Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of mirror therapy on the phantom limb pain and sexual satisfaction in men with lower limb amputation

Protocol summary

Study aim
The effect of mirror therapy on phantom limb pain and sexual satisfaction in men with lower limb amputation referred to Government clinics in Rasht

Design
A clinical trial with the control group, parallel-group, randomized groups, without blinding, sample size 50 people (intervention of 25, control of 25)

Settings and conduct
This study is a randomized clinical trial. The study population is men with lower limb amputation referred to government clinics in Rasht. The sample size is estimated at 50 people. After determining the people who are eligible to enter the study, the samples are randomly divided into two groups, intervention, and control, based on Random allocation software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: One-sided amputation of the lower limb; Pain in the phantom limb with the severity of at least 20; Married and monogamous men. Exclusion criteria: History of sexual dysfunction before amputation; Movement disorders or barriers (cast, splint, etc.) in the healthy lower limb.

Intervention groups
In the intervention group (Mirror therapy), subjects will be in front of a mirror with dimensions of 80 x 30 cm. So that the amputated limb is behind the mirror and the healthy lower limb is in front of the mirror and the person can see a clear image of the reflection of the healthy limb in the mirror. Each session of mirror therapy will be 15 minutes and 5 sessions per week for 28 days (in total, 20 sessions of 15 minutes). In each session of mirror therapy, 5 minutes will be devoted to opening and closing the healthy foot in front of the mirror, 5 minutes to rotating the ankle inward, and 5 minutes to the rotation of the ankle outward. Control group: No specific intervention by the researcher will be performed in this group.

Main outcome variables
Pain score in a Pain Visual Analogue Scale; Scores obtained in the Sexual Satisfaction Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190805044438N3**
Registration date: **2021-07-30, 1400/05/08**
Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**
Update count: **0**

Registration date
2021-07-30, 1400/05/08

Registrant information

Name
Roya Mansour-ghanaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 4256 5058

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mirror therapy on the phantom limb pain and sexual satisfaction in men with lower limb amputation

Public title
The effect of mirror therapy on the phantom limb pain and sexual satisfaction in men with lower limb amputation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Married and monogamous men Age 18 to 60 years old One-sided amputation of the lower limb at two partial levels (from toes to ankle) or extensive levels (above ankle to thigh) Pain in the phantom limb with a severity of at least 20 Sufficient cognitive ability according to AMT tool Informed consent to participate in the study

Exclusion criteria:
History of sexual dysfunction before amputation Sexual disorder drugs consumption during the study New analgesics consumption during the study Thyroid disorders Malignant diseases Visual disturbances Severe hearing loss Movement disorders or barriers (cast, splint, etc.) in the healthy lower limb

Age
From **18 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are entered into the study according to the study criteria. Individuals are simple randomly assigned to the intervention and control groups with the Random Allocation software. The unit of randomization is individual and study without blinding and parallel.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Deputy of university Research and Technology of the University, Old Bldg (building) School of Health, in front of 17 Shahrivar Hospital, Shahid Siadati Ave, Namjoo St, Rasht

City
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Province
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Postal code
4477163485

Approval date
2021-07-14, 1400/04/23

Ethics committee reference number
IR.GUMS.REC.1400.174

Health conditions studied

1

Description of health condition studied
Amputation

ICD-10 code
Y83.5

ICD-10 code description
Amputation of limb(s)

Primary outcomes

1

Description
Pain score in a Pain Visual Analogue Scale

Timepoint
Before intervention and 7, 14, 21 and 28 days after the start of mirror therapy

Method of measurement
Pain Visual Analogue Scale

2

Description
Scores obtained in the Sexual Satisfaction Questionnaire

Timepoint
Before intervention and 28 days after the start of mirror therapy

Method of measurement
Larson Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At the beginning of the study, before starting mirror therapy, the degree of phantom limb pain and sexual satisfaction in individuals will be determined before the session begins. In this method, subjects will be in front of a mirror with dimensions of 30x80 cm, in such a way that the amputated limb is behind the mirror and the healthy limb is in front of the mirror so that the subject can see a clear image of the movements of the healthy limb in the mirror. Each mirror therapy session will be 15 minutes. Subjects will have 5 sessions per week for 28 days. In each session of mirror therapy, 5 minutes will be devoted to opening and closing the healthy foot in front of the mirror, 5 minutes to rotating the ankle inward, and 5 minutes to rotation of the ankle outward. All participants will complete a total of twenty 15-minute sessions. 7, 14 and 21 days after the intervention, the degree of phantom limb pain will be measured by a VAS instrument and on the 28th day after the end of the intervention, sexual satisfaction will also be assessed in addition to the phantom limb pain. After the first session, when the researchers ensured that the patients have learned correctly how to perform mirror therapy, they provided written instructions to the patients so that they could continue the mirror therapy process at home. Every week 2 phone calls were made to review the process, to encourage people to perform the process regularly, and to answer participants' questions.

Category

Rehabilitation

2

Description

Control group: No specific intervention by the researcher will be performed on patients in this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Government Clinics of Guilan University of Medical Sciences in Rasht (Besat, Razi, Poursina)

Full name of responsible person

Roya Mansour-ghanaei

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Martyr Yaghoub Sheikhi St., Leyla Kooh, Langeroud, Rasht, Iran

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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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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Roya Mansour-ghanaei

Position

Assistant Professor, Faculty member

Latest degree

Ph.D.

Other areas of specialty/work
Health Sciences
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Person responsible for updating data

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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