Effect of Psychological Interventions on Depression and Anxiety Symptoms Among Patients with Diabetic Foot Ulcers

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Abstract

Background: Diabetic foot ulcers are among the most common complications of diabetes mellitus and associated with psychological disorders mainly anxiety and depression; therefore, psychological interventions are crucial. **Aim:** to investigate the effect of psychological interventions on depression and anxiety symptoms among patients with diabetic foot ulcers. **Setting:** The study was carried out at the outpatient clinic for blood vessels at Alhrar Hospital in Zagazig city, Sharkia governorate, Egypt. **Subjects:** A purposive sample of 60 adult patients suffering from diabetic foot ulcers. **Research design:** a one-group quasi-experimental design that measures change in depression and anxiety symptoms pre- and post-psychological interventions. **Tools:** Three tools were utilized to collect the necessary data, namely a patient assessment form, the Hamilton anxiety rating scale, and the Hamilton depression rating scale. **Procedure:** The psychological interventions was developed by the researchers and implemented to the experimental group. Participants were divided into six groups; each group consisted of ten patients. The program consisted of 12 sessions and was implemented during the morning shift, twice daily, three times per week, one session for each group every week for three months. **Results:** Significant improvement was revealed after the intervention in regular treatment and ulcer care. Most of the patients showed post-intervention Wagner grade improvement. There was significant improvement in total anxiety score and depression at the post-implementation phase. A significant positive, strong correlation was found between patients' anxiety and depression scores. The study intervention was a negative predictor of the anxiety and depression scores. **Conclusion:** The psychological interventions were effective in improving the depression and anxiety symptoms among patients with diabetic foot ulcers, with improvement in ulcer grades. **Recommendation:** The study recommends the use of the developed psychological intervention in the study settings and in similar ones. The psychological state of any patient with diabetes, especially those suffering from diabetic foot, should be closely and regularly monitored.

Keywords: psychological intervention, depression, anxiety, diabetic foot ulcers, patients.

Introduction

Diabetes represents a significant public health concern with a growing global incidence over the past three decades due to aging and changing lifestyles **(Liu et al., 2020).** The **International Diabetics Federation [IDF], (2021)** estimates that 537 million have diabetes mellitus DM, with 6.7 million persons would have died from diabetes or its complications in 2021. A major comorbidity like kidney failure, cardiovascular disease, blindness, or foot ulcers is more likely to develop over time in diabetic patients **(Ahmad et al., 2018)**.

Diabetic foot disease is one of the most dangerous complications of diabetes mellitus, which affects almost 15% of patients **(Pereira, Vilaça & Carvalho, 2022).** The most frequent causes of diabetic foot ulcers (DFUs) include underlying neuropathy, poor glycemic control, inadequate foot care, and peripheral vascular disease. DFUs affect 11–14% of diabetic individuals, which accounts for 80% of lower limb amputations among these patients **(Singh, Jajoo & Shukla, 2020).**

On the other hand, diabetic foot ulcers can negatively affect patients' everyday lives, by altering their sleep patterns and mobility concerns, resulting in sexual dysfunction and feelings of anxiety, depression, isolation, and powerlessness. Additionally, physically restrictive measures such as using lower limb off-loading techniques may exacerbate psychological distress **(Aschalew, 2020).**

Patients who have diabetic foot ulcers are also negatively impacted by intangible costs like grief, pain, suffering, and psychological burden,

particularly depression and anxiety, which significantly affect patients' quality of life **(Ahmad et al., 2018)**. In addition, the emotional burden experienced by DFU contributes to a number of factors, including practical difficulties and limitations in daily life, an increased risk of amputation, reliance on others, increased healthcare needs, frustration, helplessness, and loss of mobility connected to the severity of the ulceration **(Hanlon et al., 2024).** Moreover, patients with diabetic foot are usually treated with exercise, medication, and a healthy diet. Diabetic individuals may experience more stress due to the continual requirements of diabetes care, which include frequent exercise, food restrictions, symptom management, follow-up, blood glucose monitoring, and constant monitoring for complications. Therefore, patients may experience anxiety and depression that adversely have an effect on their health and quality of life **(Abd-Elgawad et al., 2023).**

As well, patients with diabetic foot ulcers are at a high risk of psychological problems, which could worsen their condition, lead to recurrence of the ulcers, or even suicidal tendency **(Chen et al., 2020).** According to **Tarshoby et al., (2022)**, diabetic foot patients have an approximate twofold increased risk of depression and anxiety than diabetics without foot complications.

Depression is a significant disorder that affects many people and has a detrimental impact on a person's feelings, thoughts, and behavior **(Parekh, 2019).** Symptoms of depression include a pessimistic sense of inadequacy, a loss of interest in enjoyable activities, a depressed mood, changes in eating and sleep patterns, fatigue, worthlessness, guilt feelings, and suicidal ideations or behaviors **(Abbas** et al**., 2023)**. According to the **American Psychological Association [APA] (2019)**, people with depression may also exhibit anxiety, which includes; a tense and anxious state of mind in addition to, physical changes and stress. These negative emotions have an impact on friends, family, and quality of life among patients with diabetic foot ulcers in all aspects, including nutrition, sleep patterns, job, relationships, education, and health **(Jo, 2018)**.

