

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of educational -support intervention based on Orem self-care model on controlling behavior, symptom and severity of mild peripheral diabetic neuropathy in women

Protocol summary

Summary

Purpose: to determine the effect of education - support based on Orem's self-care model for the behavior of the controller, and the severity of symptoms in women with mild peripheral diabetic neuropathy. Study design: randomized in two groups. Study population: diabetic women with mild diabetic peripheral neuropathy underlying member 22 Bahman Hospital Diabetes Clinic.inclusion Main criteria: type 2 diabetes, a hospital diabetes clinic underlying 22 Bahman, suffering from mild peripheral neuropathy, ranging from 35 to 65 years, with a minimum of literacy, the ability for self-care. Glysemic hemoglobin of greater than 7 milligram per deciliter of blood, according to the questionnaire Toobert, moderate and weak level of patient care. She is not pregnant. Exclusion criteria: uncooperative patient, damage to the lower limbs during the study, out of date Diabetes Clinic, changes in medical treatment. The sample size of 60 patients in each group (control and test). Interventions in the study and Time of study: the experimental group trained face to face and group (in terms of public needs, developmental and health deviation of the three domains of knowledge, motivation and skills), using instruments such as projectors and Whiteboard, 4 groups 15 people, over 7 sessions of 1 hour (on average) for each group are within 4 weeks. After the end of 3 months, the researcher takes a phone call every 10 days, the samples selected days of the week to go and Counseling specifies. The primary outcome and outcomes of the study: The study identified the positive effects of the intervene model and proposed its application to in the group of diabetic patients Strengthen their ability level and in the treatment and care of different aspects, direct participation will be, And to reach its optimum level of care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021521095N1**

Registration date: **2015-07-12, 1394/04/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-12, 1394/04/21

Registrant information

Name

Sayyed Behnam Mazloun Shahri

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of educational –support intervention based on Orem self-care model on controlling behavior, symptom and severity of mild peripheral diabetic neuropathy in women

Public title
The effect of educational –support intervention based on Orem self-care model on controlling behavior, symptom and severity of mild peripheral diabetic neuropathy in women.

Purpose
Supportive

Inclusion/Exclusion criteria
inclusion criteria: female patients with type 2 diabetes; covered diabetes clinic of 22 bahman hospital; with mild peripheral neuropathy; age ranging from 35 to 65 years; have the least be literate; ability to take care of themselves; glysemic hemoglobin of more than 7 milligrams per deciliter of blood; according to the questionnaire Toobert, moderate and weak level of patient care; woman is not pregnant. Exclusion criteria: uncooperative patient; damage to the lower limbs during the study; out of date Diabetes Clinic.

Age
From **35 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
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
Gonabad University of Medical Sciences
Street address
Next to the Asian Road, Gonabad University of Medical Sciences

City
Gonabad
Postal code
Approval date
2014-10-22, 1393/07/30
Ethics committee reference number
gmu.rec.1393.80

Health conditions studied

1

Description of health condition studied
Diabetic Neuropathy
ICD-10 code
G63.2
ICD-10 code description
diabetic polyneuropathy

Primary outcomes

1

Description
Controlling behavior
Timepoint
Before and 3 months after intervention
Method of measurement
Questionnaire

2

Description
The severity of peripheral neuropathy
Timepoint
Before the intervention and 3 months after intervention
Method of measurement
Toronto test

3

Description
Symptoms of neuropathy
Timepoint
Before and 3 months after intervention
Method of measurement
Inventory of Michigan

Secondary outcomes

1

Description
HbA1C measurement
Timepoint
Before and 3 months after intervention
Method of measurement
BT300 FV automated analyzer system in milligrams per deciliter

2

Description

FBS

Timepoint

Before and three months after intervention

Method of measurement

The system BT3000

3

Description

lipid of blood

Timepoint

Before and three months after intervention

Method of measurement

The system BT3000

Intervention groups

1

Description

Educational support system of Orem model for intervention group

Category

Behavior

2

Description

Training routine diabetes clinic for control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetic Clinic of 22 Bahman Hospital

Full name of responsible person

Zohre Ahrary

Street address

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for research, Gonabad University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammadpor

Street address

Next to the Asian Road, Gonabad University of

Medical Sciences

City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for research, Gonabad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Sayyed Behnam Mazloun Shahri

Position

Master of Mathematical Statistics

Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Sayyed Behnam Mazloun Shahri
Position
Master of Mathematical Statistics
Other areas of specialty/work
Street address
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City
Gonabad

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty