

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of home care program implementation versus non-home care on self-care in patients with type 2 diabetes: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of home care program implementation versus non-home care on self-care in patients with type 2 diabetes

Design

This is a randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with type 2 diabetes who will refer to the Diabetes Research Center in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 30 to 70 years; Type 2 diabetes; A history of disease for at least 6 months; Literate
Exclusion criteria: Acute or severe disease; Affecting with diabetes complications; Psychological disorders; Drug or alcohol abuse

Intervention groups

Intervention group: Routine treatment plus home care educational program for 30 to 40 minutes once a week for 2 weeks
Control group: Just routine care

Main outcome variables

Primary outcome: Assessing the self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042592N1**
Registration date: **2019-04-01, 1398/01/12**
Registration timing: **prospective**

Last update: **2019-04-01, 1398/01/12**

Update count: **0**

Registration date

2019-04-01, 1398/01/12

Registrant information

Name

hajar najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3427 3245

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of home care program implementation versus non-home care on self-care in patients with type 2 diabetes: a randomized clinical trial

Public title

Effect of home care program implementation versus non-home care on self-care in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 30 to 70 years; Type 2 diabetes; A history of

disease for at least 6 months; Literate

Exclusion criteria:

Acute or severe disease; Affecting with diabetes complications; Psychological disorders; Drug or alcohol abuse

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.UMSHA.REC.1397.960

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Assessing the self-care

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

By using standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus homecare educational program for 30 to 40 minutes once a week for 2 weeks

Category

Treatment - Other

2

Description

Control group: Just routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center in Hamadan City

Full name of responsible person

Hajar Najafi

Street address

Diabetes Research Center in Hamadan City, Eram Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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

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