

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### The survey on the effect of implementing an intervention based on the family health nurse model on glycemic and anthropometric indicators in middle-aged people with pre-diabetes

#### Protocol summary

##### Study aim

Determining the effect of implementing an intervention based on the family health nurse model on glycemic and anthropometric indicators in middle-aged people with prediabetes covered by selected comprehensive health service centers in Isfahan city in 1402

##### Design

Clinical trial with control group, with parallel groups, without randomization, on 72 patients.

##### Settings and conduct

The research population is middle-aged people with pre-diabetes under the comprehensive health service centers of Isfahan city, who were selected using systematic sampling method. One center will be randomly selected from among centers No. 1 in Isfahan, where social medicine is located, and in order for the control group to be homogenous in terms of social and economic conditions with the subjects of the intervention center, one center will be selected as the control group by lottery among the comprehensive health service centers that are located in the vicinity of the center of the intervention group, which will be implemented for the test group in a self-management program in the form of a localized family health nurse model.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness and informed consent to participate in the research. Exclusion criteria: Unwillingness to continue cooperation Failure to complete the questionnaire or its incomplete completion Disease progression and diabetes

##### Intervention groups

The intervention group includes people with prediabetes who receive educational intervention. The comparison group includes people with prediabetes who receive routine interventions from health care providers.

##### Main outcome variables

prediabetes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230516058206N1**

Registration date: **2023-07-26, 1402/05/04**

Registration timing: **prospective**

Last update: **2023-07-26, 1402/05/04**

Update count: **0**

##### Registration date

2023-07-26, 1402/05/04

##### Registrant information

##### Name

Atefe Afshari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 222 7796

##### Email address

afshar.atefe@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-08, 1402/05/17

##### Expected recruitment end date

2023-11-09, 1402/08/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The survey on the effect of implementing an intervention based on the family health nurse model on glycemic and anthropometric indicators in middle-aged people with pre-diabetes

## Public title

Investigating the effect of the family health nurse model on glycemic and anthropometric indicators

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

For the client, the diagnosis of pre-diabetes has been registered in the Sib system by the doctor of the center in the last one-month through the Hba1c test. Have the desire and informed consent to participate in the research. Having consent for home visit. Farsi speaking. Be between the ages of 30 and 59. Have minimum reading and writing literacy.

### Exclusion criteria:

Reluctance to continue cooperation Not completing the questionnaire or completing it incompletely Disease progression to diabetes Death of the patient or caregiver or causing problems in such a way that the patient and caregiver are unable to continue participating in the study.

## Age

From **30 years** old to **59 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Not 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

Research Ethics Committees of Nursing,  
Rehabilitation and Management schools- Isfahan  
University of

## Street address

Hezar Jerib street, Isfahan, Iran

## City

isfahan

## Province

Isfahan

## Postal code

8174673461

## Approval date

2023-07-08, 1402/04/17

## Ethics committee reference number

IR.MUI.NUREMA.REC.1402.054

## Health conditions studied

### 1

#### Description of health condition studied

prediabetes

#### ICD-10 code

R73.01

#### ICD-10 code description

Impaired fasting glucose

## Primary outcomes

### 1

#### Description

HbA1c

#### Timepoint

At the beginning of the study and after the end of the intervention and 3 months after the end of the intervention

#### Method of measurement

HbA1c test

## Secondary outcomes

### 1

#### Description

Anthropometric indexes

#### Timepoint

Begin, at the end of intervention, 3 months after intervention

#### Method of measurement

meter

## Intervention groups

### 1

#### Description

Intervention group: For this group, the steps of the localized family health nurse model, which was designed by Keshvari et al. in 2013 under the title "Explaining the process of providing health services to families covered by rural health centers in Isfahan city: Designing a suitable model for providing family health care", will be implemented. This model will include three stages (pre-

intervention, intervention, evaluation). The pre-intervention stage includes two preliminary stages and the first meeting with the samples, during the preliminary stage, the necessary measures will be taken to meet the people with pre-diabetes and in the first meeting with the samples, after completing the relevant questionnaires, their initial assessment will be done at the center and the time of the home visit will be coordinated with them. In the intervention stage, which includes (home visit, implementation at the center and presentation of the service package of the localized family health model, formation of self-help groups and follow-up for 3 months), during at least two home visit sessions and the selection of a family health ambassador, using the relevant forms to assess the family's educational needs with the help of family members, and after identifying the identified problems of the patient, based on the nursing diagnoses, planning nursing care for the affected person with the help of the family, and the localized model package, which includes individual counselling, training booklets and holding training sessions, is referred to The doctor will follow up the internal referrals made by the doctor to the psychiatrist, nutritionist, specialist doctor and follow up the external referrals according to the needs and problems of each patient. Then, for 3 months, in the form of holding self-help group meetings and conducting monthly care and blood sugar control, he will follow up the affected people. The evaluation stage of this model will also be done during 3 stages (during the intervention, immediately after the intervention, 3 months after the intervention) by measuring blood sugar.

#### Category

Prevention

## 2

#### Description

Control group: In this study, the control group after being called to the center, performing an initial assessment, measuring blood sugar and completing related questionnaires, were referred to health care providers and received routine care at the center for 3 months, including monthly follow-up and fasting blood sugar checks. They will receive referrals to nutrition and psychological experts, and after 3 months, the questionnaires will be completed again and their blood sugar will be measured again.

#### Category

Prevention

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

kerd abad Comprehensive health service center

##### Full name of responsible person

zohreh changanian

##### Street address

Shahid Rezaei Alley, kerd ababd square, Mahdieh

Street,J Street

#### City

isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3529 0370

#### Email

m.azadmanesh19@gmail.com

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

atefe afshari

##### Street address

isfahan university of medical science, hezar jarib ave, isfahan

##### City

isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 913 222 7796

##### Email

afshar.atefe@yahoo.com

#### Grant name

#### Grant code / Reference number

340292

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

Yes

#### Title of funding source

Esfahan University of Medical Sciences

#### Proportion provided by this source

100

#### 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Mohammad Azadmanesh

##### Position

master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Isfahan Province, Isfahan, Hazarjarib St., Isfahan  
University of Medical Sciences, Faculty of Nursing and  
Midwifery

**City**

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**Postal code**

8174673461

**Phone**

+98 911 410 8703

**Fax**

**Email**

m.azadmanesh19@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Atefe Afshari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Isfahan Province, Isfahan, Hazarjarib St., Isfahan  
University of Medical Sciences, Faculty of Nursing and  
Midwifery

**City**

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afshar.atefe@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Atefe Afshari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

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**Postal code**

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**Phone**

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**Fax**

**Email**

afshar.atefe@yahoo.com

**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

no more information

**Study Protocol**

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

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable