

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effectiveness of self-control training and communication skills on emotional regulation, perceived pain severity and self-care behaviors caused by nerve neuropathy in diabetic patients

Protocol summary

Study aim

The main goal of this study was to investigate the effectiveness of Self-Control Training and communication skills on emotional regulation, perceived pain Intensity and self-care behaviors caused by neuropathy in diabetic patients and sub goals based on variables separately by interventional methods

Design

The type of research was semi-experimental with pre-test and post-test with unequal control group. And in terms of data type, it was quantitative and methodologically, semi-experimental and purposeful, exploratory and in terms of outcome, was Applied

Settings and conduct

Individuals with diabetic neuropathy were selected at the Health Center of Mashhad, Shahid Ghodsi Health Center, self-control training and communication skills were performed on the basis of the above method in 10 sessions of 90 minutes and 15 from the experimental group, At the same time, 15 patients in the control group were pre-test. After doing the work, both post-test groups were taken. patients were provided with a researcher's own designs and the library was field-based

Participants/Inclusion and exclusion criteria

Conditions of entry; patients who have symptoms of neuropathy. patients with type 2 diabetes who have symptoms such as pain and paresthesia, pain in the limbs and leg burning during the night, patients with a duration of more than five years, people who are on the basis of a specific age found by the subject are present, conditions of non-entry; patients with type 1 diabetes, patients who have not filed a complaint at the Health Center patients not confirmed in the case of neuropathic symptoms

Intervention groups

15 subjects in experimental group that the effectiveness of self-control and communicative skills training was

performed and 15 control subjects whose effectiveness was not performed.

Main outcome variables

Emotion regulation variables, perceived pain intensity and self-care behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038109N2**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **retrospective**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Mahdi Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3869 1438

Email address

amirime@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-21, 1396/02/31

Expected recruitment end date

2017-07-04, 1396/04/13

Actual recruitment start date

2017-05-21, 1396/02/31

Actual recruitment end date

2017-07-04, 1396/04/13

Trial completion date

empty

Scientific title

The effectiveness of self-control training and communication skills on emotional regulation, perceived pain severity and self-care behaviors caused by nerve neuropathy in diabetic patients

Public title

The effect of self-control training and communication skills in nerve neuropathy of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have been diagnosed with Neuropathy symptoms in the case Patients with type 2 diabetes most of the symptoms, such as nausea, paresthesia and pain in the limbs and needle fixation at night Patients of both sexes have a duration of more than five years Patients who are based on the age range specified by the subject Patients age 47 or older are allowed to enter the study because of diabetic neuropathy that occurs at an advanced age

Exclusion criteria:

Patients with type 1 diabetes Patients who do not have a file at the Health center Patients whose symptoms of neuropathy have not been confirmed in the case Patients who are about 47 years of age or older are not allowed to enter the study because diabetic neuropathy does not occur at an early age

Age

From **47 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Ethics committee of Islamic Azad University, Science and Research Branch of Neyshabour

Street address

Research Area, Neyshabur, Razavi Khorasan Province

City

Neyshabur

Province

Razavi Khorasan

Postal code

9319797139

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.IAV.NEYSHABUR.REC.1395.13

Health conditions studied**1****Description of health condition studied**

Diabetic nerve neuropathy

ICD-10 code

E08.43

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy

Primary outcomes**1****Description**

Emotion regulation, perceived pain intensity, self-care behaviors

Timepoint

The time interval at the beginning of the study on patients, pre-test (before intervention), 10 sessions 90 minutes and 30 days to post-test (after intervention)

Method of measurement

Emotion scoring score in the Graz Thrice disorders questionnaire, perceived pain intensity score in the McGill pain questionnaire, self-care behavior score questionnaire, self-care behavior questionnaire of Tubert and Glasgow diabetic patients

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: included 15 diabetic nerve neuropathy patients in Shahid Ghodsi Health Center in

city of Mashhad. For 10 sessions of 90 minutes and for 1 month, self-control training and communication skills were performed on them

Category

Treatment - Devices

2**Description**

Control group: The study included 15 diabetic neuropathic patients in Shahid Ghodsi Health Center in city of Mashhad. The effectiveness of self-control training and communication skills on these patients was not completed and only filled the questionnaires(Pre-test and post-test) at the same time as the intervention group, and there was an explanation for routine daily care in these patients.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health Center No.3 of Mashhad, Shahid Ghodsi Comprehensive Health Center

Full name of responsible person

Esmat Surgi

Street address

Next to the Blood Transfusion Organization, at the end of Sanabad Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 51 3844 0077

Email

behdasht3@mums.ac.ir

Web page address

http://behdasht3.mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Khorasan Razavi Health Center

Full name of responsible person

Hamid Reza Bahrami

Street address

Health Center, End of Sanabad, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9185816212

Phone

+98 51 3841 5001

Fax**Email**

health@mums.ac.ir

Web page address

http://health.mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Khorasan Razavi Health Center

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Health center number 3 of Mashhad city, Shahid Ghodsi Health Center

Full name of responsible person

Seyyedeh Mehri Boland Ashtian

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Next to the Blood Transfusion Organization, at the end of Sanabad, Mashhad

City

Mashhdd

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 513844007

Email

behdasht3@mums.ac.ir

Web page address

http://behdasht3.mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad Health Center No. 3, Shahid Ghodsi Health Center

sina@mums.ac.ir

Full name of responsible person

Maryam Keivan Jafari

Position

Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Next to the Blood Transfusion Organization, at the end of Sanabad, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 513844007

Email

behdasht3@mums.ac.ir

Web page address

<http://behdasht3.mums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mehdi Amiri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychology

Street address

Astan Qods Ave., Haramali Street, Avicenna Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

919583134

Phone

+98 51371127017

Email

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

Only part of the data, such as Information on the main outcome, or the like, can be shared

When the data will become available and for how long

Start the access period from 1398

To whom data/document is available

Data is available for Researchers working in Academia and Academia

Under which criteria data/document could be used

In Patients who develop diabetic neuropathy and type 2 diabetes, they are affected by conditions and symptoms that damage their nerve and the involvement of a nerve in a region. data Analysis was analyzed using descriptive statistics (mean and standard deviation) and inferential statistics (multivariate covariance test).

From where data/document is obtainable

Mashhad Health Center No. 3, to the website:

<http://behdasht3.mums.ac.ir>, tel: 051337634007

Address: Boulevard Khayyam, Boulevard Ershad 8,

St.Petersburg, on message 6, and Shaheed Ghodsi

Health Center, at the end of Sanabad Street, along with

the blood transfusion organization, the diabetes

education unit, Mrs. Saydeh Mehri Alishi and Ms. Maryam

Keivan Jafari. Address: End of Sanabad Street, next to

the blood transfusion organization

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

The Research and research done according to the Intervention method and test hypotheses that were performed during the specified period are made. from defense date to 31/4/1396

Comments