

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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

Name

Soheila Rahmani

Name of organization / entity

Islamic Azad university

Country

Iran (Islamic Republic of)

Phone

+98 21 5532 8101

Email address

soheilahmani_sh@yahoo.com

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

Street address

No. 18, 1st West Sarvestan Ave., Rahahan Town, Tehran

City

Tehran

Province

Tehran

Postal code

1358879331

Phone

+98 21 5532 8101

Email

soheilahrahmani_sh@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University, Karaj Branch

Full name of responsible person

Shirin Naderi

Street address

Islamic Azad University, Karaj Branch, Moazzen Blvd., Rajai Shahr, Karaj, Alborz Province

City

Tehran

Province

Tehran

Postal code

13588784612

Phone

+98 34 1822 0795

Email

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

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 18, 1st West Sarvestan Ave., Rahahan Town,
Tehran

City

Tehran

Province

Tehran

Postal code

1358879331

Phone

+98 21 5532 8101

Email

soheilahmani_sh@gmail.com

Person responsible for scientific 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

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 18, 1st West Sarvestan Ave., Rahahan Town,
Tehran

City

Tehran

Province

Tehran

Postal code

1358879331

Phone

+98 21 5532 8101

Email

soheilahmani_sh@gmail.com

Person responsible for updating data

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

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 18, 1st West Sarvestan Ave., Rahahan Town,
Tehran

City

Tehran

Province

Tehran

Postal code

1358879331

Phone

+98 21 5532 8101

Email

soheilahmani_sh@gmail.com

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 soheilahmani_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