

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

atefe afshari

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isfahan university of medical science, hezar jarib ave, isfahan

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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

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Isfahan Province, Isfahan, Hazarjarib St., Isfahan
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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

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Contact

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Assistant Professor

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Other areas of specialty/work

Health Promotion

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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