

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Aug 2026

### The Effect of participation-based empowerment program on blood sugar level, physical activity, and nutritional behaviors in pre-diabetic people

#### Protocol summary

Blood sugar, physical activity, nutritional behaviors

##### Study aim

Determining the impact of participation-based empowerment program on blood sugar levels, physical activity and nutritional behaviors in prediabetic people

##### Design

A clinical trial with a control group, with parallel groups, single-blind, on 82 patients, drawing a card was used for randomization

##### Settings and conduct

This study will be conducted in the form of a field trial on 82 prediabetic people with entry criteria in 4 comprehensive health service centers affiliated to No. 1 in Mashhad in a simple random and single-blind manner. The intervention program of 6 sessions of 45-60 minutes will be held for people with pre-diabetes and their family caregivers. The educational content will include the importance of blood sugar control, regular physical activity, dietary compliance and stress management methods. The collaborative program has three stages of educational and support needs assessment, support planning and evaluation

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study (for pre-diabetics): Age 18-59 years; Having a health record in the health center; Having a family caregiver interested in participating in the study; Ability to read and write; The ability to use a smart phone; Absence of pregnancy for female clients; Blood sugar between 100 and 125 mg/dL; Lack of employment in medical science professions; Non-entry criteria Fasting blood sugar more than 126 mg/dL; Lack of literacy

##### Intervention groups

The intervention program is 6 sessions of 45-60 minutes. The educational content will include the importance of blood sugar control, regular physical activity, dietary compliance and stress management methods. The control group will receive 4 training sessions of 30-60 minutes by health care workers.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230923059494N1**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **prospective**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

##### Registration date

2023-10-29, 1402/08/07

##### Registrant information

##### Name

Elham Bagheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3623 2902

##### Email address

bagherie4012@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-01-21, 1402/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| empty                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Scientific title</b>                       | The Effect of participation-based empowerment program on blood sugar level, physical activity, and nutritional behaviors in pre-diabetic people                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Public title</b>                           | The Effect of participation-based empowerment program on blood sugar level, physical activity, and nutritional behaviors in pre-diabetic people                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Purpose</b>                                | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Inclusion/Exclusion criteria</b>           | <b>Inclusion criteria:</b><br>Age 18-59 years Having a health record in the health center Having a family caregiver interested in participating in the study Ability to read and write The ability to use a smart phone Absence of pregnancy for female clients Blood sugar between 100 and 125 mg/dL Lack of employment in medical science professions<br><b>Exclusion criteria:</b><br>Fasting blood sugar more than 126 mg/dL Lack of literacy                                                                                                             |
| <b>Age</b>                                    | From <b>18 years</b> old to <b>59 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Sample size</b>                            | Target sample size: <b>82</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Randomization description</b>              | At first, among the 20 health centers affiliated to Mashhad Health Center No. 1, 4 centers will be selected based on the goal. These four centers will have the same social and economic conditions. Then a code is assigned to each of these centers and the sheets with the codes written on them will be placed in a sealed envelope. An observer will then be asked to remove the papers from the envelope. The first and third papers will be assigned to the intervention group and the second and fourth papers will be assigned to the control group. |
| <b>Blinding (investigator's opinion)</b>      | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Blinding description</b>                   | The data analyst will not know which of the intervention or control groups the information is related to.                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Secondary Ids</b>                          | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                                                |                                                                                                                      |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| <b>Ethics committees</b>                       |                                                                                                                      |
| <b><u>1</u></b>                                |                                                                                                                      |
| <b>Ethics committee</b>                        |                                                                                                                      |
| <b>Name of ethics committee</b>                | Ethics committee of Mashhad University of Medical Sciences                                                           |
| <b>Street address</b>                          | Azadi Square, Mashhad Medical Sciences Campus                                                                        |
| <b>City</b>                                    | Mashhad                                                                                                              |
| <b>Province</b>                                | Razavi Khorasan                                                                                                      |
| <b>Postal code</b>                             | 9137913199                                                                                                           |
| <b>Approval date</b>                           | 2023-09-20, 1402/06/29                                                                                               |
| <b>Ethics committee reference number</b>       | IR.MUMS.NURSE.REC.1402.076                                                                                           |
| <b>Health conditions studied</b>               |                                                                                                                      |
| <b><u>1</u></b>                                |                                                                                                                      |
| <b>Description of health condition studied</b> | prediabetes                                                                                                          |
| <b>ICD-10 code</b>                             | R73.0                                                                                                                |
| <b>ICD-10 code description</b>                 | Abnormal glucose                                                                                                     |
| <b>Primary outcomes</b>                        |                                                                                                                      |
| <b><u>1</u></b>                                |                                                                                                                      |
| <b>Description</b>                             | Blood sugar                                                                                                          |
| <b>Timepoint</b>                               | In the study, blood sugar measurement will be done before the study, during the study and one month after the study. |
| <b>Method of measurement</b>                   | Blood sugar will be measured using laboratory fasting blood sugar measurement                                        |
| <b><u>2</u></b>                                |                                                                                                                      |
| <b>Description</b>                             | physical activity                                                                                                    |
| <b>Timepoint</b>                               | Before the study and one month after the intervention                                                                |
| <b>Method of measurement</b>                   | With International Physical Activity Questionnaire(IPAQ)                                                             |
| <b><u>3</u></b>                                |                                                                                                                      |
| <b>Description</b>                             | Nutritional behaviors                                                                                                |
| <b>Timepoint</b>                               | Before the study and one month after the intervention                                                                |
| <b>Method of measurement</b>                   |                                                                                                                      |

Nutritional behaviors will be measured using the Diabetes Self-Management Questionnaire for Pre-diabetes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention program of 6 sessions of 45-60 minutes will be held for people with pre-diabetes and their family caregivers. The educational content will include the importance of blood sugar control, regular physical activity, dietary compliance and stress management methods

#### Category

Prevention

### 2

#### Description

Control group: In the control group, all the educational content will be provided to them and in addition, 4 training sessions of 30-60 minutes will be held by health care workers for this group and their questions will be answered in this field. Before and after the sessions, diabetes self-care questionnaire and IPAQ, as well as fasting blood sugar will be measured before and after

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Comprehensive health service centers affiliated to the number one health center

##### Full name of responsible person

Dr. Baratali Arabnejad

##### Street address

Iqbal, Vakil Abad Highway

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9179793945

##### Phone

+98 51 3501 8011

##### Email

pr@mums.ac.ir.hc1

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Majid Ghayor Mobarhan

##### Street address

Azadi Square, Mashhad Medical Sciences Campus

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9919191778

##### Phone

+98 51 3841 2081

##### Email

presidentoffice@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad University of Medical Sciences

#### Proportion provided by this source

50

#### 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Hamidreza Zendehtalab

##### Position

consultant

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Azadi Square, East Gate of Ferdowsi University of Mashhad, Shahid Kharazmi Educational Complex

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

##### Phone

+98 51 3859 1511

##### Fax

+98 51 3859 7313

**Email**

zendehtalabHR@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hamidreza Zendehtalab

**Position**

consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Azadi Square, East Gate of Ferdowsi University of  
Mashhad, Shahid Kharazmi Educational Complex

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Fax**

+98 51 3859 7313

**Email**

zendehtalabHR@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Elham Bagheri

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.90, Meshkini Ave 5, Andisheh 71,Ghasemabad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9185344618

**Phone**

+98 51 3623 2902

**Fax**

**Email**

bagherie4012@mums.ac.ir

## 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