

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Designing Occupation-Centered Self-management interventions and investigating its effect on Performance, Satisfaction and self- efficacy of people diagnosed with type 2 diabetes

#### Protocol summary

##### Study aim

Designing and evaluating occupation-centered self-management interventions in people with type 2 diabetes

##### Design

A randomized clinical trial with control group, single blind(assessor blind)

##### Settings and conduct

The place of the study is the school of rehabilitation of Iran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 30 to 60 years with a diagnosis of type 2 diabetes for at least one year with no co morbidity, being literate, being in occupational imbalance, interested in engagement in related activities and the ability to use cell phone or short message system Exclusion criteria: Unwillingness to continue working with the research team, injury or severe illness, no referral for gathering blood samples, two sessions of continuous absence or four absentee sessions throughout the treatment sessions

##### Intervention groups

The occupation-centered self management intervention will be implemented in the intervention group. Details of this intervention will be determined during expert panel meetings and a preliminary study. Various ways such as education, counseling, coaching, feedback and discussion among the members of the group will be used to facilitate the performance of the participants in different areas of self-management. Initially, nine sessions of intervention, once a week, are scheduled for 60 minutes per session. In order to generalize the skills to real life, the logbook is available to each participant and homework assignments are set for individuals. In the control group, participants will receive a booklet. The content of the program and its importance will explained to them by research team members. Also, follow up is

done by telephone calls.

##### Main outcome variables

Performance, Satisfaction, Self Efficacy, Fasting Blood Sugar, A1c, Lipid profile, Creatinine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180105038224N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **prospective**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

##### Registration date

2018-12-02, 1397/09/11

##### Registrant information

##### Name

Maryam Binesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7159

##### Email address

Binesh.m@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-03-10, 1398/12/20

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Designing Occupation-Centered Self-management interventions and investigating its effect on Performance, Satisfaction and self- efficacy of people diagnosed with type 2 diabetes

**Public title**  
Designing Occupation-Centered Self-management interventions and investigating its effect on Performance, Satisfaction and self- efficacy of people diagnosed with type 2 diabetes

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosis of type 2 diabetes for at least 1 year No co-morbidity based on patient's report and doctor's diagnosis Age range of 30 to 60 years Being literate Occupational balance score of less than 2.5 according to Life Balance Inventory Interested in participating in study-related activities Ability to use cellphone or short message system

**Exclusion criteria:**  
Unwillingness to continue working with the research team Severe injury or illness during the implementation of the program No referral for gathering blood sample Two consecutive absence or four absentee sessions throughout the treatment sessions

**Age**  
From **30 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Outcome assessor

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The random allocation is done using random cards

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
All assessments in both groups will be done by an unaware examiner of the random allocation method. All assessments will be done 3 times: before the first intervention session, after the end of the intervention and three months thereafter

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran University of Medical Sciences

##### Street address

Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2018-01-20, 1396/10/30

#### Ethics committee reference number

IR.IUMS.REC1396.9321525002

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E10-E14

#### ICD-10 code description

E11.8 Type 2 diabetes mellitus with unspecified complications

## Primary outcomes

### 1

#### Description

Satisfaction

#### Timepoint

Before the intervention, after the end of the intervention, 3 months later

#### Method of measurement

The Canadian Occupational Performance Measure

## Secondary outcomes

### 1

#### Description

Performance

#### Timepoint

Before the intervention, after the end of the intervention, 3 months later

#### Method of measurement

The Canadian Occupational Performance Measure

## 2

### **Description**

Self Efficacy

### **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

### **Method of measurement**

The diabetes empowerment scale

## 3

### **Description**

Fasting Blood Sugar

### **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

### **Method of measurement**

Blood samples

## 4

### **Description**

Hemoglobin A1c

### **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

### **Method of measurement**

Blood samples

## 5

### **Description**

Lipid Profile

### **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

### **Method of measurement**

Blood samples

## 6

### **Description**

Creatinine

### **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

### **Method of measurement**

Blood samples

## 7

### **Description**

Distress

### **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

### **Method of measurement**

The diabetes distress scale

## 8

### **Description**

Self care

## **Timepoint**

Before the intervention, after the end of the intervention, 3 months later

## **Method of measurement**

The summary of diabetes self care activities measure

## **Intervention groups**

### 1

#### **Description**

Intervention group: Occupation- centered self-management intervention will be conducted in the intervention group. Intervention sessions will be hold using various methods such as education, counseling, coaching, feedback, and discussion among members by group format to facilitate performance in different areas of self-management. At intervals between sessions, the therapist will check the attendance rate through a phone call or SMS. Also, participants can ask their questions one day of per week in person or by phone. In order to generalize the skills to real life, the logbook is available to each participant and homework assignments are set for individuals. At the beginning of the meetings, people will talk about the experience of generalizing their real life skills. Details and schedules of the various intervention sessions will be determined after the expert panel sessions and a preliminary study. Initially, nine sessions of intervention, once a week, are scheduled for 60 minutes per session

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: The control group will receive the current self-management program implemented through the existing educational booklet at Endocrinology and Metabolism Research Center of Iran University of Medical Sciences. The booklet will be explained to the participants in a 15-minute session. Also, the rate of tracking the program by individuals and answering their questions will be done by the research team using telephone at regular intervals.

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Endocrinology and Metabolism Research Center affiliated to Iran University of Medical Science

##### **Full name of responsible person**

Maryam Binesh

##### **Street address**

Endocrinology and Metabolism Institute of Iran University of Medical Sciences, Firoozeh Alley, Valiasr avenue

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1593716615  
**Phone**  
+98 21 8603 6064  
**Email**  
maryami.binesh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Mansooreh Hossein Mardi  
**Street address**  
Iran University of Medical Sciences, Hemat Highway  
next to Milad Tower, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Phone**  
+98 21 8670 2543  
**Email**  
admins@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

30

#### 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Afsoon Hassani Mehraban  
**Position**  
عضو هیئت علمی  
**Latest degree**

Ph.D.

#### Other areas of specialty/work

Occupational Therapy

#### Street address

Faculty of Rehabilitation Sciences, Iran University of  
Medical Sciences, Shah Nazari St., Mother's Square,  
Mirdamad, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1545913487

#### Phone

+98 21 2222 7124

#### Email

afsoonmehraban@hotmail.com

## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Afsoon Hassani Mehraban

#### Position

Faculty member

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Occupational Therapy

#### Street address

Faculty of Rehabilitation Sciences of Iran University of  
Medical Sciences, Shah Nazari St, Mother's Square,  
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1545913487

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## Person responsible for updating data

#### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Maryam Binesh

#### Position

دانشجوی دکترای تخصصی

#### Latest degree

Master

#### Other areas of specialty/work

Occupational Therapy

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**Email**

maryami.binesh@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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