

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### To study the effect of educational package based on Islamic teachings on nutritional self-care behavior and metabolic control of middle-aged patients with type two diabetes referred to the Diabetes Center, Mazandaran University of Medical Sciences

#### Protocol summary

##### Summary

Abstract: Diabetes mellitus is the most common glandular disorder worldwide and is responsible for 4 million deaths per year. The prevalence of type two diabetes in our population over 30 years is estimated between 6/5-10/6 percent. Self-care and patient education are the bases to identify and control of diabetes. Nutritional intervention is the inseparable component of self-care education and management of diabetes. Theories of behavioral and social sciences have an important role to establish effective health education programs. There is no motive like the inner belief and incentive, to motivate the behavior. The method of care of soul is one of the common ways to self-making, behavior change and reformation in Islamic ethics and mysticism. The purpose of this study is to determine the effect of the educational package based on Islamic teachings on nutritional self-care behavior and metabolic control of middle-aged patients with type two diabetes referred to the Diabetes Center, Mazandaran University of Medical Sciences. This is a quasi-experimental study. The study population is the patients with type two diabetes attending the Diabetes Center in Sari, Mazandaran University of Medical Sciences. The study is done in two steps. In the first stage during a cross sectional study, at least 30 patients of the target population will respond to the questionnaires. The educational program will be designed and implemented based on the study results. In the interventional phase eligible patients will be divided to experimental and control groups by random assignment (at least 30 patients in each group). Questionnaires of Knowledge, Attitude and Practice (KAP) on nutritional self-care behavior and Islamic teachings will be offered to both groups as pre-tests. HbA1C, lipid and glucose will be tested. Weight and blood pressure measurements will be

performed. Afterward the teaching sessions to train educational package according to Islamic care method will be offered to the experimental group. 3 months later, KAP study of nutritional self-care behavior and Islamic teachings will be performed in both groups as post-tests. Metabolic tests and physical indices measurements will be repeated again. The results will be compared using statistical tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016010325826N1**  
Registration date: **2016-02-03, 1394/11/14**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-02-03, 1394/11/14

##### Registrant information

##### Name

Manizheh Zakizad Abkenar

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 3569

##### Email address

m.zakizadabkenar@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares University

**Expected recruitment start date**

2014-11-22, 1393/09/01

**Expected recruitment end date**

2014-12-21, 1393/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

To study the effect of educational package based on Islamic teachings on nutritional self-care behavior and metabolic control of middle-aged patients with type two diabetes referred to the Diabetes Center, Mazandaran University of Medical Sciences

**Public title**

Islamic teachings and nutrition of diabetic patients

**Purpose**

Other

**Inclusion/Exclusion criteria**

inclusion: afflicted with type 2 diabetes for at least one year before study, Age between 30 to 65 years old (middle age), HbA1C between 6.5- 9, Men and women, Adequate literacy, Belief in to Islam, No change in drug regimen by the physician at least during the first 3 months of research, to be Interested in participating in the research. exclusion: to be Pregnant (or plan to become pregnant during the study), breastfeeding,Chronic kidney disease, heart disease, cancer, No change in drug regimen by the physician at least during the first 3 months of research,Lack of interest to participate in research, Unable to Make Calls

**Age**From **30 years** old to **65 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **98****Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Tarbiat Modares University

**Street address**

Tarbiat Modares University, Jalal Ale Ahmad Highway, P.O.Box: 14115-111, Tehran, Iran

**City**

Tehran

**Postal code**

14115-111

**Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

52/1456

**2****Ethics committee****Name of ethics committee**

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**Approval date**

2014-05-17, 1393/02/27

**Ethics committee reference number**

52/1456

**3****Ethics committee****Name of ethics committee**

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14115-111

**Approval date**

2014-05-17, 1393/02/27

**Ethics committee reference number**

52/1456

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

diabetes

**ICD-10 code**

E10,E11,E1

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

WEIGHT, blood pressure, glucose, lipid, HbA1C

#### Timepoint

before and 2 months after intervention

#### Method of measurement

Weight (kg), blood pressure (mmHg), fasting plasma sugar (mg/dL), blood sugar two hours post prandial(mg/dL), Cholesterol (mg/dL), triglycerides (mg/dL), LDL (mg/dL), HDL (mg/dL), glycosylated hemoglobin (HbA1C): percent

### 2

#### Description

nutritional self-care behavior and metabolic and Anthropometric indexes

#### Timepoint

before and 2 months after intervention

#### Method of measurement

Weight (kg), blood pressure (mmHg), fasting plasma sugar (mg/dL), blood sugar two hours post prandial(mg/dL), Cholesterol (mg/dL), triglycerides (mg/dL), LDL (mg/dL), HDL (mg/dL), glycosylated hemoglobin (HbA1C): percent

## Secondary outcomes

### 1

#### Description

Knowledge, Attitude and practice of Nutritional self care

#### Timepoint

Before and 2 months after intervention

#### Method of measurement

multi choice questions of Knowledge and practice, Likert questions of Attitude

## Intervention groups

### 1

#### Description

10 hours of nutritional education, Islamic teachings and Islamic care method for intervention group

#### Category

Other

### 2

#### Description

10 hours of nutritional education for the control group

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabetes Center, Mazandaran University of Medical Sciences

##### Full name of responsible person

Fahimeh Akbardokht

##### Street address

Diabetes Center, Imam hospital

##### City

Sari

### 2

#### Recruitment center

##### Name of recruitment center

Diabetes Center, Mazandaran University of Medical Sciences

##### Full name of responsible person

Fahimeh Akbardokht

##### Street address

Diabetes Center, Imam hospital

##### City

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tarbiat Modares University

##### Full name of responsible person

Mansoureh Movahedin

##### Street address

Anatomical Sciences Dept., Medical Sciences Faculty, Tarbiat Modares University, Tehran, Iran.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tarbiat Modares University

#### Proportion provided by this source

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## 2

### **Sponsor**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mansoureh Movahedin

**Street address**

Anatomical Sciences Dept., Medical Sciences Faculty,  
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**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tarbiat Modares University

**Proportion provided by this source**

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## 3

### **Sponsor**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mansoureh Movahedin

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**City**

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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**

Tarbiat Modares University

**Proportion provided by this source**

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

### **Contact**

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**Full name of responsible person**

Manizheh Zakizad Abkenar

**Position**

PhD student in health education and health promotion

**Other areas of specialty/work**

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## **Person responsible for scientific inquiries**

### **Contact**

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**Position**

professor

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PhD student in health education and health promotion

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*