Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Ayesha Noureen

Name of organization / entity
The university of Lahore

Country
Pakistan

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person
Prof. Dr. Ashfaq Ahmad
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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
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
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Other areas of specialty/work
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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