

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of home-based mirror therapy in reducing phantom pain in below knee unilateral amputees

Protocol summary

Study aim

effective treatment for reducing pain in imaginary limb syndrome in unilateral amputation.

Design

This clinical trial study will be performed with a control group in two parallel, single-blind, randomized groups with 16 patients.

Settings and conduct

This study was performed in Isfahan Faculty of Rehabilitation Sciences with two groups of patients for the intervention group before mirror therapy for 15 minutes daily and the control group for conventional education.

Participants/Inclusion and exclusion criteria

Traumatic amputation of a male below the knee ; over 18 years ; Imaginary limb pain above 3 on a numerical scale who have not previously used mirror therapy ; the person must use a prosthesis and a maximum of 10 years have passed since the amputation

Intervention groups

Patients in the intervention group will be fully explained how to use the mirror in a face-to-face session in a 40-minute program. In this face-to-face session, things like general conversation with the patient, explaining the purpose of this technique and the expected benefits of mirror therapy and recording the amount of pain before practice, practical training to work with the mirror and finally scoring his pain after practice are done. After the mirror, he is given a 4-week schedule to take home and, without the help of others, work with the mirror for 15 minutes every day according to the instructions. He is contacted two days a week through communication methods (call, email, messaging tools, video chat tools, etc.) to share his experience. The control group uses only prostheses and will perform standard imaginary pain relief training for 4 weeks.

Main outcome variables

Change imaginary pain; Further use of prostheses in daily activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049687N3**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Alireza Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5053

Email address

taheri@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-08, 1400/08/17

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of home-based mirror therapy in reducing phantom pain in below knee unilateral amputees

Public title

The home-based mirror therapy in reducing phantom pain in below knee amputees

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Traumatic amputation Unilateral amputation Below knee amputation be over 18 years old Have phantom limb pain greater than 3 on a numerical scale Be a man A person must use a prosthesis A maximum of 10 years have passed since the amputation Have phantom limb pain Have not used mirror therapy in the past

Exclusion criteria:

Patients with stump abnormalities (patients with residual limb) Patients with addiction Patients with brain injuries have special mental health problems Have vision problems Use of analgesics Use of sleeping pills Use of antidepressants

Age

From **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization through envelopes prepared by a member of the research team and random numbers with the help of Randomaize.com will be printed and placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study is first explained to the person who meets the conditions, and the person, if desired, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, amputees in the first group will receive mirror therapy intervention and after the end of the trial group will receive conventional training without knowing the first group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Room 332, Department of Orthotics and Prosthetics, Second Floor, School of Rehabilitation Sciences, University of Medical Sciences, Hezar Jerib St., Isfahan ,Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-09-12, 1400/06/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.264

Health conditions studied

1

Description of health condition studied

Amputation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Phantom pain score in Visual Analogue Scale(VAS)

Timepoint

Measurement of phantom pain at the beginning of the study (before the intervention) and 6 weeks after the start of mirror therapy training

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, a mirror is prepared and placed in front of a healthy foot, and the amputated person tries to perform finger movements, bending, straightening of the wrist, and rotation of a healthy limb, and looks at healthy foot movements in a mirror. This is done daily for a while. It will be done for 14 minutes in a row for 6 weeks. The person is required to record the

amount of pain reduction daily on a visual analogue scale.

Category

Rehabilitation

2

Description

Control group: In this group, the usual treatments, which include repeated and low strokes by the hand to the end and around the stump, and massage by the person throughout the stump. This will be done daily for 14 minutes for 6 weeks. The person is required to record the amount of pain reduction daily on a visual analogue scale

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthosis and Prosthesis Center of Isfahan
Rehabilitation School

Full name of responsible person

Alirezataheri

Street address

Room 332, Department of Orthotics and Prosthetics,
Second Floor, School of Rehabilitation Sciences,
University of Medical Sciences, Hezar Jerib St., Isfahan
,Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaghayeghhaghjo

Street address

Room 332, Department of Orthotics and Prosthetics,
Second Floor, School of Rehabilitation Sciences,
University of Medical Sciences, Hezar Jerib St., Isfahan
,Iran

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isfahan

Province

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Postal code

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Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Alirezataheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics &Prosthetics

Street address

Room 332, Department of Orthotics and Prosthetics,
Second Floor, School of Rehabilitation Sciences,
University of Medical Sciences, Hezar Jerib St., Isfahan
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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Associate professor

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Other areas of specialty/work

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۸۱۷۴۶۷۳۴۶۱

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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

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

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

Access period starts from ۲۰۲۲

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is nothing wrong with using published content by mentioning the title in other articles

From where data/document is obtainable

Applicants should refer to my email to receive the required documents or data.

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

After the title of the study type, the applicant will email me and I will respond to their request by email if needed.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Alirezataheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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