

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of integrate peer - nurse education on diabetes quality of life and self-care in old-age patients with type 2 diabetes

Protocol summary

Study aim

To study the effect of integrate peer - nurse education on diabetes quality of life and self-care in old-age patients with type 2 diabetes

Design

Two arm parallel group randomized trial with blinded postoperative care

Settings and conduct

After goal-based sampling method, reviewing the records of diabetic patients at the Yazd diabetes research center, patients are recruited for inclusion in the study with type II diabetes. Then by random selection with Random Allocation software, It is explained in terms of research objectives and they are told that they may be in the control group or test then patients divide randomly into two intervention and control groups (each of the groups 40 people).

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent for participate in the study; patients with established diabetes type II for at least 6 month; able to be in direct or indirect communication with patients; age between 60-70 years old; ability to speak Persian. Exclusion criteria: patients with cognitive disorders; taking anti depression drugs(with or without a prescription); patients without participation in two educational sessions; patients without consent to continue in the study; death of the patients during the study.

Intervention groups

Samples were assigned into 2 groups of 40 subjects, control group and intervention group, the participants in the intervention group will educate by collaborative peer-nurse education for 6 following months (10 sessions of 2 H) they will receive these subjects: defined in relation to the identification diabetes, complications, the role of diet, physical activity, foot care, self-monitoring medications to control diabetes while Control group only received usual care including periodical physician visits and diabetic regular educational classes.

Main outcome variables

Diabetes Quality Of Life; Diabetes Self-care Activities

General information

Reason for update

modification the study process

Acronym

IRCT registration information

IRCT registration number: **IRCT20170815035709N2**

Registration date: **2018-09-20, 1397/06/29**

Registration timing: **prospective**

Last update: **2020-10-21, 1399/07/30**

Update count: **1**

Registration date

2018-09-20, 1397/06/29

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1751

Email address

n.hosseini@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

2018-10-07, 1397/07/15

Actual recruitment end date

2019-01-05, 1397/10/15

Trial completion date

2019-06-05, 1398/03/15

Scientific title

The effect of integrate peer - nurse education on diabetes quality of life and self-care in old-age patients with type 2 diabetes

Public title

The effect of education on diabetes quality of life and self-care in diabetic old-age patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent for participate in the study Patients with established diabetes type II for at least 6 month Able to be in direct or indirect communication with patients Age between 60-70 years old Ability to speak Persian

Exclusion criteria:

Patients with cognitive disorders Physical disability Taking anti depression drugs (with or without a prescription) Patients without participation in two educational sessions Patients without participation in the study Death of patients during the study

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

After goal-based sampling method, reviewing the records of diabetic patients at the clinic we select patients are eligible for inclusion in the study with type II diabetes. Then by random selection with Random Allocation software, It is explained in terms of research objectives and they are told that they may be in the control group or test then patients divide randomly into two intervention and control groups (each of the groups 40 people)

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 Shahid Sadoughi of Medical Science

Street address

Boo Ali line, Timsar Fallahi street, Yazd, Iran

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Yazd

Postal code

916877443

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

IR.SSU.REC.1396.79

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Diabetes Quality Of Life

Timepoint

Before the intervention; after intervention and six months after the intervention

Method of measurement

DQOL (Diabetes Quality Of Life), SDSCA (Summary of Diabetes Self-care Activities)

2**Description**

Diabetes Self-care Activities

Timepoint

Before the intervention; after intervention and six months after the intervention

Method of measurement

Summary of Diabetes Self-care Activities(SDSCA)

Secondary outcomes**1****Description**

Glycosylated hemoglobin

Timepoint

Before the intervention, six months after the intervention

Method of measurement

Percentage

2**Description**

Weight control

Timepoint

Before the intervention, six months after the intervention

Method of measurement

Kilogram

3**Description**

Abdominal circumference

Timepoint

Before the intervention, six months after the intervention

Method of measurement

Centimeter

Intervention groups**1****Description**

Intervention group: after preparing peers, the participants in the intervention group will educate by collaborative peer-nurse education for 6 following months (10 sessions of 2 hours) 6 sessions constantly receive these subjects: defined in relation to the identification diabetes, complications, the role of diet, physical activity, foot care, self-monitoring medications to control diabetes. In the end of each session, they asking and answering and sharing their personal experiences and success on the diabetes disease control. In the end of the period, intervention group receive the diabetes self-management booklet

Category

Lifestyle

2**Description**

Control group: control group only received usual care including periodical physician visits and diabetic regular educational classes

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Diabetes Research Center

Full name of responsible person

Saeid Hossein Khalilzadeh

Street address

Diabetes Research Center, Talar-e-Honar Alley,
Shahid Sadoughi Blvd, Yazd, Iran

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Web page address

<http://ssu.ac.ir/cms/index.php?id=1287>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

Street address

Central Administration, Bahonar Sq, Yazd. Iran

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mmirzaei@ssu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Nahid al sadat Hosseini

Position

M.A Student of Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

M.A Student of Geriatric Nursing

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mostafa Javadi

Position

Assistant Professor/Shahid Sadoughi University of Medical Sciences and Health Services

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Fax**Email****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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable