

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effects of water based exercise on falling risk factors in the patients with diabetic neuropathy

Protocol summary

Fear of falling; Static and Dynamic Balance; Reaction time; Fall index; Frequency of fall

Study aim

Effect of water exercises on falling risk factors in the Neuropathy- Diabetic patients

Design

The present research is a randomized, controlled, prospective randomized clinical trial with parallel groups.

Settings and conduct

The present study will be carried out at the research Center of Kermanshah University of Medical Sciences. Because of the nature of the study, the participants are not blind to the division into groups, but statisticians and evaluators split the participants into groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria were included; Age over 65 years old; clinical confirmation of type 2 diabetes with peripheral neuropathy; lower limb symptoms of peripheral neuropathy; ability to walk home without help or with aides; definitive electrodiagnostic evidences of peripheral neuropathy Exclusion criteria were included; Severe cardiovascular disease; unstable proliferative retinopathy; end-stage renal disease and uncontrolled high blood pressure; severe structural abnormalities of the lower extremity; history or evidence of vestibular dysfunction; history with evidence of plantar pressure ulcer

Intervention groups

The water treatment group participates in a 10-week water exercise program, 3 sessions a week, and 40-70 minutes per session. Each training session is guided by a trained sports trainer under the supervision of researchers. The water level with an average temperature of 30 ° C is considered constant within the boundary of the dagger appendage. The training program includes: tensile and warm-up exercises (10 minutes), endurance training (20 minutes walking and dancing), resistance training (15 minutes), balance exercises (15 minutes), and relaxation / cooling training (5 minutes).

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031942N10**

Registration date: **2018-09-21, 1397/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-21, 1397/06/30**

Update count: **0**

Registration date

2018-09-21, 1397/06/30

Registrant information

Name

Aynollah Naderi

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2018-08-30, 1397/06/08

Actual recruitment end date

2018-09-23, 1397/07/01

Trial completion date

2018-08-14, 1397/05/23

Scientific title

Effects of water based exercise on falling risk factors in the patients with diabetic neuropathy

Public title

Water based exercise and diabetic neuropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 65 years old
Clinical confirmation of type 2 diabetes with peripheral neuropathy
Lower limb symptoms of peripheral neuropathy
Ability to walk home without help or with aids
Definitive electrodiagnostic evidences of peripheral neuropathy

Exclusion criteria:

Severe cardiovascular disease
History with evidence of plantar pressure ulcer
unstable proliferative retinopathy
End-stage renal disease and uncontrolled high blood pressure
severe structural abnormalities of the lower extremity
History or evidence of vestibular dysfunction
History with evidence of plantar pressure ulcer

Age

From **65 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate the participants in the research groups, a computerized list of random numbers for assigning random subjects to blocks (2, 4, 6, 8) was determined using the SPSS software by the statistical consultant. Then, the assignment of the participants is carried out by one of the research team members who are not associated with the 1: 1 assignment ratio within the training and control groups. Assignment sequences are hidden by the envelopes encoded in the order numbered, and the letter envelopes are opened only after all the initial and initial evaluations of the participants have been made.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Beheshti Blvd, Kermanshah , Kermanshah Province

City

kermansah

Province

Kermanshah

Postal code

6761753164

Approval date

2018-08-14, 1397/05/23

Ethics committee reference number

IR.KUMS.REC.1397.411

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

E11.40

ICD-10 code description

Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Fear of falling

Timepoint

Measure the fear of falling at the beginning of the study (before the intervention) and 12 and 24 weeks after the beginning of the water base exercise program.

Method of measurement

Fall Efficacy Scale International

Secondary outcomes

1

Description

Static and Dynamic Balance

Timepoint

Measure the static and dynamic balance at the beginning of the study (before the intervention) and 12 and 24 weeks after the beginning of the exercise program.

Method of measurement

Frailty and Injuries: Cooperative Studies of Intervention Techniques-4 and Dynamic Gait Index

2

Description

Reaction time

Timepoint

Measure the reaction time at the beginning of the study (before the intervention) and 12 and 24 weeks after the beginning of the water base exercise program.

Method of measurement

Switch Mat

3

Description

Fall index

Timepoint

Measure the fall index at the beginning of the study (before the intervention) and 12 and 24 weeks after the beginning of the water base exercise program.

Method of measurement

Physiological Profile Assessment

Intervention groups

1

Description

Intervention group: The water treatment group participates in a 10-week water exercise program, 3 sessions a week, and 40-70 minutes per session. Each training session is guided by a trained sports trainer under the supervision of researchers. The water level with an average temperature of 30 ° C is considered constant within the boundary of the dagger appendage. The training program includes: tensile and warm-up exercises (10 minutes), endurance training (20 minutes walking and dancing), resistance training (15 minutes), balance exercises (15 minutes), and relaxation / cooling training (5 minutes).

Category

Prevention

2

Description

Control group: Participants in this group receive only routine pre-care and no new intervention is granted to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized and specialized clinics for diabetes and metabolic diseases in the city of Kermanshah

Full name of responsible person

Alireza Hassani

Street address

No. 11, Third alley, taghbostan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Proportion provided by this source

10

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

Kermanshah University of Medical Sciences

Full name of responsible person

Ainollah Sakinepoor

Position

Teacher

Latest degree

Master

Other areas of specialty/work

علوم ورزشی

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Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available