

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

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+92 304 0134576

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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

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angelnimra95@gmail.com

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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

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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

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Province

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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

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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

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