Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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HBL street, near sabzazar metro station, Bosan road Multan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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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 controoled trial will be cinducted 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, tratement 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
hhttps://www.researchgate.net.https://scholar.google.com hafizairambatool@gmail.com

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

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