

# The effects of a supportive-educational intervention on women with type 2 diabetes and diabetic peripheral neuropathy: a randomized controlled trial

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## Abstract

**Purpose:** To determine the effect of a supportive educational intervention based on the Orem self-care model on women with type 2 diabetes and diabetic peripheral neuropathy.

**Design:** A randomized controlled trial.

**Setting:** Hospital outpatient diabetes clinic.

**Subjects:** Adult women with type 2 diabetes and mild-to-moderate diabetic peripheral neuropathy. Out of 410 patients, 120 diabetic patients were recruited and randomly assigned to trial group ( $N=60$ ) and control group ( $N=60$ ).

**Intervention:** The trial group received a designed intervention consist of one-month supportive educational program with three months of follow-up (totally four months), based on self-care requisites according to the Orem self-care regarding diabetic peripheral neuropathy. The control group only received a routine care program in the diabetes clinic.

**Main measurements:** The main outcomes were symptoms and severity of diabetic neuropathy. Further outcomes were fasting blood sugar and glycosylated hemoglobin.

**Results:** By the end of the intervention, the number of participants reduced from 60 to 58 in the trial group and to 57 in the control group (totally 115). The intervention significantly decreased mean score of diabetic neuropathy symptoms (trial group: 3.26 vs. control group: 9.57,  $P=0.001$ ), severity (trial group: 5.86 vs. control group: 9.02,  $P=0.001$ ), fasting blood sugar (trial group: 151 vs. control group: 204,  $P=0.001$ ), and glycosylated hemoglobin (trial group: 7.85 vs. control group: 8.62,  $P=0.004$ ).

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**Conclusion:** Delivering a supportive-educational intervention based on the Orem self-care model on outpatient diabetes clinic can decrease the symptoms and severity of diabetic peripheral neuropathy.

**Trial registration:** It was registered in the Iranian Registry of Clinical Trials (IRCT2015021521095N1).

## Keywords

Diabetic peripheral neuropathy, supportive educational intervention, Orem self-care model, self-care, nursing care

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## Introduction

Diabetic peripheral neuropathy, with lifetime prevalence of almost 50%,<sup>1</sup> is a common microvascular complication in patients with type 2 diabetes.<sup>2-4</sup> Some patients with diabetes peripheral neuropathy suffer from neuropathic pain. This condition leads to the loss of pain sensations and heat in 70%–80% of cases. It increases the risk of injury and latent foot infections, leading to significant disability due to foot ulceration and amputation, fall-related injury, low quality of life, and substantially increases health costs associated with diabetes.<sup>1,5</sup>

Although there are many medical ways to improve the conditions, developing an educational program is an accepted non-pharmacological way to involve patients in self-management processes to do self-care in order to control type 2 diabetes and prevent its complications by both sharing therapeutic responsibility with treatment team and changing patients' lifestyles.<sup>6,7</sup> Up to now, evidences that support education to increase patients' knowledge and skills for controlling patients' glucose and self-care behaviors are focused on a diabetic foot ulcer with low methodological quality.<sup>6,8</sup> More substantiation, especially clinical evidence from clinical trials<sup>9</sup> that design the content and methodology of the training,<sup>10</sup> such as gender, patients' beliefs and motivations, and model-based training,<sup>11</sup> is needed to confirm the effectiveness of education programs in preventing or improving the pre-existing peripheral neuropathy in healthcare systems.<sup>8,10,12</sup>

Orem self-care model is a well-known self-care empowerment model in nursing discipline.<sup>13,14</sup> According to Orem's theory, humans are the agents

of self-care and they are responsible and well competent for taking care of themselves.<sup>7</sup> Also, it emphasizes that gender-based planning and cultural sensitivity are essential factors in nursing service delivery.<sup>3</sup> This model and its theories and constructs have been used extensively to prevent diseases and reduce their complications.<sup>12-15</sup> Nonetheless, using this model to empower diabetic patients to improve their neuropathy control behaviors has been somewhat neglected.

Therefore, considering the conditions of the research environment, including the larger population of women with diabetes in the clinic and gender matching with their trained nurses, and based on the above-mentioned explanations to observe the clients' communication culture and controlling its barriers, this study was conducted to determine the effects of a supportive-educational intervention on women with type 2 diabetes and diabetic peripheral neuropathy. The primary aim of this supportive educational program was improving symptoms and severity of diabetic peripheral neuropathy. To achieve this goal, it was necessary to improve self-care behaviors through improving knowledge, attitude, motivation, and skills regarding diabetic peripheral neuropathy. Moreover, we aimed to improve fast blood glucose, glycosylated hemoglobin, and self-care activities in the participants.

## Method

We performed a prospective one-center randomized controlled trial study with two groups at the same time: (1) a control group that received routine program care and (2) a trial group that received a designed supportive-educational intervention based

on their self-care needs. This study was registered at the Iranian Registry of Clinical Trials (IRCT2015021521095N1) and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guideline for randomized trials of nonpharmacologic treatments.<sup>16</sup>

### **Clinical setting, patient recruitment, and selection**

The proposal of this research was approved by Ethics Committee, in 2014-10-22. Nearly two months later, in January 2015, after coordinating with the research environment, consecutive patients were screened for demographic eligibility by clinic staff according to the records available at 22 Bahman Hospital outpatient diabetes clinic in Gonabad, Iran. The inclusion criteria were (1) women with age 35–65 years and mild-to-moderate peripheral neuropathy according to the Michigan Neuropathy Screening Instrument; (2) not being pregnant; (3) the elapse of more than 10 years since the disease diagnosis; and (4) freely willing to participate in the study and sign written informed consent. Using convenience sampling, 410 women out of 1000 women were invited to participate in the study if willing to. This process ended by reaching the desired sample size (120 persons). Using balanced block randomization, we allocated participants into the control group ( $N=60$ ) and trial group ( $N=60$ ); this process was conducted by the research analyst who was blind to the participants. Moreover, the two groups were matched in terms of the type and dosage of antidiabetic drugs. Also, they were not under the medication for diabetic peripheral neuropathy. Change in dosage and type of drugs was an exclusion criterion.

### **Outcome measures**

After randomizing the participants, a researcher/neurologist assessed their diabetic peripheral neuropathy status. They completed the *Diabetes Self-Care Activities* and *Diabetic Peripheral Neuropathy Self-Care Requisites* questionnaires. Also, fasting blood sugar and glycosylated hemoglobin were examined before the intervention. Moreover, the

history of other diseases, especially hypertension and hyperlipidemia, were assessed according to patients' responses. The patients' body mass index was determined before the intervention. This phase of the research lasted for two months.

After the intervention (one month) and at the end of the three months of follow-up, peripheral neuropathy symptoms were assessed with the *Michigan Neuropathy Screening Instrument*.<sup>17</sup> The severity of neuropathy was assessed with the *Toronto Clinical Scoring System*,<sup>10,13</sup> which was developed by Perkins et al.<sup>18</sup> This tool has also been used in Iran as a reliable clinical tool. Based on consultations with researchers who had used this tool in Iran, scores of 0–6 were considered to be indicative of mild neuropathy, 7–13 were moderate neuropathy, and scores above 13 were indicative of severe sensory disorders of the big toe.<sup>19</sup> Self-care activities were evaluated by the *Summary of Diabetes Self-Care Activities*—developed by Toobert et al.<sup>20</sup>—which is a valid tool in Iran.<sup>21</sup> Self-care requisites were assessed by the *Diabetic Peripheral Neuropathy Self-Care Requisites*, which has been developed to assess knowledge, attitude, and skills of the participants regarding universal, developmental, and health deviation self-care requisites according to the Orem self-care model with 44 items. Participants' fasting blood sugar levels (mg/dL) and glycosylated hemoglobin were also measured.

### **Interventions**

The trial group ( $N=60$ ) received a four-week intervention program of two sessions per week (eight sessions overall) by a researcher-nurse (four groups of 15, a total of 32 sessions). In order to deepen the learning, Ausubel's theory of meaningful learning, advance organizers, and learning model with three phases<sup>22,23</sup> was used as a teaching method. Because of the nature of the problem, group discussion and presentation skills were also used as other teaching methods in this research. The discussed subjects in these sessions included a wide range of topics in knowledge and attitudes, pathophysiology, complications of diabetes and methods of preventing them, especially diabetic foot, foot care training,

exercise and physical activity, sleep and rest, nutrition, stress control, oral diabetes medication use, insulin therapy, and training on insulin injection and insulin side-effects (hypoglycemia, diabetic ketoacidosis, and injection site dystrophy).

The final session devoted to an overview of the topics presented in the previous sessions. At the end of each session, the class material was distributed among the participants in the form of an educational booklet plus a checklist to enable researchers to assess participants' implementation of the materials during the week at home. During the intervals between the sessions, the patients were checked by calling them to ensure that they adhere to their given program.

Supportive services were also provided according to participants' distinct needs; for example, some sessions were held with the patient and a member of his or her family to help them eliminate any barriers to perform the materials taught in the program. In some cases, the sessions were held with patients of different groups with similar problems to learn from others' experiences.

The follow-up of the patients was done for three months after the completion of the training; follow-up group sessions were held bi-weekly over three months to assess the participants' adherence regarding the planned supportive educational program. The participants were also given the opportunity of individualistic counseling and training if required. A monthly fasting blood sugar was performed for patients in the trial group at the hospital laboratory to confirm the implementation of training programs; also, they were informed of the results as a motivating factor to follow the program.

The control group (60 people) received the routine training and care program offered by the diabetes clinic (including the usual diabetes care based on the routine program of the clinic on the management of the type 2 diabetes mellitus. The program included medication adherence, face-to-face education or distributing pamphlets, and fasting blood sugar and glycosylated hemoglobin testing by a physician. Individual training on diabetes control was also performed without using any specific models in every three-month intervals).

### **Ethical consideration**

The study protocol was reviewed and approved by the Ethical Committee of Gonabad University of Medical Sciences as an approved committee by National Ethics Committee in Biomedical Research, Iranian Ministry of Health and Medical Education, with code number GMU.REC.1393.80. To consider ethical issues, the subjects were ensured of the confidentiality of their data and their right to withdraw from the study at any stage. Written informed consent with signatures was obtained from all participants who enrolled in the study.

### **Statistics and data analysis**

Comparison of baseline values was done between the trial and control groups in terms of the demographic and health status; also, diabetic patients' self-care activities, self-care requisites, fast blood sugar, glycosylated hemoglobin, and symptoms and severity of diabetic peripheral neuropathy data were calculated using descriptive statistics (mean, frequency, and percentage) at the baseline and after completing the follow-up. The inferential statistics used for this study was Kolmogorov–Smirnov normality test. The independent *t*-test was used for comparing the mean of parametric variable including fast blood sugar, glycosylated hemoglobin, and symptoms and severity of diabetic peripheral neuropathy, and Mann–Whitney for mean score of non-parametric variable including self-care activities and self-care requisites (knowledge, attitude, and skill); the chi-square test was used for categorical data including marital status, educational status, history of hypertension, and hyperlipidemia. A blind analyzer analyzed the collected data with SPSS 17; the level of statistical significance was set at  $P < 0.05$ .

### **Results**

Although all the patients participated in pre-follow-up phases of the study (i.e. doing physical assessment, filling questionnaires and attending in all sessions of planned program), their number reduced from 60 to 58 in trial group and 60 to 57 in

control group because they were unwilling to participate in the follow-up program and final reassessment (see Figure 1).

