

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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.noureen@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

## 1

### Description

Intervention group

### Category

Rehabilitation

## 2

### Description

Control group

### Category

Rehabilitation

## Recruitment centers

## 1

### 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

## Sponsors / Funding sources

## 1

### 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

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#### 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

### Public or private sector

Private

### 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

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

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#### Phone

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## Person responsible for scientific inquiries

### Contact

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The University of Lahore

#### Full name of responsible person

Dr. zain ul Abbas

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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