Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 tree 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

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Iran (Islamic Republic of)

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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
Age
From **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
Tehran
Province
Tehran
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 Marmerstein (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, 2months 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 Marmerstein (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
Street address
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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13588784612
Phone
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info@kiau.ac.ir
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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Other areas of specialty/work

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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