



Original article

Evaluating The Effect of Establishing Protocol for Self- Care Practice of Diabetic Foot Patients Regarding Their Needs, Concerns and Medication Use: A quasi-experimental study



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ABSTRACT

Background: The practice of diabetic self-care plays a significant role in maintaining and preventing diabetic foot complications, but low commitment to self-care practices is common. This study evaluates the effect of establishing protocol for self-care practice of diabetic foot patients according to their needs, concerns, and medication use. A quasi-experimental research (pre-test and post-test) design was used in out-patient clinics at Benha University Hospital, Egypt. The study included 100 adult patients diagnosed with diabetes (types I and II) for at least six months. The findings revealed that 79% suffered from burning or tingling in legs or feet; 74% complained of presence of redness of lower limb, legs or foot pain with activity, and loss of lower extremity sensation; and 80% had changes in skin colour or skin lesions. A comparison between the group pre- and post-intervention (protocol) showed that post-intervention patient foot care knowledge and self-care practice scores were higher. Also, 72% of the participants obtained good knowledge related to foot care post- protocol intervention compared to 37% pre- intervention. Based on the findings, the establishing intervention protocol fosters self-care practice and knowledge regarding needs, concerns, and medication use among diabetic foot patients. Therefore, this protocol can be applied in health practice and research in order to prevent diabetic foot ulcer, and thereby foot amputation.

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1. Introduction

1.1. Diabetes and self-management

Diabetes mellitus (DM) is a metabolic disorder disease with multiple long-term complications that affect almost every system in the body, and representing one of the most common causes of hospitalization of diabetic patients. It is estimated that 463 million adults aged 20 to 79 years have DM worldwide, 79.4% of whom are from low- and middle-income countries. Global diabetes preva-

lence is increasing, and will reach an estimated 578.4 million by 2030, and 700.2 million by 2045 in the 20–79 age group. The Middle East and North Africa region reports surging diabetes prevalence, attributed to changes in lifestyle in the region, rapid economic development, and urbanization (International Diabetes Federation [IDF], 2019). The incidence of diabetes and its complications can be reduced by early detection of high-risk individuals and the management of glycaemia (Miller et al., 2014).

Diabetic neuropathy is the most common complication of diabetes. Peripheral neuropathy is the most significant form of diabetes neuropathy, which affects the distal nerves of the limbs, especially the feet. Peripheral neuropathy causes a change in the diabetic patient sensation, which leads to loss of feelings, gradual numbness in the feet, and the formation of ulcers (IDF, 2016). Numbness, tingling, pain, and damage to the skin are the most common symptoms of diabetic neuropathy. Diabetes-related foot problems may occur and can be difficult to treat, occasionally requiring amputation.

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Additionally, proximal diabetic neuropathy causes painful muscle atrophy and weakness (O’Gara et al., 2013). The diabetic patient foot has the risk of pathologic sequels, like infection, foot laceration, and destruction of foot deep tissues, associated with neurological abnormalities or various degrees of peripheral vascular disease, and metabolic complications of diabetes in the limb (Ha Van, 2014). Diabetic foot disease is among the most serious and chronic complications of diabetes mellitus, including lesions in deep tissues accompanied by peripheral vascular disease (PVD) in the lower limbs and peripheral neuropathy. PVD is described as a full-thickness wound below the ankle joint in a diabetic patient with adverse outcomes of diabetic foot problems as amputations, and it accounts for more admissions to hospital than any other complications of diabetes, leading to increased morbidity and mortality (Örneholm, 2017).

Diabetic foot is a cause of significant suffering and financial costs for the patient and also places a massive load on the patient’s family, healthcare providers, and society generally. Patients with diabetic foot ulcers frequently require amputation of the lower limb. It is recommended that prevention strategies can reduce the complications of diabetic foot disease and amputations by up to 85%. These prevention strategies include patient and staff education, multi-disciplinary treatment, and close risk monitoring (Basit & Nawaz, 2013; International Working Group on the Diabetic Foot [IWGDF], 2019).

