

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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 Shahrn

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

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Fax

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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

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<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

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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

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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

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Ph.D.

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

Iran University of Medical Sciences

Full name of responsible person

Parya Vakilian

Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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