Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 comittee of Shahid Sadoughi of Medical Science

Street address
Boo Ali line, Timsar Fallahi street,Yazd, Iran

City
Yazd

Province
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
City
Yazd
Province
Yazd
Postal code
8917693571
Phone
+98 35 3728 0226
Fax
+98 35 3728 0216
Email
drc@ssu.ac.ir
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
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3149 2248
Email
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
Street address
BooAli line, Timsar Fallahi street,Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Fax
Email
n.hosseini@ssu.ac.ir
Web page address

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
Street address
BooAli line, Timsar Fallahi street,Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Fax
Email
javadinurse@gmail.com
Web page address

Person responsible for updating data

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
Street address
BooAli line, Timsar Fallahi street,Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Fax
Email
n.hosseini@ssu.ac.ir
Web page address
http://ssu.ac.ir/cms/index.php?id=287

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