Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of mirror therapy on kinesiophobia and balance in patients with chronic ankle instability A Randomized clinical trial

Protocol summary

Study aim

To investigate the effect of mirror therapy on kinesiophobia and balance in patients with chronic ankle instability

Design

Approximately thirty patients aged 18 to 45 with CAI, meeting the International Ankle Consortium criteria, were enrolled and randomly assigned to two groups (intervention and control). The intervention will be conducted over four weeks, with three sessions per week (12 sessions in total).

Settings and conduct

Thirty patients aged 18 to 45 with chronic ankle instability will randomly assigned to two groups (intervention and control). The intervention for both group will be conducted over 4 weeks, with 3 sessions per week. The therapist and assessor are different. The assessor will be blinded to patient allocation. the study will be conducted at the physiotherapy clinic of Shiraz University Medical Sciences.

Participants/Inclusion and exclusion criteria

In this study, approximately 30 patients aged 18 to 45 with chronic ankle instability were enrolled based on the criteria of the International Ankle Consortium. Inclusion required a minimum of 12 months to have elapsed since the initial acute ankle sprain—which had caused pain, inflammation, and a need for rest—and at least 3 months since the most recent acute ankle sprain that had similarly resulted in pain, inflammation, and a need for rest.

Intervention groups

Participants are randomly assigned to one of two groups: intervention group (mirror therapy plus a conventional rehabilitation program), or control group (conventional rehabilitation program alone). The treatment for both group will be conducted over four weeks, with three sessions per week.

Main outcome variables

Primary outcome: • kinesiophobia Secondary outcomes: • Static balance • Dynamic balance • Ankle dorsiflexion range of motion • Ankle pain intensity • Mechanical/functional ankle instability • Lower extremity function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230205057336N4**
Registration date: **2026-09-11, 1405/06/20**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-11, 1405/06/20**
Update count: **0**

Registration date

2026-09-11, 1405/06/20

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-07, 1405/05/16

Expected recruitment end date

2027-02-05, 1405/11/16

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of mirror therapy on kinesiophobia and balance in patients with chronic ankle instability A Randomized clinical trial

Public title
The effect of mirror therapy on kinesiophobia and balance in patients with chronic ankle instability A Randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 45 years. A history of at least one significant ankle sprain requiring relative rest or activity limitation. At least 12 months have elapsed since the first acute ankle sprain that resulted in pain, inflammation, and the need for rest. At least 3 months have elapsed since the most recent acute ankle sprain that resulted in pain, inflammation, and the need for rest. Presence of chronic instability symptoms (recurrent episodes of "giving way" or a feeling of ankle instability) during at least the past 3 months (along with a CAIT score meeting the study criteria). CAIT questionnaire score ≤ 24 as an indicator of the presence of chronic ankle instability (CAI). A score of less than 90% for activities of daily living and less than 80% for sports activities on the FAAM questionnaire. Ability to walk independently (without the use of a cane or a permanent rigid ankle brace). Willingness to participate in the study and provision of written informed consent.
Exclusion criteria:
Acute ankle sprain within the past 6 weeks. History of fracture or surgery involving the ankle or lower extremity on the affected side. Presence of neurological disorders (such as stroke, multiple sclerosis [MS], or peripheral neuropathy) or vestibular disorders that may affect balance. Severe structural foot deformities (such as severe foot deformities) that prevent the performance of the assessments and exercises. Presence of talocrural joint osteoarthritis. Disabling systemic diseases (such as active inflammatory arthritis or severe cardiac or respiratory failure). Severe cognitive or psychiatric disorders that prevent cooperation with the exercise program or completion of the questionnaires. Concurrent participation in other structured ankle rehabilitation programs (outside the study protocol) during the study period.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Sequence Generation (Method Used to Generate the Random Allocation Sequence) Following completion of the baseline assessment and confirmation of eligibility according to the inclusion and exclusion criteria, participants will be randomly allocated to either the intervention group or the control group in a 1:1 ratio. The randomization sequence will be generated by an independent statistician who is not involved in participant recruitment, assessment, or treatment, using SPSS statistical software. To maintain balanced group sizes throughout the study, block randomization with variable block sizes (e.g., 4 and 6 participants) will be used. Randomization will be stratified by the key variables of sex and age to ensure a more balanced distribution of these characteristics between the two groups. Allocation Concealment Mechanism To minimize allocation bias, the randomization sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). An independent allocation officer, who is not involved in participant assessment, will open the next envelope in numerical order in the presence of the participant and assign the participant to the corresponding study group. Until the envelope is opened, neither the clinical investigators, the outcome assessor, nor the participant will be aware of the assigned group. This procedure ensures adequate allocation concealment and minimizes the risk of selection bias. Implementation The random allocation sequence will be generated by an independent statistician. Eligible participants will be recruited and enrolled into the study by the principal investigator after baseline assessment and confirmation of eligibility criteria. Group assignment will be performed by an independent allocation officer who is not involved in participant recruitment, treatment, or outcome assessment.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding Due to the nature of the intervention (mirror therapy), complete blinding of participants is not feasible. However, the following measures will be implemented to minimize information bias: The outcome assessor will be blinded to participants' group allocation, and no information regarding the type of intervention will be recorded on the data collection forms. Participants will be instructed not to disclose details of their exercise program or the use of mirror therapy during outcome assessments. The statistical analyst will also be blinded, as far as possible, by analyzing coded group data (e.g., Groups A and B) without knowledge of the intervention assigned to each group (blinded data analysis). Accordingly, the study will be conducted as an assessor-blinded randomized controlled trial with blinded statistical data analysis through group coding.
Placebo
Used
Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Alley 36.1, Alley 36, Karim Khan Zand St., Shiraz

