Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of a Transtheoretical Model-Based Foot Care Program in Improving Foot Care Behaviors and Self-Efficacy in Adults With Type 2 Diabetes: An Assessor-Blinded Randomized Controlled Trial

Protocol summary

Study aim

Determining and comparing the stage of behavior change, self-efficacy and score of self-care activities of diabetic patients before and 2 months, 6 months after the intervention in the experimental and control groups in adults with type 2 diabetes

Design

120 eligible diabetic patients of Korane Comprehensive Health Center are selected by non randomized sampling method. Then, based on the convenience sampling method, 60 people in the intervention group and 60 people in the control group are allocated in parallel and unblinded.

Settings and conduct

Adult type 2 diabetes patients are listed in Kurane comprehensive health centers of Qazvin province. Based on sample size and convenient method, patients are divided into intervention and control groups without blinding.

Participants/Inclusion and exclusion criteria

Adult patients with type 2 diabetes who have consent to participate in the study and do not have any acute, psychiatric or foot ulcers. Not having a history of recent training for foot ulcers

Intervention groups

The intervention of the training program for all patients in intervention group is based on the stages of behavior change. The intervention is carried out in person in 4 one-hour training sessions during 1 month, and the questionnaires are provided to the patients again in the period of 2 and 6 months.

Main outcome variables

Behavioral stage according to transtheoretical model; diabetes self-efficacy score; Diabetes self-care score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230112057116N2**
Registration date: **2024-04-02, 1403/01/14**
Registration timing: **prospective**

Last update: **2024-04-02, 1403/01/14**
Update count: **0**

Registration date

2024-04-02, 1403/01/14

Registrant information

Name

Peigham Heidarpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 4156

Email address

pheidarpoormd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-14, 1403/01/26

Expected recruitment end date

2024-05-15, 1403/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of a Transtheoretical Model-Based Foot Care Program in Improving Foot Care Behaviors and Self-Efficacy in Adults With Type 2 Diabetes: An Assessor-Blinded Randomized Controlled Trial

Public title
Effectiveness of a Transtheoretical Model-Based Foot Care Program in Improving Foot Care Behaviors and Self-Efficacy in Adults With Type 2 Diabetes: An Assessor-Blinded Randomized Controlled Trial

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Type 2 diabetes patients who have been approved by the doctor of the center and registered in the Sib system. Consent to participate in the study

Exclusion criteria:
The existence of a problem that causes withdrawal from the study (acute illness, surgery, having diabetic foot ulcer at the time of study.. etc.)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 commitee of school of medical education of Shahid Beheshti University of medical sciences

Street address
, Toraj allay, Valiasr street,

City
tehran

Province
Tehran

Postal code
1985717443

Approval date
2024-01-13, 1402/10/23

Ethics committee reference number
IR.SBMU.SME.REC.1402.078

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Diabestes Management self efficacy scale

Timepoint
Before the intervention, two months and six months after the intervention

Method of measurement
DMSES -Diabestes Management Self –Efficacy Scale questionnaire

2

Description
Transtheoretical Model-Based behavioral stage scale

Timepoint
Before the intervention, two months and six months after the intervention

Method of measurement
Prochaska questionnaire

3

Description
diabetes self care scale

Timepoint
Before the intervention, two months and six months after the intervention

Method of measurement
Summary of Diabetes Selfcare Activity Measure

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Educational intervention based on the resources of the "Diabetic Foot Patients Clinical

Pathway "compiling the health guide for the summer of 2021with educational topics: Diabetic foot screening and examination, principles of prevention of diabetic foot ulcers, risk classification system for diabetic foot ulcers And the preventive screening interval is based on the IWGDF, another educational resource is the Self-Care Guide for Family Health Ambassadors, Diabetic Foot Care. The intervention is conducted face-to-face during 1 month in 4 one-hour training sessions (one session per week). The first session: General diabetes, types of diabetes and the criteria for diagnosing diabetes. The second session: Treatments for diabetes, the purpose of treatment and the complications of diabetes. The third session: knowing the risk factors of the diabetic foot and the necessity of preventing diabetic foot ulcers. The fourth session: principles of diabetic foot care. Educational sessions are held in the form of slide shows and questions and answers at the designated comprehensive health center.

Category

Behavior

2

Description

Control group: Routine training conducted in comprehensive health centers

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurane comprehensive rural health service center in Qazvin city

Full name of responsible person

Peigham Heidarpoor

Street address

Qazvin Province, Kurane, Alamut Road, Imamzadeh Abazar

City

Qazvin - Kurane

Province

Qazvin

Postal code

3414116192

Phone

+98 28 3343 3700

Email

infobhc@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Peigham Heidarpoor

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

School of Medical Education and Learning technologies, Toraj Alley, Valiasr St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2621 0092

Email

peigham.heidarpoor@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Peigham Heidarpoor

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Public Health/Community Medicine

Street address
School of Medical Education and Learning technologies, Toraj Alley, Valiasr St, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2621 0092

Email
peigham.heidarpoor@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Peigham Heidarpoor

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Public Health/Community Medicine

Street address
School of Medical Education and Learning technologies, Toraj Alley, Valiasr St, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2621 0092

Email
peigham.heidarpoor@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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
Proposals, dissertations and possible articles are available

When the data will become available and for how long
2024-2025

To whom data/document is available
all related researchers

Under which criteria data/document could be used
The documentary can be used as long as the intellectual rights of the authors are respected

From where data/document is obtainable
Peigham Heidarpoor

What processes are involved for a request to access data/document
via email

Comments