Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Effects of Graded Motor Imagery Technique and Mirror Therapy on Phantom Pain and Prosthesis Embodiment in Unilateral Lower Limb Amputees: An fMRI Clinical Trial Study

Protocol summary

Study aim

Comparing the effects of progressive motor imagery and mirror therapy techniques on phantom limb pain and prosthesis embodiment in individuals with unilateral below-the-knee amputees using fMRI

Design

A two-group, parallel-group, double-blind, randomized based on the random number table, phase II clinical trial on 20 participants with unilateral below-the-knee lower limb amputations.

Settings and conduct

The samples will select based on a simple non-probability method from the available statistical population, the Red Crescent Rehabilitation Center or private clinics in Tehran, that meets the inclusion criteria. Blinding: Participants in this study do not know whether they are in the GMI intervention group or the mirror therapy control group. This blinding helps reduce psychological effects and patient expectations and prevents bias in reporting results. Also, the researcher who evaluates the results will be unaware of the groups to which the participants were assigned. The person who analyzes the data will also be unaware of the information about the group allocation.

Participants/Inclusion and exclusion criteria

Before startiing the study, a screening test will be conducted on the subjects using The Kinesthetic and Visual Imagery Questionnaire (KVIQ). Subjects will be asked to answer questions 4 and 5 of this questionnaire, which are related to lower limb function, and if they score 4 or 5 on each question, they will be included in the study.

Intervention groups

These participants will be randomly assigned to two intervention groups: GMI (intervention group) and mirror therapy (control group). GMI group will undergo GMI intervention at least once a day for 6 weeks. Control group will undergo mirror therapy daily for 15 minutes for 6 weeks (5 days a week).

Main outcome variables

Phantom pain؛ Prosthesis Embodiment؛ Graded Motor Imagery Technique؛ Activity of cortical areas of the brain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250920067297N1**
Registration date: **2025-09-26, 1404/07/04**
Registration timing: **prospective**

Last update: **2025-09-26, 1404/07/04**
Update count: **0**

Registration date

2025-09-26, 1404/07/04

Registrant information

Name

Amir Ali Gordahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-07, 1404/07/15

Expected recruitment end date

2026-02-19, 1404/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effects of Graded Motor Imagery Technique and Mirror Therapy on Phantom Pain and Prosthesis Embodiment in Unilateral Lower Limb Amputees: An fMRI Clinical Trial Study

Public title
Comparing the effects of two treatment methods on phantom pain and prosthesis embodiment in unilateral lower limb amputees: using fMRI
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
-Unilateral below knee amputations -At least one-month after receiving prosthesis -At least 3 months after amputation -Obtaining a score of 4 or 5 on each of the questions in items 4 and 5 of the Kinesthetic and Visual Imagery Questionnaire (KVIQ) Questionnaire - Eigtheen to fifteen years old -Ability to read in Persian -Absence of cortical disorders -Absence of visual impairments -Absence of comorbidities
Exclusion criteria:
-Failure to continue the GMI or mirror therapy intervention process until the end of the study -Failure to complete questionnaires -Presence of neuroma in the amputated limb -Participants with simultaneous upper limb amputations
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
In this randomized controlled study, unilateral below-knee amputees who have phantom limb pain and have recently received their prosthesis will be invited to the study if they meet the inclusion criteria. These individuals will be randomly assigned to two intervention groups: GMI (intervention group) and mirror therapy (control group). Using a random number table, participants will be randomly assigned to each of the study groups by an independent researcher. Prior to randomization, the independent researcher will conduct the necessary assessments and complete the questionnaires.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in this study do not know whether they are in the GMI intervention group or the mirror therapy control group. This blinding helps to reduce psychological effects and patient expectations and prevents bias in reporting results. The researcher who assesses the results will also be unaware of the groups to which participants are assigned. The person performing the data analysis will also be unaware of the information regarding group assignment.
Placebo
Not 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
Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Madadkaran st, Shahnazari st, Mirdamad Blv, Tehran.
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Approval date
2025-09-17, 1404/06/26
Ethics committee reference number
IR.IUMS.REC.1404.637

Health conditions studied

1

Description of health condition studied
Traumatic Unilateral Below the knee Amputees
ICD-10 code
S88.11
ICD-10 code description
Complete traumatic amputation at level between knee and ankle

Primary outcomes

1

Description
Phantom pain
Timepoint
Before and After the intervention
Method of measurement
TAPES questionnaire and VAS

2

Description
Prosthesis Embodiment
Timepoint
Before and After the intervention
Method of measurement
PES questionnaire

3

Description
Activity of cortical areas of the brain
Timepoint
Before and After the intervention
Method of measurement
fMRI

Secondary outcomes

1

Description
duration of using the present prosthesis
Timepoint
Before the intervention
Method of measurement
Questionnaire

2

Description
time to amputaion
Timepoint
Before the intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: The GMI group will undergo GMI intervention at least once a day for 6 weeks. The GMI technique has three stages, each stage lasting 2 weeks. Stage 1 (Determination of Laterality of the Involved Limb): Determining the imaged limb as right or left activates the premotor areas of the brain. For this purpose, several digital photos of the healthy limb of the person are taken in different positions and are mirrored using software to create similar images of the unamputated limb, and a bank of photos of the two limbs is created. Then, two-thirds of the photos in the bank are randomly selected and shown to the amputee on a monitor. The person is asked to say immediately after seeing the picture whether the image they see is of the right or left limb. At this stage, the speed and accuracy of the person's performance are emphasized. People are asked to do this 3 times a day (about 10 minutes each time) and after waking up at night. The duration of each test and the speed and accuracy of the performance will be recorded by software installed on the patient's Android mobile phone. Second stage (imaging limb movements): In this stage, several images of the amputated limb are randomly selected from the image bank and presented to the patient again randomly via computer. Subjects are asked to imagine moving their amputated limb to the position in the picture when they see the limb in the picture. In this phase, subjects are asked to do this 3 times (15 minutes) each time they wake up (the patient must be in a relaxed state during the test). In this stage, the emphasis is on imagining the amputated limb in the proper posture and the position of each toe. The duration of each test will be recorded in the software. Stage Three (Mirror Therapy): In this stage, a cardboard box divided into two parts by a vertical mirror will be used. A hard copy of several images of the healthy leg will be selected from the image bank and the patient will be asked to slowly and carefully align both legs with the images shown after each awakening (10 minutes). The affected leg in this test should be hidden behind a mirror and the emphasis at this stage is on looking at the reflection of the healthy leg in the mirror.
Category
Rehabilitation

2

Description
Control group: Patients will receive verbal and written instructions for the 6-week mirror therapy exercises in a face-to-face session before the training phase begins. Patients will be instructed to consciously associate the movement observed in the mirror with their imaginary limb at any time during the training period and to maintain their attention focused on this task. Each instruction will be explained verbally and then performed by the patients. In total, five different motor tasks will be designed to increase the patients' cooperation. These tasks include: (1) plantar and dorsiflexion of the ankle; (2) flexion and extension of fingers 2 through 5; (3) bringing the medial edge of the foot closer to the mirror; (4) flexion and extension of the big toe; (5) ankle rotation; (6) ankle inversion and eversion; and (7) smooth ankle and knee movements in the manner of a cyclist. All of these tasks will be designed to maximize the visibility of the movement.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Rehabilitation Sciences
Full name of responsible person
Amir Ali Gordahani
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Recruitment center
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National Brain Mapping Lab
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Vice President of Research and Technology
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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
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
Amir Ali Gordahani
Position
Phd Candidate
Latest degree
Master
Other areas of specialty/work
Others
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Person responsible for updating data

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Postal code
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
No - There is not a plan to make this available

Title and more details about the data/document
Information on the primary and secondary outcomes will extract from the documentation and will share in the article.

When the data will become available and for how long
Access will be possible starting from the end of 2026, and after the article is published.

To whom data/document is available
Researchers in the relevant field and working in academic and scientific institutions can submit applications.

Under which criteria data/document could be used
Only for conducting systematic studies or meta-analyses

From where data/document is obtainable
Dr. Behnoosh Vasaghi School of Rehabilitation Sciences, Iran University of Medical Sciences mail: bvasaghi@gmail.com

What processes are involved for a request to access data/document
Send email, review request, and then send data.

Comments