Self-management support is one of the core elements to optimize the care of patients with chronic disease. High-quality hospital care for diabetes requires standards for care delivery implemented using “best practice” protocols, reviews, and guidelines. Additionally, diabetes self-management knowledge and behaviors should be assessed on admission, and diabetes self-management education should be provided whenever possible. Education about diabetic self-management should include appropriate skills needed after discharge, such as medication dosing and administration, glucose monitoring, and recognition and treatment of hypoglycemia (American Diabetes Association [ADA], 2019). Proper care of diabetic foot needs a multi-disciplinary team to achieve the set goal objectives in treating diabetes and its complications (Yewande & Suliat, 2017).

Diabetes self-management protocol should be a complementary part of comprehensive diabetic patient care. This study discovers the magnitude of self-care practice of diabetic foot patients regarding their needs, concerns, and medication use. The importance of this research is evident in the value and quality of information it provides to those interested in scientific research, healthcare service provision, and the quality of life of diabetic patients and the community. Moreover, these results can be considered a guide in this field to establish bases and rules based on evidence-based planning to overcome diabetic foot problems and their impacts on patients and other stakeholders.

1.2. Study objective

The main objective of the study is to evaluate the effect of establish protocol for self-care practice of diabetic foot patients on their needs, concerns, and medication use.

1.3. Research hypothesis

The needs and concerns of participants for self-care practice are fulfilled by the protocol, and they followed the correct practice regarding medication use.

2. Material and methods

In this study, the researchers implemented the AGREE reporting Checklist 2016 (Brouwers, Kerkvliet, Spithoff, & AGREE Next Steps Consortium, 2016).

2.1. Study design

A quasi-experimental (one group pre-test post-test design) design was adopted.

2.2. Study population and sampling

A convenience sample was used including all available adult patients (n = 100) with diabetic foot, and DM (types I and II), diagnosed for a minimum of six months, recruited from the outpatient epidemiological clinics at Benha University Hospital. Benha is the capital city of Qaliubiya Governorate, Egypt. The area of Banha is about 1,001 km²; the total population is 5,703,000, with density of 5,697/km².

2.3. Data collection tools

2.3.1. Tool 1: Structured interview questionnaire

This was adopted by the researchers based on reviewing relevant scientific literature (ADA, 2019; Desalu et al., 2011; Pollock, Unwin, & Connolly, 2004). It was designed to assess patients’ knowledge and included two parts which cover the following data.

Part I includes socio-demographic data such as age, sex, marital status, educational level, occupation, and training for diabetic foot care. It also covers health history, including smoking and suffering from another comorbid disease (e.g., hypertension, heart disease); the presence of redness in the lower limb; lower limb amputation or surgery; prior angioplasty, stent, or leg bypass surgery; a wound requiring more than three weeks to heal; burning or tingling in legs or feet; leg or foot pain with activity; loss of lower extremity sensation; and changes in skin color or skin lesions.

Part II includes the Patients’ Knowledge Assessment Questionnaire (ADA, 2019; Desalu et al. 2011; Pollock et al., 2004). It assesses patients’ knowledge regarding foot care in 11 questions (Table 3). A binary knowledge scoring system is used for each of the 11 questions, grading answers with (1) for the correct answer, and (0) for an incorrect answer (*wrong* or *I don’t know*). The ultimate knowledge score I classified as good ($\geq 70\%$, 8–11 answers correct), satisfactory (50–69%, 6–7 answers correct), or unsatisfactory (<50%, <6 answers correct), depending upon the final aggregate score. Student *t*-test was used to compare the means of the scores, and the Chi-square test was used to assess the significance of the responses; a P-value of < 0.05 was considered statistically significant.

2.3.2. Tool II: Nottingham assessment of functional foot care (NAFF)

NAFF was developed by Lincoln, Jeffcoate, Ince, Smith, and Radford (2007) and Senussi, Lincoln, and Jeffcoate (2011). It was employed to obtain well-rounded responses regarding foot self-care practices (behaviors). The NAFF is a quantitative, 29-item self-reported scale used to assess the compliance of diabetic foot patients with foot care behavior recommended by healthcare providers; it has internal consistency of the questionnaire is 0.53, and good test-retest reliability. The researchers ask patients to indicate their responses to items on a Likert scale. The frequency of behavior occurrence is from 0 to 3. A higher total score shows better foot care behavior; a score of ≤ 50 proposes that further assessment of foot care is required. The NAFF was translated into Arabic by the researchers.

2.3.3. Tools' validity and reliability

The researchers developed the tools of data collection and their content validity was tested by a jury of 10 experts in the medical-surgical field, while reliability was tested using test-retest method. The Cronbach's alpha coefficient value of 0.086 for the structured interview questionnaire, and 0.87 for NAFF indicated good reliability.

2.4. Self-care foot booklet

The intervention protocol comprised a *Self-Care Foot Booklet* designed based on NAFF. It consisted of a theoretical and practical part.

Theoretical: This part comprised the introduction about the disease, definition of diabetes, signs and symptoms, complications, prevention, medication, and recommended actions during hyperglycemia.

Practical: This part covered the routine care of the diabetic foot, warning signs of diabetic foot ulcer, measures to prevent complications, self-care steps of Nottingham scale (e.g., examination and washing of feet frequently, checking shoes when wearing and removing them, checking feet and drying them after washing, drying between toes, wearing suitable shoes, and not walking outside in bare feet, etc.) (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, 2013; Centers for Disease Control and Prevention, 2016; Middlehurst, Ogle, Ackle, & Yeager, 2016; IWGDF, 2019).

2.5. Ethical consideration

The Ethical Committee of the faculty of nursing approved the present study. Official permission was obtained from the director of outpatient epidemiological clinics after the aim of the study and the Protocol were clarified to him. After explaining the aim of the study to the participants, all of them were given informed consent according to the Declaration of Helsinki 2013 (World Medical Association, 2013)

2.6. Pilot study

A pilot study was carried out with 10 patients suffering from diabetic foot in the study setting, who recruited to test the clarity and applicability of tools, and the researchers did some minor necessary modifications before data collection. The researchers excluded patients who participated in the pilot study from the main study.

2.7. Fieldwork

The protocol intervention was conducted through three phases as follows.

Preparation phase: The researchers reviewed the research literature and prepared the research tools and the educational materials used in the program in the preparation phase.

Implementation phase: The researchers divided the sample into 20 groups, each with five patients. The protocol intervention sessions were implemented through 10 sessions for each group. The program sessions consisted of two sessions per week on two different days, for a duration of two hours per session. The researchers welcomed the patients on the first day, and performed a pre-test on diabetic knowledge and self-care practice. After that, the intervention protocol sessions were implemented. Four sessions were held for theoretical learning, and six for foot care training. The researchers used methods of teaching for protocol intervention including lectures, group discussion, role-play, brainstorming and demonstration. The training materials involved

diabetic foot care videos, laptop computers, flip charts, and data show presentations and audio-visual aids. Each session comprised an initial hour of educational lecture and patient-based free discussion, and a second hour in which patients were trained to perform self-care practice. The *Self-Care Foot Booklet* was given to each participant in the first session.

Evaluation phase: On the last day of protocol intervention the researchers collected data from participants' post-test. The researchers asked participants about any obstacles regarding diabetic foot knowledge and self-care practice.

2.8. Statistical analysis

The collected data were tabulated and statistically analyzed using an IBM computer and SPSS Advanced Statistics, version 22 (SPSS Inc., Chicago, IL). Numerical data were expressed as mean and standard deviation. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the relation between qualitative variables. Bivariate correlation (two-tailed Pearson correlation) was used to test the correlation between numerical variables. Cronbach's alpha test was used to test the reliability of the tools; the coefficients of 0.085 for the structured interview questionnaire, and 0.87 for NAFF, indicated good reliability. The researchers considered the observed differences and associations according to the following: Not significant (NS) P greater than 0.05, Significant (S) P < 0.05*, Highly significant (HS) P < 0.001**

3. Results

The descriptive analysis of the data is presented below.

