

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Empowerment of Type 2 Diabetic Patients Visiting Fuladshahr Diabetes Clinics for Prevention of Diabetic Foot

Protocol summary

Study aim

Empowerment of Type 2 Diabetic Patients Visiting Fuladshahr Diabetes Clinics for Prevention of Diabetic Foot

Design

Sample was selected through block randomized foursome groups according to the sample size; subsequently, the sample was divided into two experiment and control groups. The number of subjects in each group was 46; then, considering about 11% sample loss (based on calculations), in the second stage, the sample size for each group was calculated to be 52.

Settings and conduct

Considering the sample's size and the necessity of grouping the subjects in order to reach more efficacy, the patients were divided into four groups of 13. The duration of each session was about 40-50 minutes. For each of the subgroups, four sessions of empowerment were held on a weekly and regular basis. According to this program, empowerment should be carried out in four steps which are presented in this study in four sessions.

Participants/Inclusion and exclusion criteria

Inclusion: Having type 2 diabetes based on diagnosis of an endocrinologist, Absence of diabetic foot, Having diabetic patient records in the hospital diabetes clinics, Absence of other chronic diseases, Willingness to participate in the study. exclusion: Having other chronic diseases, No referral to diabetes clinics

Intervention groups

Intervention was made through lectures, practically doing feet examination and special feet exercises, playing films, practicing, group discussion, question and answer, providing educational pamphlets and CDs. Also, individual counseling about foot care with the presence of a doctor and diabetes expert, and psychological counseling with a mental health professional was provided in the clinic; and suitable socks for diabetic foot prevention were distributed among experiment group

Main outcome variables

The results of this study may contribute to designing promotional interventions in these patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150531022500N4**

Registration date: **2018-09-08, 1397/06/17**

Registration timing: **retrospective**

Last update: **2018-09-08, 1397/06/17**

Update count: **0**

Registration date

2018-09-08, 1397/06/17

Registrant information

Name

Farbod Ebadi Fard Azar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8861 0120

Email address

ebadi.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-20, 1396/04/29

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Empowerment of Type 2 Diabetic Patients Visiting
Fuladshahr Diabetes Clinics for Prevention of Diabetic
Foot

Public title
Empowerment of Type 2 Diabetic Patients on Prevention
of Diabetic Foot

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Having type 2 diabetes based on diagnosis of an
endocrinologist Absence of diabetic foot Having diabetic
patient records in the diabetes clinics Absence of other
chronic diseases Willingness to participate in the study
Exclusion criteria:
Having other chronic diseases No referral to diabetes
clinics

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomized

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical
Sciences

Street address

Department of Health Services and Health Education,
School of Health, near Milad Hospital, IUMS, Shahid
Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-04-20, 1396/01/31

Ethics committee reference number

IR.IUMS.REC1395.9411107003

Health conditions studied

1

Description of health condition studied

Diabetic Foot

ICD-10 code

Z86.31

ICD-10 code description

Personal history of diabetic foot ulcer

Primary outcomes

1

Description

Perevention of Diabetic Foot

Timepoint

Before the intervention,One month and three months
after the implementation of the program

Method of measurement

Checklist

Secondary outcomes

1

Description

Empowerment

Timepoint

Before the intervention,One month and three months
after the implementation of the program

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: The experiment group participated in the Foot Care Principles program that was designed based on empowerment strategies. Intervention was made through lectures, practically doing feet examination and special feet exercises, playing films, practicing, group discussion, question and answer, providing educational pamphlets and CDs. Also, individual counseling about foot care with the presence of a doctor and diabetes expert, and psychological counseling with a mental health professional was

provided in the clinic; and suitable socks for diabetic foot prevention were distributed among experiment group. Considering the sample's size and the necessity of grouping the subjects in order to reach more efficacy, the patients were divided into four groups of 13. The duration of each session was about 40-50 minutes. For each of the subgroups, four sessions of empowerment were held on a weekly and regular basis. According to this program, empowerment should be carried out in four steps which are presented in this study in four sessions as follows: the first session included general introduction of diabetes, its mechanism, and complications; the second session was dedicated to the definition of the diabetic foot, its types, etiology, the identification of at-risk foot, risk factors and warning signs; the third session included the description of foot care principles (daily foot examinations, nail care and foot skin care measures, appropriate footwear [shoes and socks] selection criteria, and special foot exercises); and, the forth session included stress management and providing solutions to overcome issues related to foot care.

Category

Prevention

2

Description

Control group: During this period, the control group was receiving the routine services of the clinic

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinics of Shahid Motahhari Hospital

Full name of responsible person

Dr. Moazemi

Street address

Shahid Motahhari Hospital, Zobahan Highway

City

Fuladshahr

Province

Isfahan

Postal code

8491813113

Phone

+98 31 5262 4141

Email

br3171@bmi.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malakooti

Street address

Vice-Chancellor of Technology Research, near Milad Hospital, IUMS, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 4817

Email

dr-febadi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

80

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

Iran University of Medical Sciences

Full name of responsible person

Farbod Ebadi fardazar

Position

Professor of management and Health Services

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Services and Health Education, School of Health, near Milad Hospital, IUMS, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8860 4817

Email

dr-febadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farbod Ebadi fardazar

Position

Professor management and Health Services

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Hemmat Highway

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Email

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Person responsible for updating data

Contact

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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

No more 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable