

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of evidence-based foot care training on self-efficacy and foot self-care behaviors in patients with diabetic foot ulcers

Protocol summary

Study aim

The effect of evidence-based foot care training on self-efficacy and foot self-care behaviors in patients with diabetic foot ulcers

Design

This is a randomized clinical trial with a control group and a parallel design. This non-blinded, randomized study, will be performed on 62 patients with diabetic foot ulcers. A simple random method is used for randomization and the participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted at Shahid Noorani Hospital in Talesh city, is non-blinded. All patients will receive routine hospital treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Diagnosis of diabetes Age between 18 and 65 years; Patients with an active diabetic foot ulcer that does not require amputation based on the doctor's diagnosis; Ability to communicate Exclusion criteria: A history of severe physical and mental illness; Receive any written instruction before starting the study

Intervention groups

In addition to routine hospital treatment, the intervention group will receive evidence-based nursing care training. The control group will only receive routine hospital treatment.

Main outcome variables

Self-efficacy, self-care behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N204**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-09-01, 1402/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of evidence-based foot care training on self-efficacy and foot self-care behaviors in patients with diabetic foot ulcers

Public title

The effect of foot care training on self-efficacy and foot self-care behaviors in patients with diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent
Diagnosis of diabetes
Age between 18 and 65 years
Patients with an active diabetic foot ulcer that does not require amputation based on the doctor's diagnosis
Ability to communicate

Exclusion criteria:

A history of severe physical and mental illness
Receive any written instruction before starting the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the simple random method. The names of the participants are written on the card. The cards are put into a box that cannot be seen from outside. One of the colleagues of the plan is asked to remove one card from the container at a time. The names of the 31 cards that are selected first are placed in the intervention group, and the remaining 31 in the control group

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 Islamic Azad University,
Khorasgan branch

Street address

Vice Chancellor for Research Affairs, University Blvd.,
Arghwanieh, J Sharghi Street

City

Isfahan

Province

Isfahan

Postal code

8155139998

Approval date

2023-06-25, 1402/04/04

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Diabetic foot ulcer

ICD-10 code

L97

ICD-10 code description

Non-pressure chronic ulcer of lower limb, not elsewhere classified

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

self-efficacy

Timepoint

The beginning of the study and the end of the study

Method of measurement

Base on diabetic foot care self efficacy scale (DFCSES)

2**Description**

Self-care behavior

Timepoint

The beginning of the study and the end of the study

Method of measurement

Base on diabetes foot self-care behavior scale (DFSBS)

Secondary outcomes

empty

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

In addition to routine hospital treatment, the intervention group will receive evidence-based nursing care training.

Category

Treatment - Other

2**Description**

The control group will only receive routine hospital treatment.

Category

Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

Shahid Nurai Hospital
Full name of responsible person
Dr. Marziyeh Ziaeirad
Street address
Talash road towards Rasht, next to the workers'
stadium
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University, Khorasgan branch
Full name of responsible person
Dr. Majid Meshkini
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Faculty of Nursing and Midwifery, University Blvd.,
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Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Islamic Azad University, Khorasgan branch
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

Islamic Azad University, Khorasgan branch
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Dr. Marziyeh Ziaeirad
Position
Member of the faculty of Khorasan Azad University
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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