A total of 100 patients were included in this study, of whom 54% were male and 46% were female, with a mean age of 46.21 ± 8.807. Only 33% had a university education, nearly two-thirds (60%) were employees, and most of them (89%) were married (Table 1).

Table 2 illustrates that the majority of the studied sample (94%) suffer from type II DM, and 40% of them have had DM for more than ten years. Nearly two-thirds of participants (66%) had hypertension, and 42% suffered from heart disease. Almost three-quarters (74%) of patients had redness in the lower limb, but only 30% of them had lower limb amputation or surgery and prior angioplasty, stent, or leg bypass surgery. The majority of patients suffered from burning or tingling in legs or feet (79%), and leg or foot pain with activity and loss of lower extremity sensation (74%). Furthermore, 80% had changes in skin color or skin lesions.

Table 1
Frequency and percentage distribution of the studied sample according to their socio-demographic characteristics (n = 100).

Socio-demographic data	No.	%
Age (in years)		
Mean ± SD	46.21 ± 8.807	
Sex		
Male	54	54.0
Female	46	46.0
Educational level		
Illiterate	10	10.0
Primary education	24	24.0
Secondary education	33	33.0
University education	33	33.0
Occupational status		
Manual work	17	17.0
Housewife	21	21.0
Employee	60	60.0
Retired	2	2.0
Marital status		
Married	89	89.0
Single	11	11.0

Table 2
Frequency and percentage distribution of the studied sample according to their disease history (n = 100).

Disease history	No.	%
Type of DM		
Type I	6	6.0
Type II	94	94.0
Duration of disease		
<10 years	60	60.0
More than 10 years	40	40.0
Suffer from hypertension		
Yes	66	66.0
No	34	34.0
Suffer from heart disease		
Yes	42	42.0
No	58	58.0
Presence of redness of lower limb		
Yes	74	74.0
No	26	26.0
Presence of lower limb amputation or surgery		
Yes	30	30.0
No	70	70.0
Prior angioplasty, stent, or leg bypass surgery		
Yes	30	30.0
No	70	70.0
Burning or tingling in legs or feet		
Yes	79	79.0
No	21	21.0
Legs or foot pain with activity		
Yes	74	74.0
No	26	26.0
Loss of lower extremity sensation		
Yes	74	74.0
No	26	26.0
Changes in skin color or skin lesions		
Yes	80	80.0
No	20	20.0

Source: (ADA, 2019; Desalu et al., 2011; Pollock et al., 2004).

Table 3 reveals that there was a marked improvement in patients' knowledge post-implementation of the protocol for self-care practice of diabetic foot compared to pre-intervention.

Table 4 shows a marked improvement in patients' self-care foot practice post-implementation of the protocol compared to pre-intervention. Also, about 82% of the participants reported adequate self-care foot practice post-implementation of the protocol.

Table 5 illustrates a significant relationship ($p \leq 0.05$) between patients' total knowledge score and their socio-demographic characteristics pre- and post-protocol intervention.

Table 6 shows a highly positive correlation between age and educational level of participants in total self-care score pre- and post-protocol intervention.

Table 3
Frequency distribution of the responses related to the knowledge of foot care.

