

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

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 Exclusion criteria: uncooperative patient, damage to the lower limbs during the study, out of date Diabetes Clinic, changes in medical treatment.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

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5725 9902

##### Email address

ahrary.zohre@gmu.ac.ir

##### 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 Mazloum Shahri

##### **Position**

Master of Mathematical Statistics

##### **Other areas of specialty/work**

##### **Street address**

Next to the Asian Road, Gonabad University of Medical Sciences

##### **City**

Gonabad

##### **Postal code**

##### **Phone**

+98 51 5722 1918

##### **Fax**

+98 57223814

##### **Email**

b\_mazloum2005@yahoo.com;

mazloumb911@mums.ac.ir

##### **Web page address**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Gonabad University of Medical Sciences

##### **Full name of responsible person**

Shahla Khosrovan

##### **Position**

PhD in Nursing

##### **Other areas of specialty/work**

##### **Street address**

Next to the Asian Road, Gonabad University of Medical Sciences

**City**

Gonabad

**Postal code****Phone**

+98 51 5722 3028

**Fax****Email**

Khosravan@gmu.ac.ir

**Web page address****Postal code****Phone**

+98 51 5722 3028

**Fax****Email**

b\_mazloun2005@yahoo.com;

mazloub911@mums.ac.ir

**Web page address****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**Next to the Asian Road, Gonabad University of  
Medical Sciences**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*