

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of peer support on foot care in patients with type II diabetes admitted to selected hospital

Protocol summary

Study aim

This study aimed to determine the effect of peer support on foot care behavior in type 2 diabetic patients.

Design

It is a three-stage, three-group clinical trial involving two intervention groups and one control group.

Settings and conduct

This clinical trial is conducted in one of the diabetes centers in Isfahan. The target group is patients with type 2 diabetes referred to the center. Patients in the intervention group receive 5 sessions of training supported by the peer group and patients in the control group receive more limited training during two training sessions. No blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having type 2 diabetes for at least one year, Having no active diabetic foot ulcer, Not having medical and paramedical education and no participate in similar research simultaneously, Having no learning disorders
Exclusion criteria: Incomplete participation in the study, Hospitalization to treat diabetes complications during the study

Intervention groups

Intervention group: This group consist of 25 people that divided into two groups. The peers trained their groups for 45 days in 5 one-hour supportive training sessions per week. These trainings were accompanied by weekly workshops, group discussions, question & answer and bug fixes. Peers performed four key functions in peer support, including support in the daily management of foot care in a person with diabetes, providing emotional support, facilitating communication, and assisting in accessing clinical care, and ongoing support.

Main outcome variables

Self-efficacy in foot care behavior, Preventive behaviors in foot care, Harmful behaviors in foot care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037895N4**

Registration date: **2020-04-04, 1399/01/16**

Registration timing: **retrospective**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

Mohsen Torabi Khah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

2019-10-02, 1398/07/10

Actual recruitment end date

2019-12-22, 1398/10/01

Trial completion date

2020-01-12, 1398/10/22

Scientific title

Effect of peer support on foot care in patients with type II diabetes admitted to selected hospital

Public title
Effect of peer support on foot care in patients with type II diabetes

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Willingness to participate in the study Reading and writing skills Fluency in Persian Having type 2 diabetes for at least one year Not having speech or hearing disorders Having no active diabetic foot ulcer Not having medical and paramedical education and no participate in similar research simultaneously Having no learning disorders (memory problems, Alzheimer's) or using medications that affect consciousness and learning
Exclusion criteria:
 Absent more than two sessions of meetings composed by peers Patient non-cooperation Hospitalization to treat diabetes complications during the study

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
 Target sample size: **50**
 Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
 Samples were randomly divided into two groups of control and test. This way two cards in same size with number one and two were placed in a pocket. Patients were asked to select one of the cards in the pocket. Those who chose the number one card were included in the test group and those who chose the number two card were placed in the control group. The selection of cards was accompanied by replacement.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
 Not used

Assignment
Parallel

Other design features
 The study consisted of two phases of peer selection and education and peer support. In the first phase, four patients with type 2 diabetes including two women and two men who were treated in the study setting with a medical record were selected as peers. These subjects were excluded from the samples but met all the inclusion criteria. After selecting peers, three two-hour training sessions were held for them in the research setting.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences., Street Hezarjarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.MUI.REC.1396.3.211

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

2

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E08.621

ICD-10 code description

Diabetes mellitus due to underlying condition with foot ulcer

3

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

4

Description of health condition studied

Diabetic foot ulcer in type 2 diabetes

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description

Self-efficacy in foot care

Timepoint

(Before intervention) and immediately and one month after intervention

Method of measurement

Questionnaire

2

Description

Preventive Behaviors in foot Care

Timepoint

(Before intervention) and immediately and one month after intervention

Method of measurement

Questionnaire

3

Description

Harmful behaviors in foot care

Timepoint

(Before intervention) and immediately and one month after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consisted of 25 individuals divided into two groups. Each group was assigned a female and a male peer. The peers trained their groups for 45 days in 5 one-hour supportive training sessions per week. Peers performed four key functions in peer support, including support for day-to-day management of foot care in a person with diabetes, emotional support, facilitating communication, and access to clinical care, and ongoing support.

Category

Prevention

2

Description

Control group: The control group also was 25 people. Participants in the control group received routine care, including routine physician visits and participation in diabetic foot care training classes, and participated in two training sessions conducted by the researcher.

Finally, in order to observe the research ethics, the educational booklet about the test group sessions was given to the control group patients one month after the intervention and after completing the questionnaire.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kourosh health & diabetes clinic

Full name of responsible person

Sayed Mohammad Hosseini Kazerouni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

60

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

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

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Full name of responsible person

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Position

Student

Latest degree

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Full name of responsible person

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Province

Isfahan

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available