

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of hydrotherapy with and without massage on serum nerve growth factor and balance in diabetic neuropathy patients

Protocol summary

Study aim

The aim of this study is to investigate the effect of hydrotherapy and massage on NGF, balance and glycemic markers in diabetic neuropathy patients.

Design

Study design: Randomized double-blinded controlled clinical trial. Blinding is carried out for subjects and researchers and randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block. Population and sample size: 39 Type 2 diabetics patients with peripheral neuropathy who are not participated in any regular training program for at least 6 months before the study.

Settings and conduct

39 Type 2 diabetics patients with peripheral neuropathy who are eligible and are referred to a diabetes center affiliated to Ferdowsi University of Mashhad, Mashhad, Iran will be selected. Blinding is carried out for subjects and researchers and randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetics patients with peripheral neuropathy aged 38 to 58 years, sedentary and ability to walk a 1.6-km distance without assistance. Exclusion criteria: People with cardiovascular disease, arthritis or pain that limits exercise and central nervous system dysfunction.

Intervention groups

Intervention 1: aerobic and resistance training in water for 1 hour/session, three times/week, for wight weeks Intervention. Intervention 2: massage for 30 minutes/session, 3 times/week, for wight weeks Intervention. Control group: following their daily activities and avoid any regular exercise

Main outcome variables

Body fat, balance, nerve growth factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151025024699N4**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **retrospective**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Damoon Ashtary-Larky

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

2018-12-11, 1397/09/20

Scientific title

The effects of hydrotherapy with and without massage on serum nerve growth factor and balance in diabetic neuropathy patients

Public title

effects of hydrotherapy and massage on serum nerve growth factor and balance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 38-58 Type 2 diabetics patients with peripheral neuropathy Sedentary and ability to walk a 1.6-km distance without assistance Interesting in participation in research No smoking No alcoholism Not taking supplements (including vitamins, minerals, ergogenic aids) Not participating in any regular training program for at least 6 months before the study. Taking metformin (500 mg, 2 times per day with meals) and glibenclamide (5 to 10 mg in the morning in a fasted state).

Exclusion criteria:

A history or evidence on physical examination of significant central nervous system dysfunction Significant musculoskeletal deformity Arthritis or pain that limits exercise. A history or clinical evidence of severe cardiovascular diseases that limit the exercise A history or evidence on physical examination of vestibular dysfunction. A history of angina

Age

From **38 years** old to **58 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study design: Parallel double-blind (both patients and researchers) clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Ferdowsi University of Mashhad, Iran

Street address

Ferdowsi University of Mashhad, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9596116856

Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.UM.REC.1398.073

Health conditions studied

1

Description of health condition studied

Type 2 diabetics patients with peripheral neuropathy

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Nerve growth factor

Timepoint

Before and 8 weeks after intervention

Method of measurement

ELISA

2

Description

Balance

Timepoint

Before and 8 weeks after intervention

Method of measurement

Berg Balance Scale

Secondary outcomes

1

Description

Insulin

Timepoint

Before and 8 weeks after intervention

Method of measurement

ELISA

2

Description

Glucose

Timepoint

Before and 8 weeks after intervention

Method of measurement

Enzymatic method

3

Description

HBA1C

Timepoint

Before and 8 weeks after intervention

Method of measurement

Enzymatic method

4

Description

Body fat

Timepoint

Before and 8 weeks after intervention

Method of measurement

Body fat Analyzer

Intervention groups

1

Description

Intervention group: aerobic and resistance training in water for 1 hour/session, three times/week, for eight weeks Intervention.

Category

Lifestyle

2

Description

Intervention group: massage for 30 minutes/session, 3 times/week, for eight weeks Intervention.

Category

Rehabilitation

3

Description

Control group: following their daily activities and avoid any regular exercise

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vice chancellor for Research, Ferdowsi University of

Mashhad

Full name of responsible person

Dr. Amir Rashidlamir

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Physical education faculty, Ferdowsi University of Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Ferdowsi University of Mashhad, Iran.

Full name of responsible person

Aazam safari

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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

Vice chancellor for Research, Ferdowsi University of Mashhad, Iran.

Proportion provided by this source

100

Public or private sector

Public

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

Ferdowsi University of Mashhad

Full name of responsible person

Reza Bagheri

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Physiology

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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

itle and more details about the data/document
Publication of protocol study in form of the article and
also data publication in the original article. The total
potential data can be shared after unidentifiable
subjects.

When the data will become available and for how long

6 months after the publication of results

To whom data/document is available

All researchers who have access to clinical trials
databases

Under which criteria data/document could be used

The only way for using the data is after the publication of
the article in the indexed ISI journal.

From where data/document is obtainable

Via database websites such as PubMed and google
scholar and via email address:
damoon_ashtary@yahoo.com

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

The original article reaches the requestor by email within
a maximum of one week.

Comments