

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of cognitive-behavioral stress management technique (CBSMT) and self-care education and their combination on treatment adherence, diabetic self-care, health status, perceived stress, lifestyle and quality of life in patients with type 2 diabetes

Protocol summary

Study aim

Comparison of the effectiveness of cognitive-behavioral stress management technique (CBSMT) and self-care education and their combination on treatment adherence, diabetic self-care, health status, perceived stress, lifestyle and quality of life in patients with type 2 diabetes

Design

Clinical trial with one control and two intervention groups, with parallel groups, designed for 60 patients, without blindness, randomized.

Settings and conduct

This study is performed on the Iranian Diabetes Society of Kerman on the patients with type II diabetes. Blindness will not do in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age range 40-50 years, having diabetes type 2, higher education than the cycle, not using other treatments during the research and have other types of diabetes; exclusion criteria: Have severe diabetic complications, having a disease that causes problems with blood sampling.

Intervention groups

First in the intervention group 1: drug treatments and cognitive-behavioral stress management technique (CBSMT) and in the intervention group 2: drug treatments and self-care, Intervention group 3: drug treatments and 8 sessions combining the two treatments run for 8 sessions for 2 to 2.5 hours and 2 times a week.

Main outcome variables

diabetic self-care, health status, perceived stress, lifestyle and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211214053413N1**

Registration date: **2022-06-24, 1401/04/03**

Registration timing: **retrospective**

Last update: **2022-06-24, 1401/04/03**

Update count: **0**

Registration date

2022-06-24, 1401/04/03

Registrant information

Name

Amineh Jalali

Name of organization / entity

University of Tehran Kish International Campus

Country

Iran (Islamic Republic of)

Phone

+98 21 3223 5011

Email address

jalaliamineh95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-08, 1400/11/19

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of cognitive-behavioral stress management technique (CBSMT) and self-care education and their combination on treatment adherence, diabetic self-care, health status, perceived stress, lifestyle and quality of life in patients with type 2 diabetes

Public title

Comparison of the effectiveness of cognitive-behavioral stress management technique (CBSMT) and self-care education and their combination in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 40-50 years Having diabetes type 2 for at least six months with a specialist physician diagnosis Higher education than the cycle Not using other treatment psychotherapy programs and changing medications during the research

Exclusion criteria:

Have other types of diabetes Have severe diabetic complications that prevent research Acute or chronic medical illness that may cause problems with blood sampling

AgeFrom **40 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

In this research, randomization will be block, and the randomization unit will be cluster. Random assignment of patients (60 tons) to 4 groups (first 15 patients for group A, then 15 patients for group B, then 15 patients for group C and finally 15 patients for group D), using The order of generating integer random numbers (= INT (RAND (* * 60))) is performed by the rand function of Excel software. And D, will be done so that the names of the groups (intervention group 1; stress management based on cognitive-behavioral therapy, intervention group 2; self-care training, intervention group 3; stress management based on cognitive-behavioral therapy + self-care training, group Control; group 4) is written on four pieces of paper and will be folded, then by random selection of the first paper from four papers, type of intervention group A, by choosing the second paper from the remaining three papers, type of intervention group B,

by selecting the third paper From the remaining two papers, the type of intervention in group C will be determined, and the remaining paper (fourth) will determine the type of intervention for group D.

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 the Faculty of Psychology and Educational Sciences, University of Tehran

Street address

Tehran - Shahid Chamran Highway - Under Nasr Bridge (Gisha)

City

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Province

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Postal code

1358879331

Approval date

2021-11-06, 1400/08/15

Ethics committee reference number

IR.UT.PSYEDU.REC.1400.078

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

Patients with type II diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

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

adherence therapy

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Madanlu Therapy Adherence Questionnaire (2013)

2

Description

Diabetic Self-Care

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Diabetes Self-Care Questionnaire

3

Description

health status

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Questionnaire Walker Health

4

Description

Perceived Stress

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Cohen, Kamak and Marmarstein (1983) Perceived Stress Scale

5

Description

lifestyle

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Promoting Lifestyle Questionnaire (1983)

6

Description

quality of life

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Quality of Life Questionnaire 36 questions

Secondary outcomes

1

Description

Adherence of treatment

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Madanlu Therapy Adherence Questionnaire (2013)

2

Description

The amount of self-care

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Diabetes Self-Care Questionnaire

3

Description

health status

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

World Health Organization Health Status

4

Description

Lifestyle level

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Questionnaire Walker Health Promoting Lifestyle Questionnaire (1983)

5

Description

En Level of quality of life

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Quality of Life Questionnaire 36 questions

6

Description

level of Perceived stress

Timepoint

Before an intervention, immediately after the intervention, 2 months after the end of intervention

Method of measurement

Cohen, Kamak and Marmarstein (1983) Perceived Stress Scale

Intervention groups

1

Description

Intervention group 1: Medication (Use of metformin according to the instructions of an endocrinologist) and 8 sessions of cognitive-behavioral stress management therapy (CBSMT) for 2 to 2.5 hours and once a week.

Category

Diagnosis

2

Description

Intervention group 2: receive medication(Use of metformin according to the instructions of an endocrinologist) and 8 sessions of self-care training for 2 to 2.5 hours and once a week.

Category

Diagnosis

3

Description

Intervention group 3: Medication(Use of metformin according to the instructions of an endocrinologist) and 8 sessions of combination of two treatments for 2 to 2.5 hours and once a week.

Category

Diagnosis

4

Description

Control group: They only receive drug treatment(Use of metformin according to the instructions of an endocrinologist).

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Diabetes Society of Kerman

Full name of responsible person

Amineh Jalali

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Kerman. Houshang Moradi St. Kermani, Houshang Moradi 9 alley, Nikan building, second floor, unit 3.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

Title of funding source

University of Tehran

Proportion provided by this source

1

Public or private sector

Private

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

University of Tehran

Full name of responsible person

Amineh.Jalali

Position

PhD student of Health Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

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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

All related data to participants are shared after hiding patient's name.

When the data will become available and for how long

The period of access to the present research data will be available 6 months after publication of the research results in the form of research articles.

To whom data/document is available

The present study data will be available only to researchers working in the academic and scientific institutions.

Under which criteria data/document could be used

The output of statistical analysis will be available

From where data/document is obtainable

Applicants can apply for documentation and data via email at jalaliamineh95@gmail.com

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

After completion of the research and publication of the extracted articles, it will be available for a maximum 6 months later.

Comments