

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A study of effectiveness of acceptance and commitment therapy on improving psychopathological symptoms of patients with diabetic neuropathy

Protocol summary

Study aim

Determine the effectiveness of acceptance and commitment therapy on the severity of pain perception, improvement in pain acceptance, self-compassion, quality of sleep, and occupational and social function of diabetic neuropathy

Design

A randomized, clinical trial with a control group and a sample size of 24

Settings and conduct

Patients with diabetic neuropathy after diagnosis by a neurologist in Kermanshah Diabetes Centers and consideration of entry and exit criteria are included in the study and divided into control and experimental groups. Initially, a pre-test is performed from both groups, Then the test group is provided with eight therapy sessions. After the therapy is completed, the post-test is taken from the patients and eventually, a two month follow-up period is taken from the patients. The control group also receives a common psychological therapy after the end of the study. All stages of therapy are carried out at the Farabi hospital in Kermanshah.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of diabetic neuropathy is characterized by a neurologist. Patient agrees to participate in the research. Age range 35 to 65 years. Having at least the eighth grade. Exit criteria: Concurrent participation in other therapeutic plan having substance abuse and somatization disorder

Intervention groups

Experimental group: they receive 8 psychological therapy sessions. Control group: they receive only medication.

Main outcome variables

Acceptance Chronic Pain Questionnaire score, McGill Pain Revised Questionnaire score; Self-Compassion Scale (Short Form), Sleep Quality Inventory score;

Occupational and Social Adjustment scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038630N4**

Registration date: **2019-04-05, 1398/01/16**

Registration timing: **prospective**

Last update: **2019-04-05, 1398/01/16**

Update count: **0**

Registration date

2019-04-05, 1398/01/16

Registrant information

Name

Ali Akbar Foroughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 4371

Email address

aliakbar.foroughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of effectiveness of acceptance and commitment therapy on improving psychopathological symptoms of patients with diabetic neuropathy

Public title

Effect of acceptance and commitment therapy on diabetic neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of diabetic neuropathy by a neurologist
willingness to participate in the research Age range 35 to 65 years old Having at least eighth school grade

Exclusion criteria:

Drug abuse Concurrent participation in other therapeutic plan Having any somatization disorder

AgeFrom **35 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

By the simple random method, individuals are assigned to the control and test groups using a sealed envelope

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 Kermanshah University of Medical Sciences

Street address

In front of Taleghani Hospital, Naft square

City

Kermanshah

Province

Kermanshah

Postal code

56423-22222

Approval date

2019-02-16, 1397/11/27

Ethics committee reference number

IR.KUMS.REC.1397.939

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

diabetic neuropathy

ICD-10 code

E13.40

ICD-10 code description

Other specified diabetes mellitus with diabetic neuropathy, unspecified

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

Score in Acceptance Chronic Pain Questionnaire

Timepoint

At the beginning of the study, after the study (after the end of the intervention) and two months after the study

Method of measurement

Acceptance chronic pain Questionnaire

2**Description**

Score in McGill Pain Revised Questionnaire

Timepoint

At the beginning of the study, after the study (after the end of the intervention) and two months after the study

Method of measurement

McGill Pain Revised Questionnaire

3**Description**

Score in Self-Compassion Scale (Short Form)

Timepoint

At the beginning of the study, after the study (after the end of the intervention) and two months after the study

Method of measurement

Self-Compassion Scale

4**Description**

Score in Sleep Quality Inventory

Timepoint

At the beginning of the study, after the study (after the end of the intervention) and two months after the study

Method of measurement

Sleep Quality Inventory

5

Description

Score in Occupational and Social Adjustment Scale

Timepoint

At the beginning of the study, after the study (after the end of the intervention) and two months after the study

Method of measurement

Occupational and Social Adjustment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Individuals receive acceptance and commitment therapy in addition to anti-pain medication for eight weeks. After the treatment is completed, the post test will be taken from people under treatment and the two-month follow-up period will be done.

Category

Behavior

2

Description

Control group: Individuals receive anti-pain medication for eight weeks. After the treatment is completed, the post test will be taken from people under treatment and the two-month follow-up period will be done.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

leila Afshar Hazarkhani

Street address

Farabi Hospital, Dolat Abad Square

City

Kermanshah

Province

Kermanshah

Postal code

49564-39936

Phone

+98 83 3822 6451

Email

taheriamir679@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

In front of Taleghani Hospital, Naft square

City

kermanshah

Province

Kermanshah

Postal code

4562388887

Phone

+98 83 3838 4180

Fax

Email

fnajafi@kums.ac.ir

Grant name

Kermanshah University of Medical Sciences

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

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

Kermanshah University of Medical Sciences

Full name of responsible person

Amir Abbas Taheri

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Faculty of Medical, Sorkhe lize Ave, Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

8614733481

Phone

+98 31 5322 6077

Email

taheriamir679@gmail.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Ali Akbar Foroughi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Medical School, Kermanshah University of Medical Sciences, Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

671451568

Phone

+98 83 3837 4371

Email

foroughi_2002@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Amir Abbas Taheri

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Medical School, Kermanshah University of Medical Sciences, Parastar Blvd

City

kermanshah

Province

Kermanshah

Postal code

8614733491

Phone

+98 31 5322 6077

Email

taheriamir679@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available