Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Education on Self-care Improvement of Diabetic foot Patient.

Protocol summary

Study aim
Effects of Education on Self-care Improvement.
Design
In this research, 60 eligible patients referring to diabetic foot ulcer Association were chosen purposefully and were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.
Settings and conduct
This study was conducted at the health centers of Gonbade-Kavoos using educational sessions and a questionnaire.
Participants/Inclusion and exclusion criteria
Diabetes type2 diabetic foot -disaffiliation tow absentee in class
Intervention groups
In the intervention group, after 8 weeks of training, the questionnaire was completed, but in the control group only the usual training was done and the questionnaire was completed.
Main outcome variables
Empowering patients and carers-Understanding the needs of patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20140429017491N1**
Registration date: **2018-01-22, 1396/11/02**
Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**
Update count: **0**
Registration date
2018-01-22, 1396/11/02

Registrant information
Name
nadereh naderiravesh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-09-20, 1395/06/30
Expected recruitment end date
2016-12-18, 1395/09/28
Actual recruitment start date
2016-09-20, 1395/06/30
Actual recruitment end date
2016-11-28, 1395/09/08
Trial completion date
empty

Scientific title
Effects of Education on Self-care Improvement of Diabetic foot Patient.

Public title
Effects of Education on Self-care Improvement.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetes Type2 Diabetic Foot
Exclusion criteria:
Disaffiliation Tow Absentee in Class
Age
No age limit
Gender
Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **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

According to the entrance and exit conditions, samples were selected.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Intersection of nyaesh ,Valiasr Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1631675619

Approval date

2016-01-19, 1394/10/29

Ethics committee reference number

1394.267IR.SBMU.PHNM

Health conditions studied

1

Description of health condition studied

Diabetes Type2 Diabetic Foot

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

The effect of nursing education on self-care in the diabetic foot

Timepoint

After 8 weeks of training

Method of measurement

Self-care questionnaire for patients with diabetes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group saw eight weeks of self-care education based on Orumi's theory.

Category

Lifestyle

2

Description

Control group: The control group was under the normal training of the health center.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinics, Khatam Al-Anbia Hospital Gonbad-e Qabus

Full name of responsible person

Gholamreza Nobaghi

Street address

Golestan Province - Gonbad Kavoos Town - Road Sayyad Shirazi

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2

Recruitment center

Name of recruitment center

Health Center Gonbad-e Qabus

Full name of responsible person

Gholamreza Nobaghi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
هزینه شخصی
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
personal expenses
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Gholamreza Nobaghi
Position
student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
(IPD):A portion of the data is shared, such as information on the main consequences
When the data will become available and for how long
(IPD):One year after the publication of the results
To whom data/document is available
(IPD):For researchers working in academic and scientific institutions and industry professionals
Under which criteria data/document could be used
(IPD):Use for research work in nursing education
From where data/document is obtainable
(IPD):Email the above email.nobaghi49@yahoo.com
What processes are involved for a request to access data/document
(IPD):With full introduction and giving your corporate address and address within a month, information is available
Comments
(IPD):In order to improve the health and awareness of the patients, the necessary cooperation will be provided in all areas of the research.