

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the Effectiveness of Motivational Interviewing and Self Knowledge Sources on life style .in Patients with type II diabetes.

#### Protocol summary

##### Study aim

Determine the effectiveness of Motivational Interviewing and education Self Knowledge Sources on life style .in Patients with type II diabetes.

##### Design

80 patients were selected randomly and randomly divided into two groups of 40 patients. Then, patients at the Firouzgar Hospital were exposed to motivational interviewing and patients at Imam Reza Hospital were trained by Self Knowledge Sources

##### Settings and conduct

40 patients from Imam Reza Hospital and 40 patients from Firouzgar Hospital will be selected randomly. For both groups, a preliminary pre-test is performed. Then, patients in the Firouzgar Hospital are exposed to motivational interview for 10 sessions; and Imam Reza Hospital patients are exposed to Self Knowledge Sources for 10 sessions. Finally, the post-test is executed and the data is analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged over 35 Not having another chronic disease Having Type 2 Diabetes Exclusion Criteria History of the disease less than 1 year Use of non-diabetic drugs Alcohol or substance abuse Simultaneously undergo another psychological treatment Except motivational interviewing and education Self Knowledge Sources

##### Intervention groups

. In the first group, patients receive 10 sessions of motivational interviewing for 2 two hours.and the second group patients receive 10 sessions of education Self Knowledge Sources for 2 two hours.

##### Main outcome variables

life style: , lifestyle is a combination of behavioral patterns and individual habits throughout life, including nutrition, physical activity, stress, smoking and the quality of sleep that arose after being socialized. The lifestyle is a multifaceted phenomenon that all The aspects of everyday life, sleep, food, health, customs,

work, play, entertainment, time spent, consensus, thinking, behavior, feelings and emotions.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180710040411N2**

Registration date: **2018-11-14, 1397/08/23**

Registration timing: **retrospective**

Last update: **2018-11-14, 1397/08/23**

Update count: **0**

##### Registration date

2018-11-14, 1397/08/23

##### Registrant information

##### Name

Javad Kazemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0061

##### Email address

sa.khanjani@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-10-26, 1396/08/04

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparing the Effectiveness of Motivational Interviewing and Self Knowledge Sources on life style .in Patients with type II diabetes.

**Public title**

Comparing the Effectiveness of Motivational Interviewing and Self Knowledge Sources on life style .in Patients with type II diabetes.

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged over 35 Having Type 2 Diabetes Not having another chronic disease

**Exclusion criteria:**

History of illness less than 1 year Use of non-diabetic drugs Alcohol or substance abuse Simultaneously undergo another psychological treatment except motivational interviewing and Self Knowledge Sources

**Age**

From **35 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to select the samples in the experimental and control groups, simple random method with Using random numbers, was used. Cluster randomization method was used. Thus, between Firouzgar Hospital and Imam Reza Hospital, with using random numbers, patients with type 2 diabetes in Firouzgar Hospital was selected as the experimental group. Also, Imam Reza hospital patients were selected as control group.

**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**

The Ethics Committee of the Research Institute of the Baqiyatallah University of Medical Sciences

**Street address**

Health and Nutrition Research Center, Research Institute Building, Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, Sheikh Bahayi Ave., Mulla Sadra Ave., Vanak Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

ندارم

**Approval date**

2017-05-31, 1396/03/10

**Ethics committee reference number**

IR. BMSU.REC.1396.311

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

Type 2 Diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

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

Lifestyle A combination of behavioral patterns and individual habits throughout life such as nutrition, physical activity, stress, smoking and the quality of sleep that arose after socialization.

**Timepoint**

Before intervention and after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: 40 patients with type 2 diabetes mellitus in Firouzgar Hospital that exposed to Self Knowledge Sources for 10 sessions.

**Category**

Rehabilitation

**2**

**Description**

Control group: 40 patients with type 2 diabetes mellitus in Imam Reza Hospital that exposed to motivational interviews for 10 sessions.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Firouzgar Hospital

##### Full name of responsible person

Mehrnoush Isanlou

##### Street address

Firouzgar Hospital, Behafarin.St., Karim Khan St., Valiasr Square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1593747811

##### Phone

+98 21 8214 1600

##### Email

bbahmani43@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Abolfazl Rahimi Zarchi

##### Street address

Imam Reza Hospital, above the Embassy of Pakistan, Etemadzadeh Ave., West Fatemi St., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

##### Phone

+98 21 8802 8350

##### Email

bbahmani43@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bagheiat-allah University of Medical Sciences

##### Full name of responsible person

Fatemeh Rahmati

##### Street address

Health and Nutrition Research Center, Research Institute Building, Baqiyatallah University of Medical

Sciences, Shahid Nosrati Alley, Sheikh Bahayi Ave., Mulla Sadra Ave., Vanak Square, Tehran

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##### Phone

+98 21 8248 2468

##### Email

rahmati.fatemeh90@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Bagheiat-allah University of Medical Sciences

#### Proportion provided by this source

5

#### Public or private sector

Public

#### 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

Bagheiat-allah University of Medical Sciences

##### Full name of responsible person

Javad Kazemi

##### Position

PHD Student

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

##### Street address

Health and Nutrition Research Center, Research Institute Building, Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, Sheikh Bahayi Ave., Mulla Sadra Ave., Vanak Square, Tehran

##### City

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##### Province

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##### Postal code

65571-37347

##### Phone

+98 21 8248 2468

##### Email

kazemi012@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Javad Kazemi

**Position**

PHD student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Javad Kazemi

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PHD student

**Latest degree**

Master

**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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The results will be published without mentioning the names of the participants

**When the data will become available and for how long**

10 months

**To whom data/document is available**

Supervisors-Researchers - Journalists

**Under which criteria data/document could be used**

The data will be published without mentioning the names of individuals for presentation in research journals.

**From where data/document is obtainable**

Will be consulted by the University's Ethics Committee

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

About three months after the completion of the project, the results of the research will be received by the applicant.

**Comments**