According to Table 1, there were no significant differences between the participants at the commencement of the study. Most of them were middle-aged, low-educated, with a history of diabetes for about 10 years, hypertension, and hyperlipidemia (see Table 1).

The symptoms and severity of neuropathy as the main outcome measures of this study in the trial and control group before and after the intervention are shown in Table 2. As it is shown, after the intervention, the mean symptom of the neuropathy decreased significantly in the trial group (mean (SD)=3.26 (2.80)) compared with control group (9.57 (3.21),  $P<0.001$ ). Moreover, the severity of neuropathy significantly decreased in the trial group (5.86 (2.80)) compared with control group (9.02 (3.02),  $P=0.001$ ).

Likewise, fasting blood sugar (151 (53.51),  $P=0.001$ ) and glycosylated hemoglobin (7.85 (1.27),  $P=0.004$ ) were significantly decreased in the trial group compared with the control group. However, mean (SD) scores of self-care activities, knowledge, attitude, and skill all significantly increased after the intervention in the trial group (see Table 2).

## Discussion

This non-pharmacological randomized controlled trial using a supportive-educational intervention based on the Orem self-care model showed significant reductions in the symptoms and severity of diabetic neuropathy and a mild-to-moderate diabetic peripheral neuropathy in women with type 2 diabetes. The intervention improved knowledge, attitude, and self-care skills in diabetic peripheral neuropathy and reduced blood glucose. This supportive-educational intervention found further evidence for the fact that subclinical diabetic neuropathy may be reversed or improved with appropriate interventions,<sup>24</sup> despite the low literacy levels of the subjects who had a long history of diabetic neuropathy.

Some previous studies have recommended evaluating the impact of educational interventions in

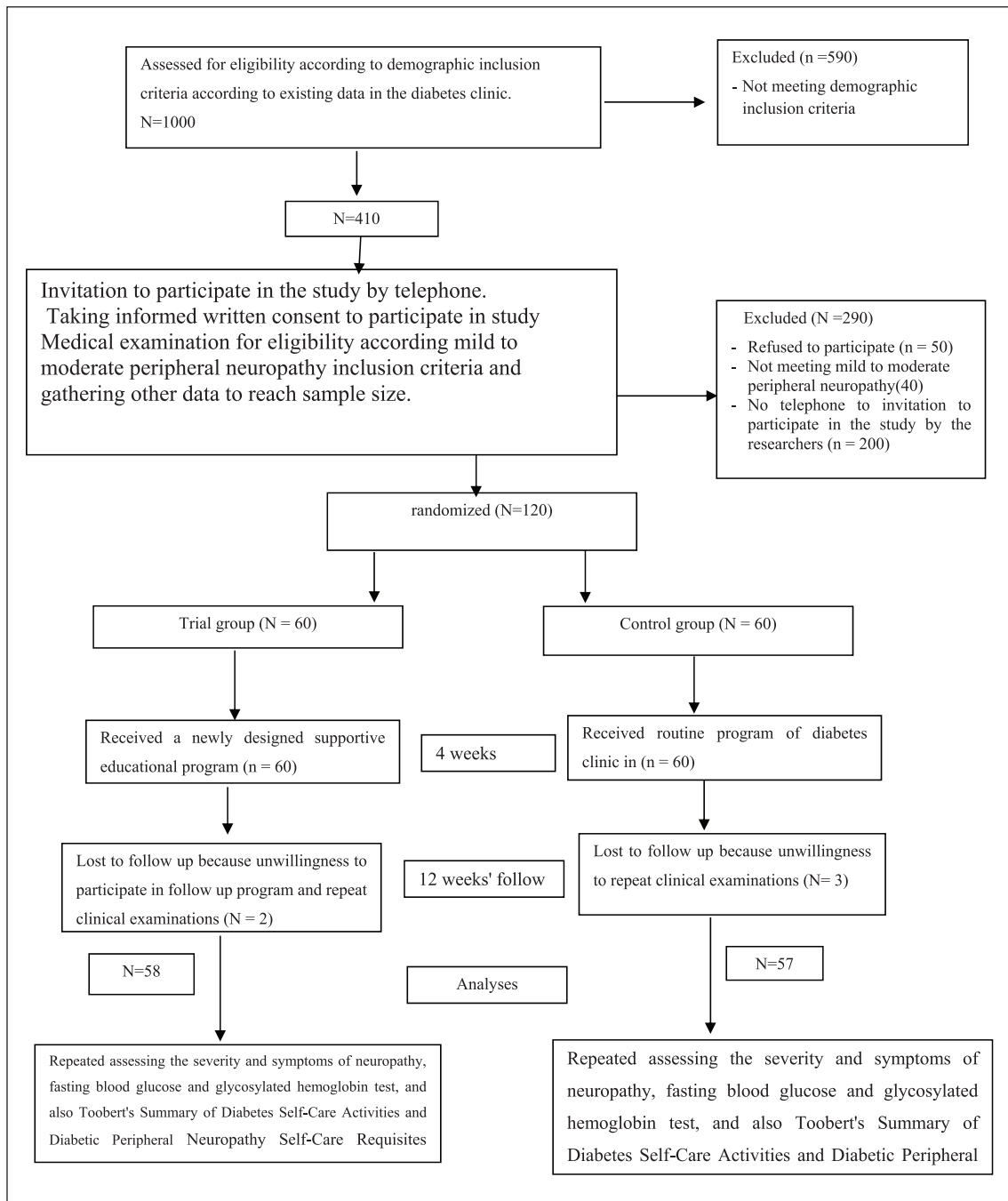
achieving clinical and para-clinical outcomes.<sup>8,25,26</sup> So, in contrast to some studies,<sup>10,13,14,27</sup> this study considered diabetic peripheral neuropathy a clinical variable in the educational intervention.

The positive results obtained from the present research, compared to those obtained from conventional patient-education approaches, can be attributed to the features of the program designed to adhere to the principles of client-centered care in the patients using the comprehensive Orem self-care model. Conventional patient training methods have mainly focused on increasing patient knowledge and determining behaviors that should be performed or avoided by patients with any diseases. These methods have also failed to assess patient conditions and other factors affecting training such as patient knowledge, beliefs, skill, emotional state of self-care motivation, and desire to do tasks.<sup>28,29</sup>

Patients can understand their disease and they can identify basic principles necessary for controlling it by acquiring knowledge; nevertheless, given the weak correlation between patient knowledge and self-care behaviors, knowledge acquisition alone does not seem to be sufficient.

In contrast to conventional patient training, this study suggested all patients tend to do their best to perform self-care if they are allowed and encouraged.<sup>21</sup> The first step therefore comprised assessing the educational content based on the unmet demand of the participants as women for self-care and their knowledge, attitudes, beliefs, motivation, and skill awareness while considering self-care requirements. Afterward, two comprehensive tools were used to explore three groups of need, that is, universal self-care, developmental self-care (adulthood) and health deviation requirements (mild-to-moderate diabetic neuropathy), and self-care performance.

Methods of teaching and supporting the patients were selected in the second step to compensate for self-care deficits in the patients based on their demographic variables, especially age, level of education, and economic status. Training models and methods were also used to promote the learning of theoretical knowledge, skills, motivation, and positive attitudes required for self-care. This group teaching program could be customized to fit the needs of patients. Therefore, they were allowed



**Figure 1.** CONSORT flowchart.



**Table 1.** Baseline values comparison between the trial and control groups in terms of the demographic and health status.

Variable	Trial group (n=60)	Control group (n=60)	P
Mean age (SD), years	54.62 (6.93)	54.62 (6.93)	0.70
Mean years of education (SD)	5.40 (2.51)	6.22 (4.25)	0.20
Mean years with diabetes (SD)	10.93 (4.62)	9.52 (3.72)	0.06
Marital status*			
Married	55 (91.7)	49 (81.7)	0.1
Single	5 (8.3)	11 (18.3)	
Employment status*			
Employed person	5 (8.3)	1 (1.7)	0.09
Unemployed person	55 (91.7)	59 (98.3)	
Person with history of hyperlipidemia*	36 (60)	46 (76.7)	0.05
Person with history of hypertension*	29 (48.3)	37 (61.7)	0.14

\*Absolute number (%).

**Table 2.** Comparison of outcome measures between trial and control groups: before and after the supportive-educational intervention with three months of follow-up.

Variables	Comparison between two groups before the supportive-educational intervention		P	Comparison between two groups after the supportive-educational intervention		P
	Trial group (n=60)	Control group (n=60)		Trial group (n=58)	Control group (n=57)	
Mean score of neuropathy symptoms (SD)	8.92 (3.77)	9.14 (2.94)	0.720	3.26 (2.80)	9.57 (3.21)	0.001
Mean score of neuropathy severity (SD)	8.28 (2.90)	8.32 (2.89)	0.950	5.86 (2.80)	9.02 (3.02)	0.001
Mean score of fasting blood sugar (SD) <sup>a</sup>	200 (62.73)	209 (65.36)	0.440	151 (53.51)	204 (69.54)	0.001
Mean score of glycosylated hemoglobin (SD) <sup>b</sup>	8.2 (0.89)	8.4 (0.99)	0.170	7.85 (1.27)	8.62 (1.49)	0.004
Mean score of self-care activities (SD)	41.81 (14.29)	38.95 (11.68)	0.104	78.67 (14.40)	40.46 (10.29)	0.001
Mean score of knowledge (SD) <sup>c</sup>	56.22 (33.73)	64.78 (38.87)	0.170	77.98 (45.23)	37.67 (21.47)	0.001
Mean score of attitude (SD) <sup>d</sup>	54.73 (32.84)	66.27 (39.76)	0.060	82.30 (47.73)	33.27 (18.96)	0.001
Mean score of skill (SD) <sup>e</sup>	63.90 (38.34)	57.10 (34.26)	0.280	85.10 (51.06)	35.90 (21.54)	0.001

<sup>a</sup>mg/dL.<sup>b</sup>%.<sup>c</sup>Scores range from 0 to 105, with higher scores indicating more knowledge about self-care activities.<sup>d</sup>Scores range from 0 to 100, with higher scores indicating better attitude regarding diabetic peripheral neuropathy.<sup>e</sup>Scores range from 0 to 100, with higher scores indicating better skills regarding diabetic peripheral neuropathy.

to participate in the question-and-answer sessions at the clinic or by phone in both training and follow-up phases even individually or with a family member.

The social and mental determinants of health include knowledge, positive attitudes, and motivation, which are vital for self-care in diabetics.<sup>30,31</sup> This dimension is therefore required to be modified, especially in cases of unpreventable and uncontrollable attitudes that inhibit motivation for self-care.<sup>32</sup>

Despite statistically significant findings, further studies are needed to confirm the measurement accuracy of the study methods and tools, data collection, execution duration, generalizability of the data to males, and the program feasibility in all clients. This study also failed to use magnetic resonance imaging (MRI) and electrodiagnostic tests. Future research works are recommended that employ more accurate instruments to investigate males with diabetic neuropathy.

### Clinical messages

- Implementing supportive-educational programs with a three-month follow-up based on the Orem self-care model improved self-care in the participants with diabetic peripheral neuropathy.
- The supportive-educational intervention decreased the mean scores of fasting blood sugar and glycosylated hemoglobin.
- The intervention reduced the symptoms and severity of peripheral neuropathy.

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A.A., Z.H., and M.N.N. drafted the manuscript and reviewed it and provided critical insights.

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