

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the Effect of Implementing the Family Health Nurse Model on Self-management and Glycosylated Hemoglobin of Middle-aged Women with Type 2 Diabetes

Protocol summary

Study aim

Determining the effect of implementing the family health nurse model on self-management and glycosylated hemoglobin of middle-aged women with type 2 diabetes

Design

A clinical trial with a control group, with parallel groups, without blinding, without randomization, on 84 patients.

Settings and conduct

The research population of middle-aged women with type 2 diabetes was covered by the centers of Isfahan city, and the control and intervention center was selected through lottery and the subjects were selected by systematic method. For the test group, a self-management program is implemented in the form of a localized family health nurse model.

Participants/Inclusion and exclusion criteria

Inclusion criteria: suffering from diabetes during the last year, not controlling HbA1c according to the opinion of the attending physician of the center
Exclusion criteria: unwillingness to continue cooperation, failure to complete questionnaires and tests, death of the affected person

Intervention groups

Intervention group: For the test group, a self-management program is implemented in the form of a localized family health nurse model. This model includes 3 stages before intervention, intervention, and evaluation, in the pre-intervention stage, preparations are made and in the intervention stage, home visits and identification are carried out. The patient's problems are presented with the service package of the localized family health model. Evaluation is done in 3 stages during, immediately, and 3 months after the intervention
Control group: they receive the center's routine care.

Main outcome variables

Diabetes self-management; Glycosylated hemoglobin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230522058256N1**

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

Tayebeh Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7509

Email address

tkarimi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-08, 1402/05/17

Expected recruitment end date

2023-11-08, 1402/08/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Implementing the Family Health Nurse Model on Self-management and Glycosylated Hemoglobin of Middle-aged Women with Type 2 Diabetes

Public title

Investigating the effect of implementing the Family Health Nurse Model on Self-management and Glycosylated Hemoglobin

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Have an active file in the center At least one year has passed since the diagnosis of their disease There should be no restrictions on entering the house and visiting the house. HbA1C should be considered uncontrolled according to the patient's medical record and the doctor's opinion Willingness and informed consent to participate in the research Have Iranian nationality

Exclusion criteria:

Suffering from chronic and advanced complications of diabetes such as nephropathy, proliferative retinopathy, amputation Suffering from cognitive problems including mental retardation or known psychological disorders Failure to complete HBA1c questionnaires and tests or their incomplete completion

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

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

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hazar Jarib Street, Isfahan University of Medical Sciences, School of Nursing and Midwifery

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-07-08, 1402/04/17

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.055

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.00

ICD-10 code description

Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)

Primary outcomes

1

Description

Diabetes self-management score in the Schmitt diabetes self-management questionnaire

Timepoint

Before, immediately and 3 months after the intervention

Method of measurement

Diabetes Self-Management Questionnaire

2

Description

The percentage of people who have glycosylated hemoglobin above 7.7

Timepoint

Before and 3 months after the intervention

Method of measurement

Glycosylated hemoglobin blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For this group, the steps of the localized family health nurse model, which was developed by Kishori 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" It has been designed and will be implemented. This model will include three stages (before intervention, intervention, and evaluation). The pre-intervention stage included two preliminary stages and the first meeting with the samples, during the preliminary stage, the necessary measures were taken to meet the people with diabetes, and in the first meeting with the samples, after completing the relevant questionnaires, their initial evaluation in The home visit center and time will be coordinated with them. In the intervention stage, which includes (home visits, implementation in the center and provision of a localized family health model service package, formation of self-help groups, and follow-up for 3 months), at least during two home visit sessions and the selection of a family health ambassador, with Use the relevant forms to assess the educational needs of the family with the help of family members and after identifying the identified problems of the patient, based on the nursing diagnoses, plan nursing care for the affected person with the help of the family and a localized model package that includes (counseling Individual, educational booklet and holding training sessions, referral to the doctor, follow-up of internal referrals made by the doctor (to a psychiatrist, nutritionist, internal specialist) and follow-up of external referrals) will be provided according to the needs and problems of each patient. Then, for 3 months, in the form of self-help group meetings and monthly care, and fasting blood sugar control, he will follow up with the affected people. The evaluation stage of this model will be done in 3 stages (during the intervention, immediately after the intervention, and 3 months after the intervention by diabetes self-management questionnaire and glycosylated hemoglobin test).

Category

Treatment - Other

2

Description

Control group:Control group: In this study, the control group after being called to the center, performing the initial assessment, glycosylated hemoglobin test, and completing the relevant questionnaires, will be referred to the health care providers and will receive the center's routine care for 3 months, and after 3 months, the questionnaires will be re-administered. Completion and testing of their glycosylated hemoglobin will be done

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan comprehensive health service centers

Full name of responsible person

Tayyaba Karimiç

Street address

Esfahan, Ibn Sina St., next to Amin Hospital, Health Vice District

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4, Headquarters, Research and Technology Vice-Chancellor of the University, 1st Floor

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Email

research@mui.ac.ir

Web page address

<https://tech.mui.ac.ir/>

Grant name

Grant code / Reference number

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

Tayebeh Karimi

Position

Assistant professor, member of the faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Tayyaba Karimi

Position

Assistant professor, member of the faculty of nursing and midwifery in Isfahan

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable