Original Article

The Effects of Home-based Nursing Care on Metabolic Control among Patients with Type II Diabetes Mellitus: A Randomized Clinical Trial

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ABSTRACT

Background: Diabetes mellitus (DM) management is challenging, particularly for people in developing countries. **Objective:** This study aimed to examine the effects of a home-based nursing care (HBNC) program on metabolic control among patients with type II DM. **Methods:** This single-blind randomized controlled trial was conducted in Hamadan, Iran, in 2014. Sixty patients with type II DM were consecutively recruited from a public diabetes care clinic in Hamadan, Iran, and randomly allocated to an experimental and a control group. Patients in the control group received usual discharge services, while their counterparts in the experimental group received HBNC services in addition to usual discharge services. The levels of fasting blood glucose, hemoglobin A_{1C}, total cholesterol, triglycerides, high- and low-density lipoprotein cholesterols, and systolic and diastolic blood pressures were measured before and 3 months after the intervention. Data analysis was performed through the Chi-square, the paired-sample and the independent-sample t-tests. **Results:** HBNC program significantly decreased the levels of fasting blood glucose (from 206.60 ± 84.93 to 141.40 ± 48.75; $P < 0.001$), hemoglobin A_{1C} (from 9.25 ± 2.19 to 7.55 ± 1.54; $P < 0.001$), and triglycerides (from 165.80 ± 78.96 to 126.63 ± 45.21; $P < 0.01$). However, it had no significant effects on total cholesterol, high- and low-density lipoproteins, and systolic and diastolic blood pressures ($P > 0.05$). **Conclusion:** HBNC is an effective strategy for managing type II DM and decreasing the risk of its complications.

KEYWORDS: *Home care services, Metabolic syndrome, Type II diabetes mellitus*

INTRODUCTION

With an increasing prevalence, diabetes mellitus (DM) is a major health problem throughout the world.[1,2] According to the American Diabetes Association, DM was the seventh leading cause of death in the United States in 2010.[3] It is also a major health problem in the Middle East countries such as Iran.[4,5] Estimates show that from 78 million Iranians in 2015, 4.6 millions suffered from DM.[6]

DM causes frequent hospitalizations. A study showed that adult people with DM are hospitalized 2.4 times more than the general population.[7] Besides, DM is associated with heavy personal, social, and national burdens.[8]

Several models have been developed and tested for DM management, including the chronic care model,[9] the health belief model,[10] the explanatory model of diabetes management,[11] and the stages of change model.[12] Pinto *et al.* used the health belief model to study factors behind patient retention in diabetes-related pharmaceutical care services and reported that the perceived susceptibility and the perceived threat constructs of the model significantly affected the use of the services.[10] Sunaert

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et al. also found the effectiveness of the chronic care model in moderately improving the quality of diabetes care in Belgium. They finally concluded that two components of the chronic care model, i.e., delivery system design and clinical information systems need further improvement.[9]

Patients with chronic diseases need detailed information and adequate support for the management of their diseases after hospital discharge. Such information and support should be provided not only at hospital discharge but also during the postdischarge period and even at patient home.[13] One potential strategy for effective postdischarge DM management is home-based nursing care (HBNC).[8] A recent study reported that patient education provided by nurses during home visits significantly improved quality of life among patients with congestive heart failure.[14] Other studies also showed the effectiveness of different care delivery models in improving patient outcomes among patients with DM[9-12] as well as patients who had undergone coronary artery bypass graft surgery.[15] However, it is yet unclear whether HBNC can affect metabolic control. Therefore, this study sought to narrow this gap.

Objectives

This study aimed to examine the effects of an HBNC program on metabolic control among patients with type II DM.

METHODS

A single-blind randomized controlled trial was conducted from January to November 2014.

The sample size was calculated using the formula depicted in Figure 1 and the results of a study which reported that the means of blood glucose levels in an experimental and a control group were 167.0 ± 31.9 and 198.7 ± 43.1, respectively.[16] Considering an α of 0.05 and β of 0.20, the largest sample size was estimated to be 44 for each group, i.e., 88 for two groups. Yet, after applying the finite population correction, a sample of sixty patients was determined to be adequate. Thus, sixty patients with type II DM were consecutively recruited to the study from a public diabetes care clinic in Hamadan, Iran. Inclusion criteria were a diagnosis of type II DM for more than 1 year (according to the

American Diabetes Association criteria), an age of eighteen or more, basic literacy skills, and no history of serious illnesses such as renal failure, hepatic failure, or mental illnesses (according to patients' medical records). Exclusion criteria were voluntary withdrawal from the study, move to another place for residence, and affliction by serious illnesses during the study.

