

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The Effect of Pender's Health Promotion Model on Life Style And Self Efficacy of Clients With Diabetic Foot

#### Protocol summary

##### Study aim

Evaluating the effect of Pender's Health Promotion Model education on diabetic foot patients lifestyle and self-efficacy

##### Design

Double-blind, randomized community-based Clinical trial with pragmatic control group, with parallel groups

##### Settings and conduct

After obtaining permission from the Ethics Committee and the Research Council of Iran University of Medical Sciences, researcher will refer to the endocrine clinics of Rasoul Akram and Firoozgar Hospitals and People with diabetic foot ulcers who has all inclusion criteria will be selected.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with grade 1 or 2 of diabetes which should be diagnosed by his physicians. Patients with diabetic foot ulcers. Ability to read and write. Having 18 years of age or older. Not being employed in or graduate from Health Care affiliated courses. Ability to communicate. No history of caring of diabetic foot patients. Exclusion criteria: absence of even one training session. Having Vascular Disease

##### Intervention groups

"Intervention group": People with diabetic foot ulcer which has all the criteria for entering the research. The educational sessions were 4 and each 2 hours which were held in 2 weeks. At the end of sessions the booklet was given to the samples. Control group": People with diabetic foot ulcer which has all the criteria for entering the research, The educational of this group is done with the usual method by the medical staff.

##### Main outcome variables

Diabetic foot ulcers education principles were used by researcher in the research environments To change the lifestyle of patients with diabetic foot ulcers in research environments To improve the self-efficacy of diabetic foot ulcers in research environments

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180726040606N1**

Registration date: **2019-01-05, 1397/10/15**

Registration timing: **retrospective**

Last update: **2019-01-05, 1397/10/15**

Update count: **0**

##### Registration date

2019-01-05, 1397/10/15

##### Registrant information

##### Name

Parya Vakilian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4435 5764

##### Email address

mahmoudi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-11-22, 1397/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Pender's Health Promotion Model on Life Style And Self Efficacy of Clients With Diabetic Foot

#### Public title

The Effect of Pender's Health Promotion Model on Life Style And Self Efficacy

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with type 1 diabetes or 2 with medical diagnosis included in the case Patients with diabetic foot ulcers Literacy reading and writing Aged 18 years and older Unemployment or Graduate in Health Care Ability to communicate No history of diabetic foot scars

##### Exclusion criteria:

Not attending even in a training session Vascular Disease

#### Age

From 18 years old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: 70

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In the process of selecting samples from a continuous method and Assignment of samples to the test and control group Blocked randomization method will be used. The researcher designed a 4-part package and Based on sample count, Possibilities of the test and control group in that package. The selection of samples from the test and control group is on the responsibility of the Nurses Which does not know the flow of the study. With her choice The distribution of samples is randomly assigned to the test and control group.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

This study will be done in two blind ways. As a researcher when collecting information, The presence of samples in the test and control group is not known. On the other hand, samples are also unaware of being in the test and control group. This method increases the power of study.

#### Placebo

Not used

#### Assignment

Parallel

#### 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

No. 1, 13 Ave., Asgari Street., North Shahran

##### City

Tehran

##### Province

Tehran

##### Postal code

1478738933

#### Approval date

2018-04-07, 1397/01/18

#### Ethics committee reference number

IR.IUMS.REC.1397.339

## Health conditions studied

### 1

#### Description of health condition studied

Clients with Diabetic Foot

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Study of lifestyle in diabetic foot ulcers

#### Timepoint

The beginning of the study (before the intervention) and 50 days after the intervention

#### Method of measurement

Health Promoting Lifestyle Profile II

## Secondary outcomes

### 1

#### Description

Self-efficacy study in diabetic foot ulcers

#### Timepoint

The beginning of the study (before the intervention) and 50 days after the intervention

#### Method of measurement

Diabetic Foot Care Self Efficacy Scale

## Intervention groups

### 1

#### Description

"Intervention group": For this group by lecturing and giving booklets training was done. The main dimensions of Pender's model as nutrition, exercise, responsibility about his health, stress management (Identify Stress Resources, Stress management actions), Interpersonal support( Maintaining relationships with proximity), self actualization(Having a sense of purpose, Looking for personal progress and Self-knowledge and satisfaction experience). In the lecture method, firstly the test group is in the clinic classroom, Training related to Pender Health Promotion Model, Using Whiteboard and Powerpoint (The educational sessions were 4 and each 2 hours which were held in 2 weeks). At the end of sessions the booklet was given to the samples. In the first and fourth sessions the HPLP 2 and self efficacy instrument for diabetic foot patients were completed. Every 15 days Questions will be asked by the researcher on the educational materials of the samples(Within 50 days after intervention, The researcher will call you three times). After 50 days, samples in the dates that the researcher co-ordinated with them, They go back to the treatment centers. The mentioned tools will be completed again by the intervention group.

**Category**

Lifestyle

**2**

**Description**

"Control Group": In this group also completes the mentioned forms(HPLP 2 and self efficacy instrument for diabetic foot patients), Common trainings will be received by clinic staff before discharge. The group also returned to the clinic after 50 days, with previous coordination and The forms will be completed and Finally, the instruction book will be delivered to this group as well.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasoul-e-Akram Hospital

**Full name of responsible person**

Leila Abbasi

**Street address**

Sttarkhan Street., Mazyar Mansouri Street., Rasoul-e-Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 9595

**Fax**

**Email**

br0926@bmi.ir

**Web page address**

http://hrmc.iums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Fariba Razm Ahang

**Street address**

Valieasr Street., Karimkhan Street., Behafarin Street., Firoozgar Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1600

**Email**

h\_firoozgar@yahoo.com

**Web page address**

http://firoozgar.iums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Masoumeh Kheirkhah

**Street address**

Rashid Yasemi Street., Above the Vanak Square., Valiasr Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1996713883

**Phone**

+98 21 8820 8159

**Email**

kheirkhah.m@iums.ac.ir

**Web page address**

http://http://fnm.iums.ac.ir

**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**

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**

Iran University of Medical Sciences

**Full name of responsible person**

Parya Vakilian

**Position**

Masters student of Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 1, 13 Ave., Asgari Street., North Shahran

**City**

Tehran

**Province**

Tehran

**Postal code**

1478738933

**Phone**

+98 21 4435 5764

**Email**

p.vakilian1395@gmail.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Alice Khachian

**Position**

Consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

No. 5, 11 Ave., Asgari Street., North Shahran

**City**

Tehran

**Province**

Tehran

**Postal code**

1478738944

**Phone**

+98 21 8888 2885

**Email**

alicekhachian@hotmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Parya Vakilian

**Position**

Masters Student In Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 1, 13 Ave., Asgari Street., North Shahran

**City**

Tehran

**Province**

Tehran

**Postal code**

1478738933

**Phone**

+98 21 4435 5764

**Email**

p.vakilian1395@gmail.com

**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**

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**

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**

I will share some of the data

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academia and academia

**Under which criteria data/document could be used**

To improve self-efficacy and lifestyle of patients with diabetic foot ulcer

**From where data/document is obtainable**

Perya Vakilian, Faculty of Nursing and Midwifery, Tehran, p.vakilian1395@gmail.comn

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

Applying through the researcher's personal email from

the supervisor

**Comments**