Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Exclusion criteria: uncooperative patient, damage to the lower limbs during the study, out of date Diabetes Clinic, changes in medical treatment.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

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Name of organization / entity

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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
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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
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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
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Sayyed Behnam Mazloum Shahri
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Master of Mathematical Statistics
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Person responsible for updating data

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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