

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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**

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**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**

Islamic Azad University, Karaj Branch

**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?**

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

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Soheila Rahmani

**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University, Karaj Branch

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**Position**

PhD Student of Health Psychology

**Latest degree**

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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 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**