Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial of the effectiveness of self-care training on health-related quality of life among older adults with diabetes

Protocol summary

Summary

Abstract Objectives: Investigation of the effect of self-care training on the health quality of life among elderly with diabetes referring to Isfahan Diabetes Center in 2014. Setting and design: A total of 64 elderly people will be selected using census sampling then subjects will be allocated to the two equal group, 32 subjects will be in experimental group and 32 subjects in control group, via randomized by computer. Outcomes measurement: the intervention group will receive self-care training program designed for elderly with diabetes. The control group will receive routing care, then health quality of life will be measured and compared in the two groups, in the time before the intervention and after the intervention. Major inclusion and exclusion criteria: In this study, all subjects over 60 years old diagnosed with Type II diabetes and using insulin to control blood sugar, will be included in the study, and elderly who do not have the ability to self-care training classes or are hospitalized or died during the study or immigrated will be excluded. Intervention: The intervention group will receive six sessions of self-care training to the elderly included: lecture, group discussion and practical work in a form of slides and videos. Hemoglobin of the both groups will be measured before and after the intervention. Variables of main outcome: The main variable is the health-related quality of life and will be measured through self-care training in elderly with diabetes.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015060122528N1**
Registration date: **2016-07-11, 1395/04/21**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name

Hojjatollah Mahdi

Name of organization / entity

University of Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3766 0394

Email address

ho.mahdi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Research funding was provided by the University of Welfare and Rehabilitation Sciences and Alzahra Diabetes Center

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the effectiveness of self-care training on health-related quality of life among older adults with diabetes

Public title

Effectiveness of self-care training on quality of life

among older adults with diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 60 and older have; suffering from diabetes; are under treatment by a physician or medical group; physically have the ability to participate in the study; The patient has cognitive health; More than 5 years of diabetes they have; The use of insulin to control blood sugar; severe health complications such as blindness, amputation, heart problems, respiratory, cerebral and renal dialysis may not have. Exclusion criteria: Opt out of the study during study; Failure to attend training sessions; hospitalization during the study; The use of psychotropic drugs and physical medicine (except blood glucose lowering drugs) that affect on blood sugar; migration or death

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

University of Welfare and Rehabilitation

Street address

University of Welfare and Rehabilitation Sciences, Koodakyar end, Daneshjoo B, Evin, Tehran

City

Tehran

Postal code

Approval date

2014-10-20, 1393/07/28

Ethics committee reference number

IR.USWR.REC.1393.241

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

VI

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Health-related quality of life

Timepoint

Pre-intervention and three month after intervention

Method of measurement

health status quality of life in elderly questionnaire, Hba1c test

Secondary outcomes

1

Description

HBA1C TEST

Timepoint

3 Months

Method of measurement

Colorimetric method

Intervention groups

1

Description

Intervention Group: self-care training in 6 sessions + HBA1C TEST

Category

Other

2

Description

Control group: HBA1C TEST

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Diabetes Center

Full name of responsible person

Hojjatollah Mahdi

Street address

Diabetes center,Alzahra Hospital, Shohadaye soffeh Street. Esfahan

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research University of Welfare and Rehabilitation Sciences, Vice chancellor for

Full name of responsible person

Hamidreza Khankeh

Street address

University of Welfare and Rehabilitation Sciences, Koodakyar end, Daneshjoo B, Evin, Tehran, Vice Chancellor for Research

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research University of Welfare and Rehabilitation Sciences, Vice chancellor for

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation

Full name of responsible person

Hojjatollah mahdi

Position

MS of nursing

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Rehabilitation Sciences and Social Welfare

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Sadat Mohammadbagher maddah

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Hojjatollah Mahdi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty