Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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, beetween 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 Emam 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

City

Tehran

Province

Tehran

Postal code

ندارم

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

Tehran

Province

Tehran

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

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Email
kazemi012@gmail.com

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