

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of routine physical therapy with and without mirror therapy on phantom limb pain and psychosocial adjustment to amputation among prosthetic users

Protocol summary

Study aim

To determine the effectiveness of routine physical therapy with and without mirror therapy on phantom limb pain and psychosocial adjustment to amputation among prosthetic users.

Design

Single Blinded, Parallel Groups, Randomized Controlled Trial

Settings and conduct

setting was University of Lahore teaching hospital and study was single blinded

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Diagnosed patients with phantom limb pain having unilateral lower extremity limb traumatic amputation. • Age 18-45 years. • Both gender. • Base line score 3 or more on 0-10 NPRS. • Minimal one episode of phantom limb pain reported. • Participant have sufficient cognitive and communication skills. • Prosthetic user. Exclusion Criteria: • Any condition that restrict movement of opposite limb, pain or limited range of motion in intact limb. • Any diagnosed psychological disorder that could restrains the ability to concentrate during therapy. • Patients having residual limb pain. • Infectious and systematic diseases. • Patients having neuropathic pain other than phantom limb pain. • Severe mental disorder, neglect syndrome, visual spatial hemi neglect, confusion, dizziness.

Intervention groups

Group-A received Mirror therapy in addition with Routine Physical therapy Group-B received Routine Physical Therapy only

Main outcome variables

reduction of pain on NPRS scale and improvement on TAPES scale i.e. Psychosocial Adjustment, Prosthesis Satisfaction, Activity Restriction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048239N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**

Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Ayesha Noreen

Name of organization / entity

The university of Lahore

Country

Pakistan

Phone

+92 42 35963424

Email address

ayesha.noreen@uipt.uol.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-28, 1399/01/09

Expected recruitment end date

2020-05-15, 1399/02/26

Actual recruitment start date

2020-03-31, 1399/01/12

Actual recruitment end date

2020-05-19, 1399/02/30

Trial completion date

2020-08-08, 1399/05/18

Scientific title

Effects of routine physical therapy with and without mirror therapy on phantom limb pain and psychosocial adjustment to amputation among prosthetic users

Public title

Effects of routine physical therapy with and without mirror therapy on phantom limb pain and psychosocial adjustment to amputation among prosthetic users

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed patients with phantom limb pain having unilateral lower extremity limb traumatic amputation. Age 18-45 years Both gender. Base line score 3 or more on 0-10 NPRS. Minimal one episode of phantom limb pain reported. Participant have sufficient cognitive and communication skills. Prosthetic user.

Exclusion criteria:

Any condition that restrict movement of opposite limb, pain or limited range of motion in intact limb. Any diagnosed psychological disorder that could restrains the ability to concentrate during therapy Patients having residual limb pain. Infectious and systematic diseases. Patients having neuropathic pain other than phantom limb pain. Severe mental disorder, neglect syndrome, visual spatial hemi neglect, confusion, dizziness.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

we allocated numbers to participants in advance and then generated a table of random number based on these numbers. simple randomization was done with help of a random number table generated with excel. The first number was allocated to group-A and the second number was allocated to group-B and the same pattern was followed for the rest of the study participants for treatment allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

it was a single blinded study the assessor was blinded while ensuring confidentiality. An initial assessment of all patients was done by a trained physical therapist before allocation who was not allowed any access to allocation process and treatment. The treatment plan for both groups was executed by the researcher himself. Post trial

assessment was performed by a physiotherapist having more than five years of experience in clinical field.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional review board/Faculty of Allied Health Sciences

Street address

1 km defense road Lahore

City

Lahore

Postal code

54000

Approval date

2020-03-05, 1398/12/15

Ethics committee reference number

IRB-UOL-FAHS/718-VIII/2020

Health conditions studied

1

Description of health condition studied

Phantom limb Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduction of score on NPRS scale, improvement of score on TAPES scale i.e. psychosocial adjustment, prosthesis satisfaction, activity restriction

Timepoint

At baseline, at 2nd week and at 4th week

Method of measurement

NPRS (Numeric Pain Rating Scale) and TAPES (Trinity Amputation and prosthesis Evaluation Scale)

Secondary outcomes

empty

Intervention groups

<u>1</u>	Description Intervention group Category Rehabilitation	Public or private sector Private Domestic or foreign origin Domestic Category of foreign source of funding <i>empty</i> Country of origin Type of organization providing the funding Academic
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<u>2</u>	Description Control group Category Rehabilitation
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Recruitment centers

<u>1</u>	Recruitment center Name of recruitment center University Of Lahore Teaching Hospital Full name of responsible person Dr. Zain ul Abbas Street address 1 km defense road Lahore City Lahore Postal code 54000 Phone +92 42 32560865 Email zain.abbas@uipt.uol.edu.pk
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Sponsors / Funding sources

<u>1</u>	Sponsor Name of organization / entity The University of Lahore Full name of responsible person Prof. Dr. Ashfaq Ahmad Street address 1 km defense road Lahore City Lahore Postal code 54000 Phone +92 42 32300865 Email ashfaq.ahmad@uipt.uol.edu.pk Grant name Grant code / Reference number Is the source of funding the same sponsor organization/entity? Yes Title of funding source The University of Lahore Proportion provided by this source 100
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Person responsible for general inquiries

Contact Name of organization / entity The University of Lahore Full name of responsible person Dr. zain ul Abbas Position Lecturer Latest degree Master Other areas of specialty/work Physiotherapy Street address 1 km defense road Lahore City Lahore Province Punjab Postal code 54000 Phone +92 42 32300865 Email zain.abbas@uipt.uol.edu.pk
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Person responsible for scientific inquiries

Contact Name of organization / entity The University of Lahore Full name of responsible person Dr. zain ul Abbas Position lecturer Latest degree Master Other areas of specialty/work Physiotherapy Street address 1 km defense road Lahore City Lahore Province Punjab Postal code 54000 Phone +92 42 32300865 Email zain.abbas@uipt.uol.edu.pk
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Person responsible for updating data

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Dr. zain ul Abbas

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available