

# 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**