Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 tail 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
Isfehan
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
Isfehan

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

City
isfahan

Province
Isfehan

Postal code
8174673461

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 ,Iran

City
Isfahan

Province
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Postal code
۸۱۷۴۶۷۳۴۶۱

Phone
+98 31 3792 5053

Email
taheri@rehab.mui.ac.ir

Person responsible for scientific 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
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۸۱۷۴۶۷۳۴۶۱
Phone
+98 31 3792 5053
Email
taheri@rehab.mui.ac.ir

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
Orthotics & Prosthetics
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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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taheri@rehab.mui.ac.ir

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