

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of massage therapy with and without aerobic exercises on glucose, blood pressure and diabetic peripheral neuropathy

#### Protocol summary

##### Study aim

Aim of the study is to explore the effects of massage therapy with and without aerobic exercises on glucose, blood pressure and diabetic peripheral neuropathy

##### Design

94 Patients will be randomized into treatment group(47) and control group(47) by lottery method. It is a single blinded randomized controlled trail. In this study patients will be completely blinded about intervention protocol

##### Settings and conduct

Muhammad physical therapy clinic and rehabilitation cenetr, Al khaliq hospital, Multicare physical therapy clinic Multan

##### Participants/Inclusion and exclusion criteria

Patients with diabetic peripheral neuropathy and hypertension will be included in this study. Patients with angina, stroke, myocardial infarctio, acute illness and any fracture of the lower limb will be excluded from this study

##### Intervention groups

Group 1 will be treatment group in which patients receive massage therapy with aerobic exercises(cycling and walking) and group 2 will be control group in which patients receive massage therapy alone.

##### Main outcome variables

Blood pressure, glucose level and neuropathic pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220603055065N1**

Registration date: **2022-06-22, 1401/04/01**

Registration timing: **prospective**

Last update: **2022-06-22, 1401/04/01**

Update count: **0**

##### Registration date

2022-06-22, 1401/04/01

##### Registrant information

###### Name

Hafiza Iram Batool

###### Name of organization / entity

Muhammad Institute of Medical and Allied Sciences  
Multan

###### Country

Pakistan

###### Phone

+92 304 0134576

###### Email address

hafizairam@mimas.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-25, 1401/04/04

##### Expected recruitment end date

2022-08-31, 1401/06/09

##### Actual recruitment start date

2022-06-25, 1401/04/04

##### Actual recruitment end date

2022-08-31, 1401/06/09

##### Trial completion date

2022-08-31, 1401/06/09

##### Scientific title

Effects of massage therapy with and without aerobic exercises on glucose, blood pressure and diabetic peripheral neuropathy

##### Public title

Effects of massage therapy with and without aerobic exercises on glucose, blood pressure and diabetic peripheral neuropathy

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diabetic peripheral neuropathy patients Hypertension

### Exclusion criteria:

Stroke Myocardial infarction Any fracture Foot ulcer

Unstable heart disease Acute illness

## Age

From **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **94**

More than 1 sample in each individual

Number of samples in each individual: **47**

47 patients in each group

Actual sample size reached: **94**

More than 1 sample in each individual

Actual sample size in each individual: **47**

47

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients simply randomized into two groups by using convenient sampling technique. Patients will be randomized by lottery method (Draw numbers from the box randomly to choose samples).

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Data analyzer will be blinded when analyze the data that which group has which outcome. So, data analyzer will be completely blinded.

## Placebo

Not used

## Assignment

Parallel

## Other design features

Patients will be included in this study by filling questionnaire about diabetes

## Secondary Ids

### 1

#### Registry name

#### Secondary trial Id

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Ethical Committee of Muhammad

Institute of Medical and Allied Sciences, Multan.

### Street address

HBL street, near sabzazar ,etro station, bosan road  
Multan

### City

Multan

### Postal code

60700

### Approval date

2021-11-10, 1400/08/19

### Ethics committee reference number

2021/IRB/12/PT/12

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic peripheral neuropathic patients

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition neuropathy

## Primary outcomes

### 1

#### Description

Diabetic peripheral neuropathy

#### Timepoint

Patients will be evaluate before and after treatment  
seesion

#### Method of measurement

Sphygmomanometer, Stethoscope, Glucometer,  
Neuropathy pain scale (NPS)

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Before and after treatment

#### Method of measurement

With the help of sphygmomanometer and stethoscope  
for blood pressure and neuropathy pain scale for  
neuropathic pain

## Intervention groups

### 1

#### Description

Treatment group: Patients of treatment group receive  
massage therapy with aerobic exercises. After taking  
consent from patients they will be assess by using  
questionnaire for diabetes, pin-prick testing, neuropathy  
pain scale will be used to check pain, and blood pressure  
will be monitor by sphygmomanometer and stethoscope.

Glucose level will be checked by glucometer. Aerobic exercises include 4-minute walking on electronic treadmill and 6-minute cycling on stationary bicycle. Session lasted for four days per week for six weeks. Glucose level, blood pressure and neuropathic pain will be measured before and after treatment sessions.

**Category**

Treatment - Devices

**2****Description**

Control group: Patients of control group receive massage therapy alone. After taking consent from patients they will be assess by using questionnaire for diabetes, pin-prick testing, neuropathy pain scale will be used to check pain, and blood pressure will be monitor by sphygmomanometer and stethoscope. Glucose level will be checked by glucometer. Glucose level, blood pressure and neuropathic pain will be measured before and after treatment sessions. Treatment session lasted for four days per week for six weeks.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Muhammad Institute of Medical and Allied Sciences,  
Multan

**Full name of responsible person**

Dr. Nimra Arif

**Street address**

HBL street, near sabzazar metro station, Bosan road  
Multan

**City**

Multan

**Postal code**

60700

**Phone**

+92 304 0134576

**Email**

angelnimra95@gmail.com

**Web page address**

http://mimas.edu.pk

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences,  
Multan

**Full name of responsible person**

Imran Ahmad Khan

**Street address**

HBL strret, near sabzazar metro station, bosan road  
Multan

**City**

Multan

**Postal code**

60700

**Phone**

+92 304 0134576

**Email**

imranahmadkhandurrani@gmail.com

**Web page address**

http://mimas.edu.pk

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Muhammad Institute of Medical and Allied Sciences,  
Multan

**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**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences,  
Multan

**Full name of responsible person**

Dr. Nimra Arif

**Position**

Senior Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

HBL, street near sabzazar metro station, bosan road  
Multan

**City**

Multan

**Province**

Punjab

**Postal code**

60700

**Phone**

+92 333 3877032

**Email**

angelnimra95@gmail.com

**Web page address**

http://mimas.edu.pk

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences,  
Multan

**Full name of responsible person**

Imran Ahmad Khan

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cardiology

**Street address**

HBL street, near sabzazar metro station, Bosan road  
Multan

**City**

Multan

**Province**

Punjab

**Postal code**

60700

**Phone**

+92 304 0134576

**Email**

imranahmadkhandurrani@gmail.com

**Web page address**

<http://www.mimas.edu.pk>

**Phone**

+92333877032

**Email**

angelnimra95@gmail.com

**Web page address**

<http://mimas.edu.pk>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Title of my study effects of massage therapy with and without aerobic exercises on glucose, blood pressure and diabetic peripheral neuropathy. The basic purpose of my study is to assess the effects of massage therapy with aerobic exercises on diabetic peripheral neuropathic patients. A randomized controlled trial will be conducted at Muhammad physical therapy clinic and rehabilitation center Multan. 94 subjects will be selected who met the inclusion criteria will be randomized into two groups, treatment group(1) and control group(2). Sampling technique is Convenient. Group 1 receive massage therapy with aerobic exercises(cycling and walking) and group 2 receive massage therapy alone.

**When the data will become available and for how long**

This expected that this study or data will be available at the end of this year 2022, no exact date can be expected.

**To whom data/document is available**

Nimra Arif

**Under which criteria data/document could be used**

For research purposes

**From where data/document is obtainable**

<https://www.researchgate.net>.<https://scholar.google.com>  
m hafizairambatool@gmail.com

**What processes are involved for a request to access data/document**

Open assess

**Comments**

I want randomized controlled trial registration, please provide me as soon as possible, so that I can continue my study

## Person responsible for updating data

### Contact

**Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences  
Multan

**Full name of responsible person**

Dr. Nimra Arif

**Position**

Senior Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

HBL street, near sabzazar metro station, Bosan road  
Multan

**City**

Multan

**Province**

Punjab

**Postal code**

60700