Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effectiveness of Motivational Interviewing in Accordance with the AIM model and Family Empowerment model Based on Self-Compassion on Adherence to Treatment, Self-Care, Health-Related Quality of life Dependent Diabetes and Glycosylated Hemoglobin in Patients with Diabetes II

Protocol summary

Study aim

The effectiveness of motivational interviewing in accordance with the AIM model and family empowerment model based on self-compassion on adherence to treatment, self-care, quality of life and glycosylated hemoglobin in patients with type II diabetes

Design

Clinical trial with one control and two intervention groups, with parallel groups, designed for 120 patients, without blindness, randomized.

Settings and conduct

This study is performed on the metabolism section of Imam Hossein Hospital and Iranian Diabetes Society of Tehran on the patients with type II diabetes. Blindness will not do in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age range 30-55 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 motivational interviewing in accordance with AIM model and in the intervention group 2: drug treatments and motivational interviewing in accordance with family empowerment model based on self-compassion run for 8 sessions for 2 to 2.5 hours and 2 times a week.

Main outcome variables

Adherence to treatment; self-care; quality of life; glycosylated hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190528043744N1**
Registration date: **2019-10-12, 1398/07/20**
Registration timing: **retrospective**

Last update: **2019-10-12, 1398/07/20**
Update count: **0**

Registration date

2019-10-12, 1398/07/20

Registrant information

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Soheila Rahmani
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Islamic Azad university
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-09, 1397/11/20

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2019-02-09, 1397/11/20

Actual recruitment end date
2019-04-19, 1398/01/30
Trial completion date
2019-09-23, 1398/07/01

Scientific title
Comparison of the effectiveness of Motivational Interviewing in Accordance with the AIM model and Family Empowerment model Based on Self-Compassion on Adherence to Treatment, Self-Care, Health-Related Quality of life Dependent Diabetes and Glycosylated Hemoglobin in Patients with Diabetes II

Public title
Comparison of the Effectiveness of Motivational Interviewing in Accordance with the AIM Model and Family Empowerment Model Based on Self-Compassion in treatment of diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 30-55 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 **30 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, individuals are randomly divided into two groups of intervention and one control group using random number table. In this method, the first selected number (randomly) set in the first intervention group and the next numbers assign to the second intervention and control groups respectively. Intervention group 1 receive drug treatments 8 sessions of motivational interviewing in accordance with AIM model, intervention group 2 receive drug treatments and 8 sessions of motivational interviewing in accordance with family empowerment model based on self-compassion and the third group as the control, only receive drug treatments.
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, Karaj Branch
Street address
Islamic Azad University, Karaj Branch, Moazzen Blvd., Rajai Shahr, Karaj, Alborz Province
City
Tehran
Province
Tehran
Postal code
1358879331
Approval date
2018-10-02, 1397/07/10
Ethics committee reference number
IR.IAU.K.REC.1398.021

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
The effectiveness of motivational interviewing of the AIM model in adherence to treatment
Timepoint
Before an intervention, immediately after the intervention, 3 months after the end of intervention
Method of measurement
Morisky's adherence treatment questionnaire

2

Description
The effectiveness of motivational interviewing of the AIM model in self-care
Timepoint
Before an intervention, immediately after the

intervention, 3 months after the end of intervention

Method of measurement

Short-term scale of Tobert's diabetics self-care activities

3

Description

The effectiveness of motivational interviewing of the AIM model in quality of life

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Wang's Quality of Life Questionnaire of Diabetes

4

Description

The effectiveness of motivational interviewing of the AIM model in glycosylated hemoglobin

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Blood test

5

Description

The effectiveness of Family Empowerment Model Based on Self-Compassion on adherence to treatment

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Morisky's adherence treatment questionnaire

6

Description

The effectiveness of Family Empowerment Model Based on Self-Compassion on self-care

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Short-term scale of Tobert's diabetics self-care activities

7

Description

The effectiveness of Family Empowerment Model Based on Self-Compassion on quality of life

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Wang's Quality of Life Questionnaire of Diabetes

8

Description

The effectiveness of Family Empowerment Model Based on Self-Compassion on glycosylated hemoglobin

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Adherence of treatment

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Morisky's adherence treatment questionnaire

2

Description

The amount of self-care

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Short-term scale of Tobert's diabetics self-care activities

3

Description

Level of quality of life

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Wang's quality of life questionnaire of diabetes

4

Description

Amount of glycosylated hemoglobin

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

Blood test

5

Description

Score of self-compassion

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

The scale of self-compassion

6

Description

Score of the coping styles

Timepoint
Before an intervention, immediately after the intervention, 3 months after the end of intervention
Method of measurement
Lazarus coping strategies questionnaire

7

Description
Score of perceived social support
Timepoint
Before an intervention, immediately after the intervention, 3 months after the end of intervention
Method of measurement
Multidimensional scale of Ziment perceived social support

Intervention groups

1

Description
The intervention group 1: Drug treatments and 8 sessions of motivational interviewing in accordance with AIM model receive 2 to 2.5 hours and twice a week.
Category
Diagnosis

2

Description
Intervention group 2: Drug treatments and 8 sessions of motivational interviewing in accordance with family empowerment model based on self-compassion receive 2 to 2.5 hours and twice a week.
Category
Diagnosis

3

Description
Control group: They only receive drug treatment.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital and Iranian Diabetes Society of Tehran
Full name of responsible person
Soheila Rahmani
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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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Islamic Azad University, Karaj Branch, Moazzen Blvd., Rajai Shahr, Karaj, Alborz Province
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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?
Yes
Title of funding source
Islamic Azad University, Karaj Branch
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
Islamic Azad University, Karaj Branch
Full name of responsible person
Soheila Rahmani
Position
PhD student of Health Psychology
Latest degree
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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 soheilarahmani_sh@yahoo.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