Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 cardiovasculardiseases 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 wight weeks Intervention.
Category
Lifestyle

2

Description
Intervention group: massage for 30 minutes/session, 3 times/week, for wight 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Ferdowsi University of Mashhad, Iran.
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?
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
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Position
Researcher
Latest degree
Master
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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