Knowledge items	Patient foot care knowledge			
	Pre-intervention		Post-intervention	
	Correct	Wrong /I don't know	Correct	Wrong /I don't know
1- DM patients should take medication regularly because of liability to DM complications	69	31	85	15
2- DM patients should look after their feet because they may not feel a minor injury to their feet	70	30	89	11
3- DM patients should look after their feet because wounds and infection may not heal quickly	35	65	68	32
4- DM patients should look after their feet because they may get a foot ulcer	68	32	80	20
5- DM patients should not smoke because smoking causes poor circulation affecting the feet	42	58	62	38
6- How often do you think you should inspect your feet?	54	46	40	60
7- If you found redness/bleeding between your toes what is the first thing you would do?	49	51	83	17
8- Even if you have never had a corn/ hard skin lesion, what would you do if you had one?	41	59	78	22
9- How often do you think you should wash your feet?	90	10	99	1
10- What temperature of water do you think you should wash your feet in?	50	50	71	29
11- How often do you think you should inspect the inside of your footwear for objects or torn lining?	48	52	80	20

Source: (ADA, 2019; Desalu et al. 2011; Pollock et al., 2004).

Table 7 concludes that a strong significant relationship exists between total knowledge and total practice level pre- and post-intervention.

4. Discussion

Egypt has high diabetic prevalence, with about 8.9 million diabetic patients aged between 20 and 79. It is also located in the region with the second-highest proportion of diabetes-related deaths for patients aged under 60 years, and the proportion of undiagnosed adults with diabetes in Egypt is an estimated 54.4%, which is the eighth highest rate in the world (IDF, 2019). In 2019, the number of deaths resulting from diabetes and its complications was 4.2 million people aged between 20 and 79 years, and undiagnosed cases are over 50%. There is thus a need the urgent investigation of undiagnosed cases and the provision of convenient and timely care as early as possible. Type 2 DM accounts for 90% of all diabetes, and it can be effectively managed through health education, support, and healthy lifestyle choices, combined with medication as needed. Global health expenditure on diabetes every year is estimated to be USD 760 billion. It is thought that expenses will run to USD 825 billion by 2030, and USD 845 billion by 2045. Self-care practices for diabetes are a significant part of prevention and delaying complication of diabetes, and saving health system costs for diabetes care (IDF, 2019)

Foot ulcers arise from a combination of numerous causes, including peripheral neuropathy and peripheral arterial diseases. More than 50% of diabetic patients who have severe sensory loss because of neuropathy may be asymptomatic. Ulcer complications may result from the inability of patients to recognize the first signs of infection, breakdown of the skin tissue, and a change in the degree of skin temperature, in addition to insufficient vascular perfusion. It is evident that loss of hair growth and skin discoloration may be the first signs of inadequate vascular perfusion, while skin hypertrophy and calluses are common (Boulton et al. 2008; Singh, Armstrong, & Lipsky, 2005; Pham et al., 2000). It was noticeable that most participants in the current study suffered from health problems mentioned in previous literature, which are common among diabetic foot patients: 79% of the current studied sample suffer from burning or tingling in legs or feet; 74% complain of the presence of redness of lower limb, leg or foot pain with activity, and loss of lower extremity sensation); and 80% had changes in skin color or skin lesions. Diabetic patients need a full assessment for risk of feet ulceration, especially those with a longer time of diagnosis and chronic complications (Woodbury, 2016).

Involving diabetic patients in the treatment process is necessary to reduce the possibility of complications and subsequent amputa-

Table 4
Frequency distribution of the responses regarding self-care foot practice.