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Province
Fars

Postal code
7135744661

Approval date
2026-07-28, 1405/05/06

Ethics committee reference number
IR.SUMS.REHAB.REC.1405.004

Health conditions studied

1

Description of health condition studied
Chronic ankle instability

ICD-10 code
M25.373

ICD-10 code description
Other instability, unspecified ankle

Primary outcomes

1

Description
Fear of movement (kinesiophobia) based on the score of the Tampa Scale for Kinesiophobia (TSK-17) questionnaire – validated Persian version.

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
Tampa Scale for Kinesiophobia (TSK-17) questionnaire – validated Persian version.

Secondary outcomes

1

Description
Static balance

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
Berg balance scale

2

Description
Dynamic balance

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
Modified Star Excursion Balance Test

3

Description
Dorsiflexion range of motion

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
weight bearing lunge test

4

Description
pain

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
Numerical analogue scale

5

Description
Mechanical/functional ankle instability

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
Cumberland Ankle Instability Tool

6

Description
Lower limb function

Timepoint
Assessments are conducted at three time points: before the intervention, immediately after the intervention, and four weeks after the end of the intervention.

Method of measurement
Foot and ankle ability measure

Intervention groups

1

Description

Intervention group: Intervention GroupIntervention Group (Standard Exercise Therapy + Mirror Therapy)Participants in the intervention group will receive treatment over 12 sessions conducted across 4 weeks (3 sessions per week). Each treatment session will last approximately 30–45 minutes and will consist of the following components:1. Preparation and Warm-up (5 minutes)The participant will be seated on a chair or treatment bench. Initially, simple active ankle movements, including dorsiflexion, plantarflexion, inversion, and eversion, will be performed in two sets of 10 repetitions for each movement. This phase is designed to prepare the soft tissues and reduce the risk of injury (55).2. Main Phase – Mirror Therapy (25–35 minutes)Mirror:A vertical mirror measuring at least 40 × 60 cm (preferably 60 × 80 cm) will be positioned along the participant's midline. Mirrors of this size have been recommended in review studies on lower-limb mirror therapy (56).Participant Position:The participant will be positioned either sitting or standing (depending on the stage of progression) in front of the mirror. The unaffected limb will be placed in front of the mirror, while the affected limb will remain behind the mirror and out of sight. The distance between the participant and the mirror will be adjusted to 30–60 cm to ensure that the reflected image appears life-sized (57).Exercise Performance:Under the supervision of the therapist, the participant will perform the following movements with the unaffected limb while simultaneously observing its mirror reflection:Ankle dorsiflexion and plantarflexion (2–3 sets of 10 repetitions)Ankle inversion and eversion (2 sets of 10 repetitions)Ankle circumduction in both directions (2–3 sets of 10 repetitions)Functional movements such as bilateral heel raises in standing (2 sets of 10 repetitions in the advanced stage)Strengthening exercises for the peroneal and tibialis anterior muscles using resistance bands (2–3 sets of 10–15 repetitions)Proprioceptive exercises on a foam pad or balance board (single-leg stance maintained for 20–40 seconds, 3 trials)Sit-to-stand exercises (2–3 sets of 10–15 repetitions)Weight-shifting exercises onto the unaffected limb (2–3 sets of 10–15 repetitions)Forward and backward stepping exercises (2–3 sets of 10–15 repetitions) (58,59).Participants will be instructed to maintain their visual focus on the mirror reflection and imagine that the observed movements are being performed by the affected limb. Previous studies have shown that this type of training may enhance sensorimotor neural pathways and perceptual processing in individuals with ankle injuries (59).3. Cool-down and Session Summary (5 minutes)The session will conclude with gentle stretching exercises followed by a brief recording of the