On the same line, anxiety increases the patient's mental tension, but depression lowers the patient's sense of self-worth and self-evaluation. Together, the two lessen the patient's optimistic attitude, which is detrimental to the therapy and recovery from the illness **(Wen et al., 2023).**

Depressed and anxious individuals are less likely to adhere to the additional burden of diabetic self-care recommendations, engage in physical activity, maintain their diet, and take prescribed medications **(Alzahrani et al., 2019)**. Hence, in order to enhance psychosocial and clinical outcomes of diabetic foot ulcers, it is necessary for taking effective and timely measures to decrease the symptoms of depression and anxiety in these patients, such as psychosocial interventions and complementary therapy **(Sunny et al., 2019).** In this regard, psychological intervention is advised by the Institute for Health and Clinical Excellence for managing anxiety and depression among diabetic foot ulcer patients **(Norman et al., 2020).**

As well, psychological interventions are those that use 'therapeutic alliance between patient and therapist in order to change cognitive, emotional, and behavioral functions'. Psychological interventions are unlike other forms of intervention such as medication or education; their objective is to enhance patients' physical and mental well-being by utilizing a kind of communication, usually talking therapy, to build a supportive relationship that encourages patient empowerment and autonomy in managing their diabetic foot **(McGloin, et al., 2021).**

In addition, **Pereira et al., (2023)** stated that psychological interventions, such as hypnosis or relaxation training techniques, have already demonstrated significant effects in lowering anxiety and depression, improving patients' confidence in managing their diabetes, and preventing ulcer recurrence. These interventions help patients make lifestyle changes that promote wound healing, such as getting enough sleep, exercising, elevating and offloading their limbs, wearing appropriate footwear, maintaining a healthy diet, smoking cessation, reduced alcohol intake, and enhancing social interaction.

Nurses can significantly reduce the incidence of foot ulcers and lower limb amputations through screening high-risk individuals, providing healthcare, and implementing educational interventions. In addition, teach patients how to perform routine physical examinations and take care of their feet. Since nurses' primary

responsibility is to care for patients, they can also provide individuals with diabetic foot problems with emotional, intellectual, spiritual, and psychological support to diminish the symptoms of depression and anxiety **(Ali and Ghonem 2019**).

Significance of the study

The prevalence of diabetes mellitus (DM) is becoming more common in both developed and developing countries. According to the International Diabetes Federation (IDF), Egypt ranks among the top 10 countries in the world for the highest prevalence of DM, with around 9 million adults between the ages of 20 and 79 having the disease in 2019. The number of diabetic patients in Egypt has been rising quickly, from about 4.5 million in 2007 to 7.5 million in 2013, and is predicted to reach 13.1 million by 2035 (**International Diabetes Federation, IDF 2019**).

The most frequent complications of diabetes mellitus are ulcers of the lower limbs, according to research done in Egypt; found that the prevalence of diabetic foot ulcers (DFUs) ranged from 6.1% to 29.3% **(Gala et al., 2021).** The prevalence of depression is 22.4% and anxiety is 32% among DFUs **(Adam et al., 2014; Bala et al., 2015)**. These patients also experience negative feelings, including helplessness, worry, and frustration. The association between diabetes and depression is bidirectional, but there is a lack of documentation regarding significant factors related to the disease state, (e.g., number of complications, other medical co-morbidity). These factors contribute to the development of various psychiatric disorders, including anxiety and depression **(Ahmad et al., 2018)**.

Although psychological interventions for individuals with DFU might be helpful, there might be difficulties to implementation, For instance, some health professionals are unaware that psychological problems are more prevalent in people with diabetes and connected with adverse outcomes, and treating these problems might require further training **(Pereira et al., 2023).** Thus, it is considered essential to carry out this study to investigate the effect of psychological intervention on depression and anxiety symptoms among patients with diabetic foot ulcers.

Aim of the Study

This study was aimed at investigating the effect of psychological interventions on depression and anxiety symptoms among patients with diabetic foot ulcers. Through the following objectives:

1. Assessing the level of depression and anxiety symptoms among patients with diabetic foot ulcers.
2. Designing and implementing psychological interventions for patients with diabetic foot ulcers.
3. Evaluating the effect of psychological interventions on depression and anxiety symptoms among patients with diabetic foot ulcers.

Research Hypotheses

The psychological interventions will improve the depression and anxiety symptoms among patients with diabetic foot ulcers.

Operational definition:

Diabetic foot ulcers are a complex and multifactorial clinical problem that affects numerous patients with diabetes who experience ulceration and infection, are always associated with neuropathy and/or peripheral artery disease (PAD), disrupt the foot's epidermis and dermis, burst the skin envelope, expose sterile structures, and finally form full-thickness lesions (**Wang et al., 2022).**

Subjects and Methods

Research design:

A quasi-experimental research design with one-group pretest-posttest was used to achieve the aim of the current study.

Setting

The study was conducted at the outpatient clinic for blood vessels at Alhrar Hospital in Zagazig city, Sharkia governorate, Egypt.

Subjects:

A purposive sample of 60 adult patients with diabetic foot ulcers was recruited from the above-mentioned setting. Patients were selected according to the following inclusion criteria: a) both genders b) adult patient aged 18 years or older, c) diagnosed type I and type

II diabetes mellitus, d) suffering from diabetic foot ulcer(s), e) free from arterial occlusion and vascular disease. f) Having no chronic disease (e.g., chronic neurological deficit, cancer, liver cirrhosis), and g) Free from any psychiatric disorder.

Sample size:

The sample size was calculated to determine an improvement in the percentage of depression among patients with diabetic foot ulcers from a pre-test level of 22.06% to 3.5% post-test **(Hulley et al., 2013; Neeru et al., 2015)**. The sample size for a difference between two proportions at a 95% confidence level and with 80% study power was determined utilizing the Open-Epi computer software program. After taking into consideration a dropout rate of around 10%, the necessary sample size was 60 patients.

Tools of data collection:

Three tools were utilized to collect the necessary data**:**

I. A patient assessment form:

This scale was constructed by **Kaufiman, (2008)** and modified by the researchers to suit the study setting and objectives. Comprising three parts: 1) demographic characteristics of patient: such as gender, age, education level, etc. 2) details about diabetic foot such as ulcer numbers, sites, causes, duration, care, etc. and history of smoking and amputation. 3) The Wagner diabetic foot ulcer classification system developed by **Wagner, (1987)** to determine the extent of the ulcer and whether osteomyelitis or gangrene was present: including the following grades: 0 = no ulcer, 1 = superficial ulcer of skin, 2 = ulcer with deep infection without bone involvement, 3 = deep ulcer with osteomyelitis, 4 = partial foot gangrene, and grade 5= whole foot gangrene.

II. Hamilton Anxiety Rating Scale (HAM-A):

This tool designed by **Hamilton (1959)** and translated into Arabic by **Fatim (2012)** and composed of 14 items that measure symptoms of both somatic and psychic anxiety; with every item being ranked on a 5-point scale from 0 (not present) to 4 (severe). The total score can range from 0 to 56, with a score of less than 14 indicating no symptoms, 14-17 mild, 18-24 moderate, and more than 25 severe symptoms.

III. Hamilton Depression Rating Scale (HAM-D):

It was created by **Hamilton (2004)** and translated into Arabic by **Fatim (2012)**, including 17 items that determine the respondent's level of depression symptoms. Every item is rated on a 3 or 5-point scale according to the items; nine items are scored from 0-2, while eight items are scored on a 5-point scale, ranging from 0 = not present to 4 = severe. The total score is calculated by summing the individual scores from every question, so that a higher score indicates more severe depression symptoms. Levels of depression were classified as the following:

- Less than 7: no depression.
- 7-17: mild depression.
- 18-24: moderate depression.
- 25 and above: severe depression.

Validity and reliability of the tools:

The data collection tool was reviewed by five panels of experts in the fields of psychiatric and medical-surgical nursing, and their opinions were requested via an assessment form. Each item was rated by the experts as "essential," "useful but inadequate," or "unnecessary," and modifications were done based on the experts' judgment on the clarity and content appropriateness. Meanwhile, the anxiety and depression scales are standardized validated tools, and the reliability of these scales was checked through assessing their internal consistency utilizing Cronbach's alpha test. They show excellent levels of reliability with coefficients of 0.98 and 0.97, respectively.

Pilot study:

It was conducted on 10% of the total study sample, constituting about 6 patients with diabetic foot ulcers, to examine the viability, clarity, and reliability of tools and determine how long it would take to fill-in the tools. From the results of the pilot study, the average time to fill-in the tools were 30-45 minutes. The patients from the pilot study were involved in the main study sample, since no modifications were done.

Administrative design and ethical considerations:

Official approval was attained from the managers of Zagazig Alhrar Hospital as well as outpatient administration through official channels to carry out the study. Also, the research ethics committee at the Zagazig University Faculty of Nursing gave its approval to the research protocol. The researchers met with every eligible patient to discuss the aims of the study, significance, and procedures in order to get informed consent for participation. Participants received assurances regarding the confidentiality and anonymity of any collected data. There was no potential for participant harm during the study procedures.

Field of Work:

When the tools were finalized after pilot testing, the actual field started. After obtaining official permissions, the researchers started to prepare a schedule for program implementation. The fieldwork was executed in five months, starting from the beginning of January to the end of May 2024. It involved the four phases of program development through assessment, planning, implementation, and evaluation.

I-Assessment phase:

The patients were interviewed individually using the prepared study tools; the data pertaining to the Hamilton Depression Rating Scale and Hamilton Anxiety Rating Scale, as well as diabetic foot ulcers were considered baseline or pre-intervention data. The researchers then asked each patient about the available and most convenient time to demonstrate to him/her the psychological intervention. The researchers visited the outpatient clinic for diabetics three days per week during the morning shift, from 9:00 am to 12:00 pm. The time needed for completing the interview was about 30-45 minutes with each patient. The collected data were considered pre-test results and subsequently compared with post-test results.

Planning phase:

The program was designed by the researchers after reviewing recent and relevant literature and in view of the patients' needs identified in the assessment phase. The program was designed in the form of psychological intervention, using an integrated approach to help in the alleviation of their depression and anxiety symptoms. It comprised of 12 sessions, including theoretical and practical information. The theoretical part was aimed at providing detailed but simple knowledge about the nature, etiology, types, signs and symptoms, complications, and management of diabetes mellitus, as well as knowledge regarding depression and anxiety, including their definitions, types, risk factors, complications, and treatment. The practical part involved training the patient in adequate personal hygiene, proper diet, and physical activity, as well as providing training in relaxation exercises to overcome depression and anxiety.

Teaching methods were chosen to suit the teaching of small groups and involved interactive mini-lectures and brainstorming. Teaching media prepared included PowerPoint presentations, pictures, printed materials, etc. Moreover, the researchers prepared a booklet that covered all the theoretical and practical information provided in the training program.

Objectives of the intervention

1. Understand the definition and causes of diabetes mellitus.
2. Recognize the signs and symptoms of diabetes mellitus and its complications.
3. Discuss the etiology of diabetic foot, signs and symptoms, and its complications.
4. Recognize the method of prevention and management of diabetic foot ulcers.
5. Identify the signs and symptoms, causes, and prevention of anxiety and depression.
6. Identify coping strategies (such as relaxation techniques, mindfulness activities, and thought replacement) to alleviate depression and anxiety.
7. Apply relaxation training, mindfulness, and replacement of irrational thoughts to overcome depression and anxiety symptoms.
8. Acquire the necessary practical skills to provide appropriate care for diabetic foot ulcers.

Implementation phase:

The intervention consisted of 12 sessions (8 theoretical and 4 practical). The group of 60 diabetic patients was subdivided into six small groups; each group consisted of ten patients. Sessions were implemented during the morning

shift, twice daily, three times per week, one session for each group every week. Each session lasts roughly 30-45 minutes. The intervention lasted for three months. The timing and schedule of the training were set according to participants' convenience. The active involvement and interaction concepts of adult learning were implemented. Motivation and reinforcement were utilized to enhance learning.

The practical part was applied to every patient separately to ensure that the patients learned the skill. At the end of this stage, every participant received a booklet that contains all the information presented during the training sessions. As well, participants were encouraged to set weekly action plans and goals they aim to achieve during their participation in this study. Moreover, all patients were assessed throughout the practical sessions to determine whether or not they followed the prescribed program. Simple Arabic language was used by the researchers to promote cooperation and interaction as well as to help them understand the sessions of each program.

The sessions were as follows:

Session 1 (30-45 min):

During this initial session, the researcher explained the purpose of the program and provided instructions regarding the meeting place, the timetable that was one/week for each study group, in addition to information about the booklet and its use.

Session 2 (30-45 min):

The focus of this session was providing an overview of diabetes mellitus, such as its etiology, types, signs, and symptoms.

Session 3 (30-45 min):

This session was for providing knowledge about the complications and treatment of diabetes.

Session 4 (30-45 min):

This session was intended to discuss definition of foot ulcers, their causes, symptom, and complications.

Session 5 (30-45 min):

This session provided knowledge and skills about the care and treatment of foot ulcers.

Session 6 (30-45 min):

This session was focused on providing knowledge about depression: definition, causes, symptoms, and signs.

Session 7 (30-45 min):

This session was dedicated to providing knowledge about types of depression, risk factors, complications, and treatment.

Session 8 (30-45 min):

This session was focused on knowledge about the definition of anxiety, its causes, symptoms, types, complications, and treatment.

Session 9 (30-45 min):

This session was intended to provide training skills and tips to protect the feet for diabetic patients.

Session 10 (30-45 min):

This session's focus was providing training in relaxation exercises to overcome depression and pessimism, such as relaxation techniques, mindfulness activities, and thought replacement.

Session 11 (30-45 min):

This session's focus was providing training in relaxation exercises to overcome anxiety; including deep breathing, muscular progression, meditation, visualization, guided imagery, yoga, and light massage.

Session 12 (30-45 min):

This session was a termination of the program sessions, including; a review of the achievement of program objectives, revising the learned skills, and summarizing of what was taught during the sessions.

Evaluation phase:

Immediately after the program's implementation, a channel of communication was created between the researchers and the participants for the purpose of monitoring, providing feedback, and assessing their knowledge and practices, utilizing the same data collection tools. The effect of psychological interventions on depression and anxiety symptoms among patients with diabetic foot ulcers was evaluated by comparing the pre- and post-test results.

Statistical design:

Data were entered and statistical analysis was performed utilizing SPSS 20.0 (SPSS Inc., Chicago, IL, USA, 2011). The Cronbach alpha coefficient was used to assess the internal consistency of the scales. Quantitative continuous data from two independent groups were compared using the Student t-test; dependent groups were compared using the Paired t-test. The appropriate chi-square or Fisher exact tests were utilized to compare qualitative category variables. The interrelationships between ranked and quantitative variables were evaluated using Spearman rank correlation. Multiple linear regression analysis and analysis of variance for the full regression models were performed to determine the independent predictors of anxiety and depression scores. Every test had two sides. A p-value < 0.05 was statistically significant (S), while a p-value ≥ 0.05 was statistically insignificant (NS).

Results

As shown in **table 1**, the study sample comprised 60 patients with ages ranging from 35 to 80 years old, with a median age of 58.0 years. About two-thirds of them were males (63.3%), illiterate (71.7%), and residing in rural areas (75.0%). The table also reveals that, half of them (50.0%) were working, and all (100%) reported having insufficient income. The duration of diabetes ranged from one to fifty years, with a median age of 15.0 years.

Table 2 indicates that there were statistically significant improvements in patients' regular treatment of diabetes mellitus as well as in ulcer care and ulcer exudates ($p<0.001$) after the intervention. There were no changes detected in the numbers of ulcers or their sites. On the other hand, the percentage of patients with Wagner Grade 3/4 dropped from 71.7% before the intervention to 8.4% post-intervention. However, 26.7% improved to Grade 1 after the intervention compared to only 1 (1.7%) before the intervention. Overall, 91.7% of the patients showed post-intervention Wagner grade improvement.

Table 3 points to statistically significant improvements in patients' scores of anxiety symptoms as indicated by the negative post-pre differences in the scores ($p<0.001$). This was revealed in all 14 symptoms. Overall, the total anxiety score dropped by a mean of 26.5 points at the post-intervention phase ($p<0.001$).

Regarding the depression symptoms, **table 4** demonstrates statistically significant improvements in patients' scores as shown by the negative pre-post differences in the scores ($p<0.001$). This was noticed in relation to all 17 symptoms of depression. Overall, the total depression score decreased by a mean of 27.5 points at the post-intervention phase ($p<0.001$).

Table 5 shows that there were statistically significant improvements in anxiety levels at the post-intervention phase, where all patients had moderate to severe anxiety at the pre-phase compared with none at the post-phase ($p<0.001$). Additionally, the mean score has been diminished from 45.0 to 18.4 ($p<0.001$). As regards depression, the table also shows that all patients were having moderate to severe depression at the pre-phase, which dropped to 41.7% at the post-phase; this difference was statistically significant. Furthermore, the total mean score decreased from 44.6 to 17.1 ($p<0.001$).

Table 6 and figure 1 clarify that there was a statistically significant positive correlation between the pre-post differences of anxiety and depression scores ($r = 0.558$). Meanwhile, the table shows that none of these scores had any statistically significant correlation with patients' age, education, and duration of DM.

In multivariate analysis, **table 7** shows that the main statistically significant independent negative predictor of patients' anxiety score was the study intervention. While, the ulcer grade was a positive predictor; the model explains that 91% of the variation in the anxiety score and none of the other patients' characteristics had a significant effect on this score. As for patients' depression score, the main statistically significant independent negative predictor of this score was the study intervention. While being in an urban residence was a positive predictor, the model explains 95% of the variation in the depression score. This score was not significantly impacted by other patients' characteristics.

Table 1: Demographic characteristics of patients in the study sample (n=60).

Demographic characteristics	Frequency	Percent
Age:		
<60	33	55.0
60+	27	45
Range	**35.0-80.0**	
Mean±SD	**57.6±10.3**	
Median	**58.0**	
Gender:		
Male	38	63.3
Female	22	36.7
Residence:		
Rural	45	75.0
Urban	15	25.0
Education:		
Illiterate	43	71.7
Educated	17	28.3
Job:		
None	30	50.0
Working	30	50.0
Income:		
Sufficient	0	0
Insufficient	60	100.0
Duration of DM:		
<10	26	43.3
10+	34	56.7
Range	**1.0-50.0**	
Mean±SD	**15.0±8.7**	
Median	**15.0**	

Table 2: Changes in diabetes and diabetic foot care among studied patients before and after the intervention (n=60).

	Time				X^2 test	p-value
	Pre (n=60)		Post (n=60)			
	No.	%	No.	%		
Regular treatment:						
No	29	48.3	0	0.0		
Yes	31	51.7	60	100.0	38.24	<0.001*
Ulcer care:						
No	30	50.0	0	0.0		
Yes	30	50.0	60	100.0	40.00	<0.001*
Number of ulcers:						
Range	1.0-5.0		1.0-5.0			
Mean±SD	2.0±1.3		2.0±1.3		0.02	0.90
Median	1.00		1.50			
Ulcer Wagner grade:						
1	1	1.7	16	26.7		
2	16	26.7	39	65.0	U=52.95	<0.001*
3	36	60.0	4	6.7		
4	7	11.7	1	1.7		
Ulcer Wagner grade:						
Improved by at least 1 grade	-	-	55	91.7		
Ulcer site:						
Single	50	83.3	52	86.7		
Multiple	10	16.7	8	13.3	0.26	0.61

(*) Statistically significant at p<0.05 (U) Mann Whitney test

Table 3: Description of mean scores and standard deviations of anxiety symptoms scores for the studied patients at pre-post intervention.

Anxiety symptoms	Pre-post difference			Paired t-test	P-value
	Range	Mean±SD	Median		
Mood change	-3.0-0.0	-1.3±0.8	-1.00	11.87	<0.001*
Nervousness	-3.0-0.0	-1.7±0.8	-2.00	16.93	<0.001*
Phobias	-3.0-0.0	-1.4±1.1	-1.00	9.79	<0.001*
Insomnia	-3.0-0.0	-2.1±0.8	-2.00	21.08	<0.001*
Memory	-3.0-0.0	-1.9±0.9	-2.00	17.48	<0.001*
Depressed mood	-3.0-0.0	-1.5±0.7	-1.00	16.65	<0.001*
Behavior	-3.0-(-1.0)	-2.4±0.6	-2.00	29.00	<0.001*
Sensory feelings	-3.0-0.0	-2.2±0.9	-2.00	19.36	<0.001*
Somatic feelings	-3.0-(-1.0)	-2.2±0.7	-2.00	23.41	<0.001*
Cardiovascular	-3.0-(-1.0)	-2.3±0.7	-2.00	25.63	<0.001*
Respiratory	-3.0-0.0	-1.9±0.9	-2.00	15.88	<0.001*
Gastrointestinal	-3.0-(-2.0)	-2.2±0.7	-2.00	24.22	<0.001*
Genitourinary	-3.0-0.0	-1.5±0.8	-2.00	15.01	<0.001*
Neurologic	-3.0-0.0	-2.1±0.7	-2.00	22.30	<0.001*
Pre-post difference	-38.0-(-7.0)	-26.5±7.0	-28.50	29.19	<0.001*

(*) Statistically significant at p<0.05

Table 4: Description of mean scores and standard deviations of depression symptoms scores for the studied patients at pre-post intervention.

Depression symptoms	Pre-post difference			Paired t-test	P-value
	Range	Mean±SD	Median		
Depressed mood	-4.0-0.0	-2.4±0.7	-3.00	25.19	<0.001*
Guilt feelings	-4.0-(-1.0)	-2.6±0.8	-3.00	24.54	<0.001*
Suicide	-4.0-0.0	-2.4±1.1	-2.00	16.38	<0.001*
Insomnia - early	-4.0±0.0	-2.4±0.9	-3.00	19.83	<0.001*
Insomnia - middle	-4.0-0.0	-2.3±1.1	-2.50	17.18	<0.001*
Insomnia - late	-3.0-(-1.0)	-2.6±0.6	-3.00	34.95	<0.001*
Work and activities	-4.0-0.0	-2.0±0.9	-2.00	17.72	<0.001*
Retardation - psychomotor	-4.0-0.0	-2.2±0.9	-2.00	17.85	<0.001*
Agitation	-2.0-0.0	-1.0±0.6	-1.00	12.20	<0.001*
Anxiety - psychological	-2.0-0.0	-1.0±0.6	-1.00	13.43	<0.001*
Anxiety - somatic	-2.0-0.0	-1.1±0.5	-1.00	15.69	<0.001*
Somatic symptoms GI	-2.0-0.0	-1.2±0.5	-1.00	18.08	<0.001*
Somatic symptoms - General	-2.0-0.0	-1.0±0.4	-1.00	18.25	<0.001*
Sexual dysfunction - menstrual disturbance	-2.0-0.0	-1.1±0.6	-1.00	14.39	<0.001*
Hypochondrias	-2.0-0.0	-0.8±0.5	-1.00	12.05	<0.001*
Weight loss by history	-2.0-0.0	-1.2±0.6	-1.00	14.71	<0.001*
Insight	-2.0-0.0	-0.4±0.5	0.00	6.30	<0.001*
Pre-post difference	-38.0-(-15.0)	-27.5±4.7	-28.00	44.87	<0.001*

(*) Statistically significant at p<0.05

Table 5: Total anxiety and depression symptoms among patients in the study sample before and after the intervention.

Variables	Time				X^2 test	P-value
	Pre (n=60)		Post (n=60)			
	No.	%	No.	%		
Anxiety:						
No	0	0.0	12	20.0		
Yes	60	100.0	48	80.0	13.33	<0.001*
Range	**27.0-54.0**		**15.0-23.0**			
Mean±SD	**45.0±6.6**		**18.4±1.5**		U=90.26	<0.001*
Median	**48.00**		**18.00**			
Anxiety symptoms severity:						
None	0	0.0	12	20.0		
Mild	0	0.0	48	80.0	120.00	<0.001*
Moderate/Severe	60	100.0	0	0.0		
Depression:						
No	0	0.0	35	58.3		
Yes	60	100.0	25	41.7	49.41	<0.001*
Range	**33.0-50.0**		**10.0-25.0**			
Mean±SD	**44.6±3.7**		**17.1±2.7**		U=89.74	<0.001*
Median	**45.00**		**17.00**			
Depression symptoms severity:						
None	0	0.0	6	10.0		
Mild	0	0.0	29	48.3	---	---
Moderate/Severe	60	100.0	25	41.7		

(*) Statistically significant at p<0.05 (U) Mann-Whitney test
(--) Test result not valid

Table 6: Correlation between studied patients' anxiety and depression total scores (pre- post differences) and their characteristics.

Variables	Spearman's rank correlation coefficient	
	Anxiety (Pre-post difference)	Depression (Pre-post difference)
Depression (pre-post difference)	0.558**	
Age	-.049	-.033
Education	-.010	-.016
Duration of DM	-.024	-.214

(*) Statistically significant at p<0.05
(**) Statistically significant at p<0.01

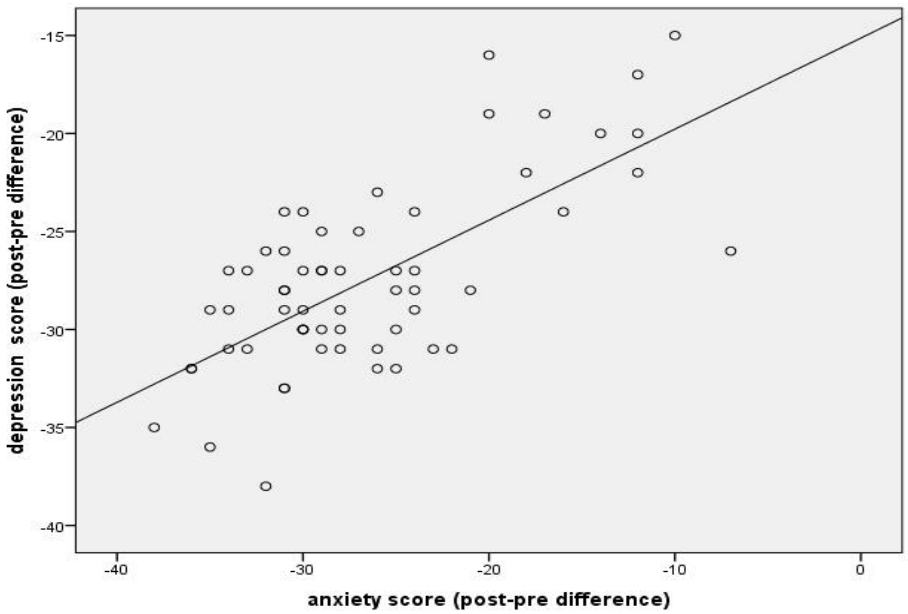

Figure 1: Correlation between nurses' anxiety and depression scores (pre-post differences)

Table 7: Best fitting multiple linear regression models for the anxiety and depression scores.

Anxiety							
	Unstandardized Coefficients		Standardized Coefficients	t-test	p-value	95% Confidence Interval for B	
	B	Std. Error				Lower	Upper
Constant	59.06	2.72		21.746	<0.001	53.68	64.44
Intervention	-23.31	1.01	-0.83	23.076	<0.001	-25.32	-21.31
Ulcer grade	3.26	0.63	0.18	5.141	<0.001	2.00	4.51
r-square=0.91 Model ANOVA: F=568.77, p<0.001							
Variables entered and excluded: age, gender, education, residence, duration of DM, effective treatment							
Depression							
	Unstandardized Coefficients		Standardized Coefficients	t-test	p-value	95% Confidence Interval for B	
	B	Std. Error				Lower	Upper
Constant	64.87	2.04		31.767	<0.001	60.83	68.92
Intervention	-26.07	0.71	-0.93	36.815	<0.001	-27.48	-24.67
Urban residence	1.44	0.64	0.04	2.242	0.027	0.17	2.72
r-square=0.95 Model ANOVA: F=813.37, p<0.001							
Variables entered and excluded: age, gender, education, ulcer grade, duration of DM, effective treatment.							

Discussion

Diabetic foot ulcers develop in about 15 percent of the patients with DM, mainly on the sole of the foot. Hospitalization is required for about 6% of these patients as a result of related complications **(American Podiatric Medical, 2019)**. Symptoms of anxiety and depression are the main psychological effects of diabetic foot on patients. These symptoms are more frequent among diabetic foot ulcer patients, which can be alleviated by a variety of methods, such as psychological approaches, pharmacological therapies, and other complementary techniques **(Polikandrioti et al., 2020)**. Therefore, the present study aimed to investigate the effect of psychological interventions on depression and anxiety symptoms among patients with diabetic foot ulcers.