Practice items	Patient self-care foot practice					
	Pre-intervention			Post-intervention		
	Adequate	Fairly adequate	Inadequate	Adequate	Fairly adequate	Inadequate
1-Do you examine your feet?	27	26	47	61	28	11
2-Do you check your shoes before you put them on?	20	36	44	46	39	15
3-Do you check your shoes when you take them off?	36	14	50	93	6	1
4-Do you wash your feet?	23	50	27	38	46	16
5-Do you check your feet are dry after washing?	34	23	43	44	33	23
6-Do you dry between your toes?	22	39	39	44	49	7
7-Do you use a moisturizing cream on your feet?	40	22	38	71	17	12
8-Do you put moisturizing cream between your toes?	12	43	45	58	29	12
9-Are your toenails cut?	32	34	34	51	39	10
10-Do you wear slippers with no fastening?	27	26	47	100	0	0
11-Do you wear rubber shoes or sneakers?	18	35	47	38	38	24
12-Do you wear shoes with lace-up, Velcro, or strap fastenings?	50	21			35	22
			29	43		
13-Do you wear pointed-toed shoes?	27	62	11	45	43	12
14-Do you wear flip-flops or mules?	9	73	18	67	20	13
15-Do you break in new shoes gradually?	43	26	31	47	29	24
16-Do you wear artificial fiber (e.g. nylon) socks?	16	21	63	41	35	24
17-Do you wear shoes without socks/stockings/tights?	29	23			0.0	0.0
			48	100		
18-Do you change your socks/stockings/tights?	28	14	58	30	33	37
19-Do you walk around the house in bare feet?	12	76	12	62	20	18.0
20-Do you walk outside in bare feet?	60	24	16	66	15	19.0
21-Do you use a hot water bottle in bed?	63	6	31	63	24	13.0
22-Do you put your feet near the fire?	29	32	39	56	36	8
23-Do you put your feet on a radiator?	87	11.0	2.0	78	19	3.0
24-Do you use corn remedies/corn plasters/ paints when you get a corn?	13	53			16	5.0
			34	79		
25-Do you put a dry dressing on a blister when you get one?	50	21			8.0	6.0
			29	86		
26-Do you put a dry dressing on a graze, cut, or burn when you get one?	29	58			37	12
			13	51		
Total score	29	58	13	82	16	2

Source: NAFF (Lincoln et al., 2007; Senussi et al., 2011).

Table 5
Relation between patients' socio-demographic characteristics and total knowledge score pre and post protocol intervention (n = 100).

Socio-demographic characteristics	Total knowledge score				
	Pre-intervention		Post-intervention		
	r	p-value	r	p-value	
Age	-0.389**	<0.001**	-0.142-	<0.05*	
Sex	0.142	<0.05*	0.112	<0.05*	
Occupation	0.088	<0.05*	-0.073-	<0.05*	
Educational level	-0.223*	<0.05*	-0.035-	<0.05*	
Marital status	-0.166-	<0.05*	-0.083-	<0.05*	

*Statistically significant at p ≤ 0.05. **Highly statistically significant at p ≤ 0.001.

Table 6
Relation between socio-demographic characteristics and total self-care score pre- and post-protocol (n = 100).

Socio-demographic characteristics	Total self-care score				
	Pre-intervention		Post-intervention		
	X1	P-value	X2	P-value	
Age	-0.243*	<0.05*	0.033	<0.05	
Sex	-0.107-	<0.05	-0.036-	<0.05	
Occupation	-0.071-	<0.05	-0.158-	<0.05	
Educational level	-0.289**	<0.001**	-0.041-	<0.05	
Marital status	-0.114-	<0.05*	0.057	<0.05	

*Statistically significant at p ≤ 0.05. **Highly statistically significant at p ≤ 0.001.

tions. It was found that the self-care behaviors of diabetic foot patients improved significantly after even simple health education (Abbott et al., 2002; Dorresteijn & Valk, 2012; Lincoln, Radford, Game, & Jeffcoate, 2008; McMurray, Johnson, Davis, & McDougall,

2002). One of the most common barriers to preventing diabetes complications is a patients' lack of understanding of self-care. Therefore, El-Nahas, Gawish, Tarshoby, State, and Boulton (2009) found that the recurrence of more than 90% of the diabetic ulcers

Table 7
Correlation between total knowledge score & total self-care score pre & post protocol intervention (n = 100).

