

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 88465512

Email address

n.naderiravesh@sbmu.ac.ir

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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Gonbad-e Qabus

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Postal code

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Phone

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nobaghi49@yahoo.com

2

Recruitment center

Name of recruitment center

Health Center Gonbad-e Qabus

Full name of responsible person

Gholamreza Nobaghi

Street address

استان گلستان - گنبدکاووس

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nobaghi49@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

هزینه شخصی

Full name of responsible person

Gholamreza Nobaghi

Street address

Golestan-Gonbad-Kavoos

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Province

Golestan

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Email

nobaghi49@yahoo.com

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

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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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.