Recruited patients were randomly assigned to an experimental and a control group using the balanced block randomization method. Primarily, two blank cards were labeled with the 'C' letter for the control group and two other cards with the 'E' letter for the experimental group. All cards were placed in a container. For each patient, one card was drawn from the container without replacement. After drawing all four cards for four patients, the cards were put back in the container, and the same process was gone through for every four patients until thirty patients were recruited to each group [Figure 2].

Patients in the control group received usual discharge services from registered nurses who were experienced in diabetes care. One day before discharge, nurses visited patients at the bedside and provided them with educations about DM causes, symptoms, symptom recognition, symptom management, treatments, medications, and complications as well as lifestyle modifications. Moreover, they answered patients' questions, if any. Patients in the experimental group
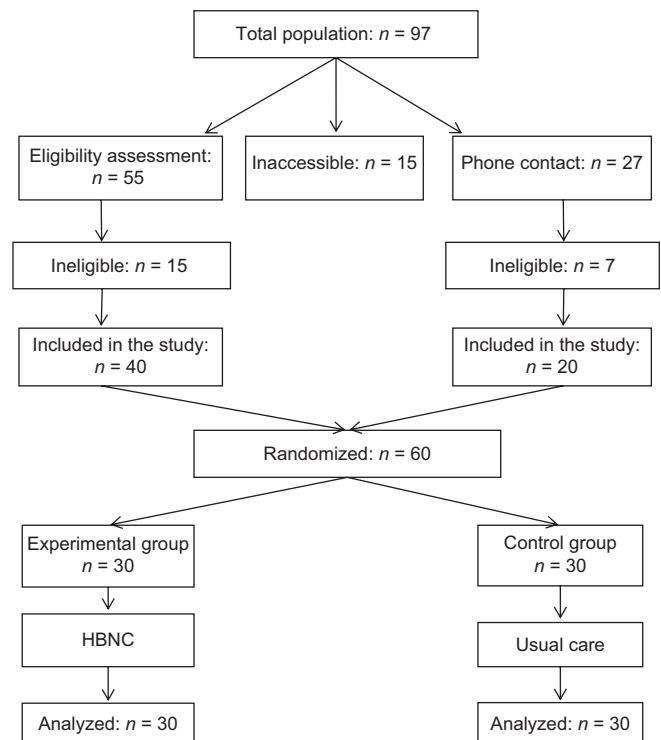
$$n = \frac{\left(\sigma_1^2 + \sigma_2^2\right)\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\left(\mu_1 - \mu_2\right)^2}$$

Figure 1: Sample size calculation formula

Figure 2: Study flow diagram

were offered an HBNC program in addition to the usual discharge services. Accordingly, registered nurses who were experienced in diabetes care performed three home visits during a month for each patient in this group. The components of the HBNC program were as follows: physical, functional, psychological, financial, and social assessments; medication preparation and administration; medication management; measurement and documentation of blood glucose level; foot care; wound dressing; personal hygiene; consumption of a balanced diet; engagement in balanced physical activities; and patient and family education. Patients in this group also received an educational package which included a diabetes care booklet and an educational video.

Instruments

At the beginning of the study, we assessed and documented patients' demographic characteristics including age, gender, body mass index, marital, educational, and employment status, income level, illness duration, and smoking history. Moreover, after an overnight fasting, blood samples were obtained from each patient before discharge and 3 months afterward for the measurement of blood glucose level (with the glucose oxidase method and the Pars Azmoon kit), hemoglobin A_{1C} (with the NYCOCARD Hemoglobin A_{1C} kit), and total cholesterol, triglycerides, and high- and low-density lipoprotein cholesterols (HDL-C and LDL-C) (with an automatic blood analyzer). All blood tests were performed in the same laboratory. In addition, blood pressure was measured twice before and twice after the intervention. All blood pressure measurements were made after a 15-min calm sit on a seat in a quiet room and using a portable sphygmomanometer (Microlife AG1-20).

Ethical considerations

The study was approved by the Research Ethics Committee of Hamadan University of Medical Sciences, Hamadan, Iran (approval code: P. 16.35.9.759). Moreover, it was registered in the Iranian Registry of Clinical Trials (registration code: IRCT2013070113834N1). Each participant signed a written informed consent at the time of recruitment to the study. They were assured of the confidentiality of their data as well as their ability to voluntarily withdraw from the study.

Data analysis

The data were analyzed using the SPSS software version 13.0 (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test was applied for normality testing and the descriptive statistics measures for data description. Between-group and within-group comparisons respecting numerical and categorical variables were made through the Chi-square and the paired- and the independent-sample t-tests. The results of statistical analyses were considered statistically significant at the level of <0.05.

RESULTS

Among sixty patients, 73.3% were women. Their age was 53.7 ± 17.1, on an average. No significant difference was found between the groups regarding patients' demographic characteristics ($P < 0.05$), [Table 1].

The results of the independent-sample t-test illustrated no significant between-group differences regarding the pretest mean values of total cholesterol, triglycerides, HDL-C, LDL-C, fasting blood glucose, hemoglobin A_{1C}, and systolic and diastolic blood pressures ($P > 0.05$). However, after the intervention, the mean values of total cholesterol, triglycerides, HDL-C, LDL-C, fasting blood glucose, and hemoglobin A_{1C} in the experimental group were significantly lower than the control group ($P < 0.05$), [Table 2].

The paired-sample t-test showed that in the control group, except for the mean value of diastolic blood pressure, the mean values of other parameters did

Table 1: Patient's demographic characteristics

Variable	Group[a]		P[b]
	Control	Experimental	
Gender			
Male	22 (73.3)	22 (73.3)	0.99
Female	8 (26.7)	8 (26.7)	
Age (year)			
<40	3 (10)	2 (6.7)	0.175
40-50	12 (40)	10 (33.3)	
>50	15 (50)	18 (60)	
BMI (kg/m^2)			
<18.5	3 (10)	2 (6.7)	0.402
18.5-25	12 (40)	10 (33.3)	
25-30	13 (43.3)	17 (56.7)	
>30	2 (6.7)	1 (3.3)	
Smoking history			
Yes	4 (13.3)	5 (16.7)	0.718
No	26 (86.7)	25 (83.3)	
Marital status			
Single	5 (16.7)	4 (13.3)	0.718
Married	25 (83.3)	26 (86.7)	
Income ($)			
<300	22 (73.3)	23 (76.6)	0.766
>300	8 (26.7)	7 (23.3)	
Educational status			
Illiterate	14 (46.7)	10 (33.3)	0.572
Below diploma	7 (23.3)	9 (30)	
Diploma and higher	9 (30)	11 (36.7)	

BMI: Body mass index, [a]Data are presented as n (%), [b]Results of the Chi-square test

not significantly change during the study. The mean value of diastolic blood pressure in this group decreased significantly from 83.50 ± 12.67 to 78.33 ± 9.58 (P = 0.011). In the experimental group, the mean values of total cholesterol, HDL-C, LDL-C, and systolic and diastolic blood pressures did not change significantly (P > 0.05), while the mean values of triglycerides, fasting blood glucose, and hemoglobin A_{1C} decreased significantly (P < 0.05).

DISCUSSION

The aim of this study was to examine the effects of an HBNC program on metabolic control among patients with type II DM. Findings revealed that the HBNC program improved metabolic control in patients with type II DM.

DM is a serious health-care challenge worldwide, particularly in Asia;[9] hence, different interventions (such as electronic education, telephone consultation and follow-up, and phone text messaging) have been developed and used to improve DM-related outcomes.[10-12,14,15,17] A meta-analysis concluded that text messaging is an effective method for patient

education about glycemic control.[18] Another study showed that patient and family education based on empowerment models had positive effects on metabolic control among diabetic patients.[19] Three other studies also reported that HBNC programs were effective in improving glycemic and metabolic control among these patients.[20-22]

The study findings showed a significant decrease in fasting blood glucose after the HBNC program, denoting the effectiveness of the program in decreasing blood glucose level among patients with type II DM. Similarly, Ko *et al*. and Oduwole *et al*. in their study reported that individually tailored education provided by visiting nurses[20] and home visits[21] significantly decreased blood glucose.