Knowledge	Total self-care score			
	Pre-intervention		Post-intervention	
	r	P-value	r	P-value
Pre-intervention	0.388**	<0.001**	0.011	<0.05*
Post-intervention	0.025	<0.001**	0.000	<0.001**

was a result of the lack of adequate health education regarding diabetes, which emphasizes the need for repeated education for patients exposed to complications (El-Nahas et al., 2009; Van Houtum, 2012). The results of the present study for pre- and post-protocol intervention scores demonstrated that patient foot care knowledge and self-care practice scores post-intervention were better than pre-intervention. Also, 72% of the participants obtained good knowledge related to foot care post- protocol intervention, Fig. 1 compared to 37% pre- intervention. The results were consistent with other previous studies that addressed, to some extent, the same factors (Abu-elenin, Elshoura, & Alghazaly, 2018; Desalu et al., 2011; Seid & Tsige, 2015).

In the literature, the vital management of diabetes includes life-long self-care practices, but not all diabetic patients follow self-care activities as recommended (ADA, 2019; Angamo, Melese, & Ayen 2013). The prevention strategies for diabetic foot complications include daily foot inspection and hygiene that help the patients to identify early signs of complications. Diabetic patients should be instructed to avoid any activities that may cause foot damage, using suitable footwear, and follow the right toenail care, healthy diets, and daily exercise (Bakker, Schaper, & International Working Group on Diabetic Foot Editorial Board, 2012). The essential components of diabetic foot complications are stopping smoking, management of glycemic and lipid metabolism, regular exercise, and healthy diet (Kurniwawan, Sae-Sia, Maneewat, & Petpichetchian, 2011). Based on reviewing studies that assess the efficacy of diabetic foot program regarding improving diabetic foot knowledge and self-care practices for diabetic patient, educational programs are effective in improving the performance of diabetic foot patients, as reflected in improved mean scores of attitude, knowledge, and foot care practice among intervention groups after intervention programs (Beiranvand, Fayazi, & Asadizaker, 2015; Monami et al., 2015). Correct knowledge has a significant role in preventing diabetic foot ulcer as well as reinforcing patient self-care practice (Fan, Sidani, Cooper-Brathwaite, & Metcalfe, 2013). Another study reported that knowledge and self-care practice was considered a milestone for diabetic foot ulcer protection (Rocha et al., 2009).

The prevalence of lower limb amputation in diabetic patients is relatively common, and is twenty times higher the rate for patients without diabetes (Moxey et al., 2011). Foot ulcers and amputations are more common in low- and middle-income countries than in high-income countries (Mishra, Chhatbar, Kashikar, and Mehndiratta 2017). Diabetic foot complications are higher in men and people with type 2 diabetes (Zhang et al., 2017). The prevalence of the peripheral vascular disease in people with diabetes is 20% in patients over 40 years, and 29% in patients over 50 years (Yost, 2016). Diabetic patients with foot ulcers incur five times more health expenditure than other patients (Driver, Fabbii, Lavery, & Gibbons 2010). Regarding the relation between socio-demographic characteristics and diabetic foot patients, in both total knowledge and total self-care practice scores the present research a showed significant relation ($p \leq 0.05$) pre- and post-protocol intervention. The mean age of participants was 46.21; more than two-thirds of them were highly educated, and less than two-thirds of them were working. Also, more than half of the studied sample was male, while the vast majority (94%) had type II DM. As mentioned in the literature, there is a relationship between educational level and diabetic patient foot care knowledge. Chellan et al. (2012) reported that the highly educated participants have higher foot care knowledge and lower incidence of diabetic foot ulcer. Patient age can affect diabetic foot knowledge, with older age patients generally having less foot care knowledge (Desalu et al., 2011; Vedhara et al., 2014).