participant's pain level.Standard Rehabilitation ProtocolThe rehabilitation program for patients with ankle sprain is designed to restore ankle range of motion, improve muscle strength, enhance balance, and optimize proprioception. The exercises progress in a stepwise manner according to the participant's functional status, aiming to prevent recurrent injury while facilitating a safe return to daily and sports activities.1. Range-of-Motion ExercisesAt the beginning of the program, the primary focus is on restoring or maintaining ankle joint mobility. Active and passive movements will be performed in the directions of dorsiflexion, plantarflexion, inversion, and eversion. Gentle stretching exercises for the muscles surrounding the ankle, particularly the calf muscles, will also be included. This phase helps reduce joint stiffness and prepares the participant for subsequent rehabilitation stages.2. Strengthening ExercisesAs pain decreases and ankle mobility improves, resistance exercises will be introduced. Initially, isometric contractions of the peroneal and tibial muscles will be performed in opposing directions.These exercises will then progress to resistance-band exercises targeting inversion, eversion, dorsiflexion, and plantarflexion. Subsequently, weight-bearing exercises, including heel raises, partial squats, and lunges, will be incorporated. Exercise intensity will be progressively increased by modifying the number of repetitions, resistance level, and exercise difficulty.3. Balance TrainingBalance training will initially consist of single-leg standing on a stable surface, with the duration gradually increased. The exercises will then progress to unstable surfaces, such as foam pads or balance boards, to provide greater neuromuscular challenge. During the advanced stages, dynamic balance exercises, including weight-shifting tasks, single-leg standing while catching or throwing a ball, and tandem walking, will be incorporated.4. Proprioceptive TrainingThis component aims to improve proprioception and reduce the risk of recurrent ankle injury. Participants will begin with simple exercises such as single-leg standing with the eyes open. Exercise difficulty will then be increased by closing the eyes or adding upper-body and trunk movements. In the advanced stages, dynamic tasks such as short hops, single-leg landing, rapid changes of direction, and combined exercises (e.g., jumping onto a balance board) will be included.Principles of Exercise ProgressionThe primary criterion for exercise progression will be the participant's tolerance and the absence of increased pain or swelling.Whenever a participant is able to perform an exercise comfortably and with adequate stability, progression to a more challenging level will be permitted. The number of repetitions and the duration of each exercise will also be increased gradually.Conversely, if pain or inflammatory symptoms increase following a particular exercise, the participant will return to the previous rehabilitation stage until symptoms subside.Overall, this rehabilitation protocol provides a gradual progression from simple movements to more complex, sport-specific functional activities, with the aim of restoring the participant's previous level of function while minimizing the risk of recurrent ankle injury.

Category

Rehabilitation

2

Description
Control group: Participants in the control group receive only the standard rehabilitation program over the same timeframe and with the same number of sessions. The structure of the sessions is similar to that of the intervention group, with the difference that exercises involving the unaffected side are performed in front of an opaque screen.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Clinic, Chamran Hospital
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Faculty of Rehabilitation Sciences, Shahid Doran Campus, Sadra City Road, after Amir al-Momenin (AS) Burn and Accident Hospital, Shiraz
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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
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
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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
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
Undecided - It is not yet known if there will be 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