The study findings also indicated a significant decrease in the level of hemoglobin A_{1C} 3 months after the intervention. In line with this finding, Lashkari *et al*. reported the effectiveness of telenursing in decreasing hemoglobin A_{1C}.[17] A study by Sadeghi *et al*.[19] and Keogh *et al*.[23] also found that family-centered care programs can significantly decrease hemoglobin A_{1C}.

The other finding of the study was a significant decrease in the blood level of triglyceride following the HBNC program. This is consistent with the findings of a study made by Partapsingh *et al*. which showed that the stages of change model was effective in significantly decreasing the level of total triglyceride.[12]

The positive effects of HBNC on metabolic control among diabetic patients can be attributed to the supportive roles of families in Iranian society. When family members are engaged in patient care, they can directly supervise patients' health-related activities, encourage them for regular physical activity and healthy eating, warn them against unhealthy lifestyle behaviors, promote their adherence to dietary and treatment regimens, and thereby improving metabolic control among them. On the other hand, the insignificant effects of HBNC on blood pressure may be because at baseline, systolic, and diastolic blood pressures in both groups were within normal ranges. Moreover, we monitored patients only for 3 months. Follow-up assessments in longer periods of time may produce different findings.

This study had three limitations. First, only those patients who referred to a public diabetes care clinic were included. Second, this was a single-blind study, in which complete blindness was not possible. Third, the follow-up period was as short as 3 months. Therefore, triple-blind trials with larger samples and longer follow-up periods are needed to produce conclusive

Table 2: Pre-test and post-test mean values of the assessed parameters in both groups[a]

Variable	Group	Before	After	P^b
Total cholesterol	Experimental	187.03 ± 51.42	166.54 ± 90.53	0.057
	Control	191.13 ± 39.03	193.10 ± 46.25	0.806
	P^c	0.729	0.001	
Triglycerides	Experimental	165.80 ± 78.96	126.63 ± 45.21	0.017
	Control	193.53 ± 77.12	174.06 ± 74.03	0.161
	P^c	0.174	0.004	
HDL-C	Experimental	39.7 ± 43.43	42.13 ± 9.71	0.078
	Control	45.63 ± 25.34	42.96 ± 20.14	0.228
	P^c	0.207	0.001	
LDL-C	Experimental	130.30 ± 85.23	109.90 ± 29.86	0.194
	Control	113.66 ± 36.03	122.24 ± 32.89	0.209
	P^c	0.329	0.047	
Fasting blood glucose	Experimental	206.60 ± 84.93	141.40 ± 48.75	<0.001
	Control	196.60 ± 52.89	180.83 ± 67.03	0.367
	P^c	0.048	0.012	
Hemoglobin A1c	Experimental	9.25 ± 2.19	7.55 ± 1.54	<0.001
	Control	8.30 ± 1.24	8.60 ± 1.40	0.102
	P^c	0.045	0.001	
Systolic BP	Experimental	122.33 ± 16.20	120.50 ± 28.11	0.688
	Control	131.33 ± 22.04	120.50 ± 24.71	0.099
	P^c	0.076	0.738	
Diastolic BP	Experimental	78.33 ± 9.31	75.83 ± 8.51	0.113
	Control	83.50 ± 12.67	78.33 ± 9.58	0.011
	P^c	0.077	0.970	

[a]Data are presented as Mean ± SD, [b]The paired - sample *t*-test, [c]The independent - sample *t*-test. BP: Blood pressure, HDL-C: High-density lipoprotein cholesterol, LDL-C: Low-density lipoprotein cholesterol

evidence respecting the effects of HBNC on DM-related outcomes such as hospitalization rate and medical costs.

Conclusion

The findings of this study revealed that HBNC is an effective strategy for improving DM management and decreasing the risk of DM complications. However, despite the effectiveness of HBNC in maintaining care continuity after hospital discharge and improving patient outcomes, HBNC programs are not widely used for diabetic patients in Iran. Community health nurses can use HBNC to actively involve patients and their family members in the process of care and thereby, improve metabolic control and prevent DM complications.

Conflicts of interest

There are no conflicts of interest.

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