Regarding patient knowledge and diabetic foot self-care practice, some studies confirmed that the determination of diabetic foot complications depends on both of the good knowledge and self-care practices of the patients (Muhammad-Lutfi, Zaraiyah, & Anuar-Ramdhan, 2014; Seid & Tsige, 2015). Adequate patient knowledge and self-care practice regarding foot care controls potential and existent complications, especially foot ulcers (Muhammad-Lutfi, Zaraiyah, & Anuar-Ramdhan, 2014). Appropriate patient knowledge of foot care is connected to the good self-care practice for diabetic foot issues, and simple interventions like the *Self-Care Foot Booklet* used in this study (based on NAFI) can guide diabetic patients to determine early foot problems and

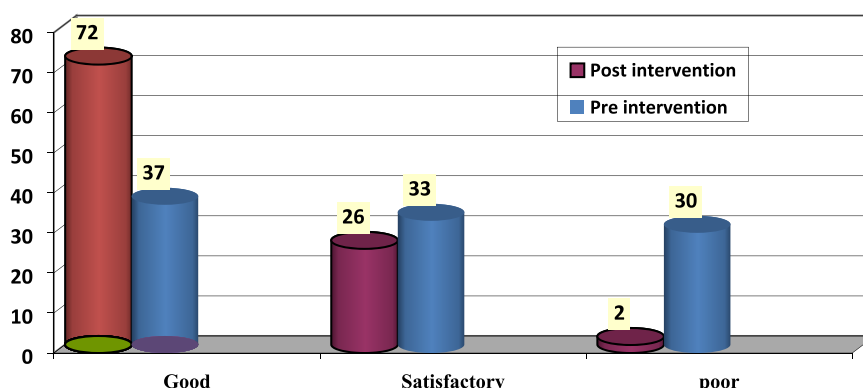


Fig. 1. Total score knowledge pre & post protocol intervention (n = 100). About 72% of the participants obtained good knowledge related to foot care post- protocol intervention, Fig. 1.

thereby prevent and minimize diabetic foot complications. Educational programs seeking to enhance the knowledge and practice of diabetic foot care showed statistically significant improvement in minimizing foot ulcer and other risks (Monami et al., 2015). The current study result showed statistical significance between the patients' total knowledge score and their total self-care practice scores pre- and post-protocol intervention. Thus, enhancing basic knowledge regarding diabetes management can improve diabetic self-care practice.

5. Limitation

The use of a nonprobability convenience sample to select the study sample created some selection bias; also, the present sample is not representative of all diabetic foot patients. Therefore, the results of this study need further confirmation by studies using probability randomized samples in the future.

6. Implications

6.1. Patients

For patients, enhancing patient knowledge regarding diabetic foot can avoid risks and help healing, improving their health and quality of life, while reducing the risk of the physical, social, and emotional impacts of associated problems. Furthermore, there is a critical need to develop a more specific protocol that contains multi-dimensional strategies to address diabetic foot patient care needs, concerns, and medication use.

6.2. Health practice

The results of the current study may encourage decision makers to formulate efficient policies and standards, and establish bases and rules for evidence-based planning to overcome the diabetic foot problems and their impacts on patients' lives, and their costs for health systems. The *Self-Care Foot Booklet* used in this study can be applied in its current form or in more developed and adopted versions for nursing practice to prevent ulcer of the diabetic foot, and thus reduce the risk of amputation.

6.3. Research

The results of the present study can be used as baseline information for future researches to explore aspects of diabetic foot care knowledge and behavior in more depth. Further study is recommended and essential, given the magnitude of diabetes and the challenges it poses the current and future health systems.

7. Conclusion and recommendations

Based on the findings in the current study, the establishing protocol was found to foster self-care practice and knowledge regarding needs, concerns, and medication use among diabetic foot patients. Therefore, this protocol can be applied in nursing practice and research in order to prevent diabetic foot ulcer, and thereby foot amputation. Thus, health education programs related to diabetic foot should be accessible and persistently provided to diabetic foot patients to improve their health and to lower the risk of the physical, social, and emotional impacts of this problem. Moreover, future studies are needed about diabetic foot issues and associated factors, to develop evidence-based nursing management guidelines from different health centers in Egypt and other contexts.

Declaration of Competing Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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Author contributions

All authors have directly participated in the planning, execution, and analysis of this study. All authors have critically reviewed and approved the final draft and are responsible for the content of the manuscript.

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