Mohammadreza Pourahmadi

Name of organization / entity
Rehabilitation Research Center, Department of Physiotherapy

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-21, 1402/09/30

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of cupping therapy in patients with chronic nonspecific low back pain: a randomized sham-controlled trial

Public title

Effect of cupping therapy in chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic non-specific low back pain lasting for a minimum of 3 months The pain intensity is rated between 3 and 6 on the visual analog scale The body mass index falls between 19 and 23. No restrictions for therapeutic exercise and electrotherapy.

Exclusion criteria:

The presence of comorbidities such as diabetes and cardiovascular problems. The presence of spinal column deviations, such as scoliosis, is observed. Signs of serious pathology of the spine (eg, fractures, inflammatory diseases, infection or tumours). Consecutive absence of more than three sessions. Patients' dissatisfaction with their participation in the study Receiving physiotherapy, analgesics, and therapeutic procedures during the past 4 weeks. Individuals who have been treated with cupping in the past. Neurological, vestibular, visual or auditory deficits.

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

All Eligible patients with chronic non-specific low back pain will be randomly assigned to either the intervention group (cupping therapy combined with routine physical therapy) or the control group (sham cupping therapy combined with routine physical therapy) in a 1:1 ratio. The randomization process will employ a permuted block method using four-letter blocks made up of letters A and B. Subsequently, the randomized treatment list will be placed in sealed and numbered envelopes, with letters A representing actual cupping therapy and letters B representing sham cupping therapy. Six four-letter blocks comprising letters A and B, with no more than two repetitions of either letter, will be created, including sequences like AABB, ABAB, BBAA, BAAB, ABBA, and BABA. Given that each block represents 4 participants and the study requires 48 participants, 12 sets of four blocks are needed. Selection of 12 random numbers from 1 to 6, representing the blocks created, will be carried out using the Google random number generator. The allocation process will be managed by an individual external to the research team prior to the study. Following the initial patient assessment, sequentially numbered envelopes will be assigned to individuals based on their entrance order into the study. Subsequently, therapists will tailor the treatment interventions based on the letters within the envelopes upon each patient’s entry into the treatment sessions. Patients are instructed not to disclose their group allocation to the assessor to prevent data contamination.

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals allocated to the control group will assume the same position as those in the intervention group. However, in the control group, two cups with a diameter of 5 cm will be placed solely on the lumbar region, positioned 2-3 cm away from the spinous processes, without being longitudinally moved along the paraspinal regions, and will be placed for only one minute.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahnazari St., Madar Sq., Mirdamad Biv., Tehran 1545913187, Iran

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Approval date

2022-08-27, 1401/06/05

Ethics committee reference number

IR.IUMS.REC.1401.455

Health conditions studied

1

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

Primary outcomes

1

Description
Pain Intensity: It is an unpleasant sensory and emotional experience that occurs with real or potential tissue damage or is expressed as such damage. Therefore, pain is more than a signal for tissue damage.
Timepoint
At the start of the study, at the end of the study (session 10), and two weeks post-study completion.
Method of measurement
Numeric pain rating scale

2

Description
Functional Disability: The effects and consequences of chronic or acute conditions are said to affect various body systems and cause limitation or lack of people's ability to perform basic and functional activities, such as standing, sitting, dressing and walking in a natural range.
Timepoint
At the start of the study, at the end of the study (session 10), and two weeks post-study completion.
Method of measurement
In this research the Persian version of the Oswestry Questionnaire is used to evaluate the level of functional disability of the patients. The total score of the items of this scale is considered as the functional disability level of the people, which is zero without disability and 100 as maximum disability. This questionnaire has ten parts, each part has six sub-parts, which are graded from 0 to 5. The individual's disability score is calculated by multiplying the total points obtained by 2 and then dividing by 100 and is displayed as a percentage.

Secondary outcomes

1

Description
Quality of life: Quality of life is the perception of each person of their health status and the degree of satisfaction with this situation.
Timepoint
At the start of the study, at the end of the study (session 10), and two weeks post-study completion.
Method of measurement
Persian version of the 36-item SF-36 questionnaire

Intervention groups

1

Description
Intervention group: The treatment in the main group is as follows: The patient lies prone with body oil applied from the 12th thoracic vertebra to the first sacral vertebra. The therapist places two cups, each with a 5 cm diameter, 2 cm away from the spinous processes on either side of the vertebrae, creating negative pressure manually between the cups and the skin using two to three sections, pulling about 1.5 to 2 cm of skin into the cup. Then, the therapist pulls the cups down the length of the vertebrae at a moderate speed (approximately one centimeter per second). After reaching the alignment of the first sacral vertebra, the therapist moves the cups upwards again. This procedure is performed for three minutes. In addition to cupping therapy, patients in this group receive routine physiotherapy treatment, including 20 minutes of transcutaneous electrical nerve stimulation (frequency: 150 Hz, duration: 250 microseconds) with hot packs, as well as therapeutic exercises to strengthen the abdominal and trunk muscles (including abdominal hollowing and bridging exercises). Patients will undergo treatment for 10 sessions (three sessions per week).
Category
Rehabilitation

2

Description
Control group: In the control group, the patients' position will be exactly the same as the intervention group. The area of the lower back will be massaged with oil. Two cups with a diameter of 5 cm will be placed on the lower back, and the physiotherapist will create negative pressure between the skin and the cups by performing a suction. The cups will then be left on the skin without any movement for one minute. Additionally, the routine treatment and number of therapy sessions will be the same as the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation Sciences of Iran University of Medical Sciences
Full name of responsible person
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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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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mohammadreza Pourahmadi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

The raw data of research and its analysis will be available to the researcher if they request it.

When the data will become available and for how long

After six months from the date of publication.

To whom data/document is available

The data will be available for physical therapists working in academic institutions and also clinicians working in the field of low back pain.

Under which criteria data/document could be used

The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of low back pain.

From where data/document is obtainable

Applicants can contact Dr. Mohammadreza Pourahmadi by email. Email address: pourahmadipt@gmail.com

What processes are involved for a request to access data/document

Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.

Comments