The study sample included patients from a wide range of ages, from adulthood to the elderly, which corresponds to the prevalence of diabetes mellitus on a large age spectrum. These results are to some extent in harmony with that of **Khan et al., (2019)** study in

Pakistan about "predicting factors of anxiety and depression among patients with type II DM", which showed that the problem of diabetic foot is unusual in patients younger than 40 years old, and it increases with increasing age through their study. Similarly, **Fawzy et al., (2019)** demonstrated that, DFU occurrence was more likely to occur in older individuals, with a mean age of 56 years in Saudi Arabia. However, **Al-Rubeaan et al., (2015)** found no connection between age and the development of diabetic foot problems.

In the present study, there was a majority of male diabetic patients, with approximately two-thirds of the sample being males. This suggests a good representativeness of the sample given the prevalence of diabetes mellitus in addition to the existence of diabetic foot problems. According to a study in Australia about the burden of diabetes mellitus, male diabetic patients had an almost twofold higher chance of developing diabetic foot problems than female patients **(Zhang et al., 2020)**. This result goes in line with the study of **Yazdanpanah et al., (2018)** in Iran, which displayed that male sex is a risk factor for diabetic foot ulcers. These findings were in contrast with those of **Galal et al., (2021),** who found no correlation between gender and DFU development in Egypt. On the other hand, **Fawzy et al. (2019)** reported that female patients were more likely than male patients to experience DFUs in Saudi Arabia. These differences can be caused by variations in the study's methodology and participants.

The current study revealed that, three quarters of the patients were found to be living in rural areas. In the same line, **Abdelsalam et al., (2017),** who studied “Effectiveness of health education intervention on foot self-care practice among diabetics,” found that most of the participants were from rural areas. In contrast, **Ali and Ghonem's (2019)** stated that about half of patients with diabetic foot ulcers lived in an urban environment. Similarly, **Mohamed et al., (2023)** in their study about "Factors Affecting Compliance of Patients with Diabetic Foot Ulcer Undergoing Hyperbaric Oxygen Therapy" reported that more than half of the patients were urban residents.

Concerning the duration of diabetes mellitus among the studied patients in the present study, it was quite variable, ranging between one and fifty years, with a median age of 15.0 years. The median indicates a generally long duration of the disease in more than half of them. This is to be expected in a group of diabetic individuals with diabetic foot, a complication that often occurs after many years of the onset of DM. In the same context, the study of **Saintrain et al., (2019)** in Brazil found that the mean duration of DM among diabetic patients with diabetic foot was 14.1 years.

The current study showed that psychological intervention provided to patients with diabetic foot ulcers was effective in improving ulcer grades and associated with a significant increase in the patients' adherence to treatment for both ulcers and diabetes mellitus. The key reason for the success of the program could be its practical component, which helped these patients take proper care of their foot and ulcers, as well as correct any misconceptions or false practices. This result is congruent with a study done by **Ali and Ghonem (2019)** in Egypt, which provided evidence of a health education program in improving diabetic foot ulcers among diabetic patients.

The main objective of the present study was to improve diabetic patients’ anxiety and depression symptoms through the implementation of psychological intervention. Regarding anxiety, the current study showed that all of the patients were having either moderate or severe anxiety symptoms at the pre-implementation phase. This is to be expected considering the severity of the grade of diabetic ulcers and the seriousness of diabetic foot problems. Similarly high prevalence of anxiety was found among Jordanian patients with diabetic foot **(Ahmad et al., 2018)**. Also, a study conducted by **Abd-Elgawad et al. (2023)** in Egypt about "prevalence of depression and anxiety among diabetic patients" revealed that the Fayoum governorate had a higher prevalence of anxiety among diabetic foot patients. The finding disagrees with the study performed by **Polikandrioti, et al. (2020)** entitled "Quality of life in diabetic foot ulcers: associated factors and the impact of anxiety/depression and adherence to self-care." That found more than

two-thirds had low levels of anxiety.

Upon the implementation of the present study psychological intervention, significant improvements were observed in the severity of anxiety symptoms among studied patients, where none of them had moderate or severe anxiety symptoms at the post-intervention phase. Moreover, all 14 of the anxiety symptoms showed improvements (this result accepts the research hypothesis). This improvement is due to the effect of the intervention as confirmed in the multivariate analysis, which was identified as the main independent negative predictor of the anxiety score. This success of the intervention is certainly related to its being custom-tailored to patients' identified needs. This is supported by a randomized clinical trial conducted in China, which found that the "implementation of an intensive patient education program" significantly reduced the anxiety levels of diabetic foot patients **(Chen et al., 2020)**.

The current study results indicate that all of the patients experienced moderate to severe depressive symptoms at the pre-intervention phase. This is to be expected considering the length of time these ulcers have been present, as well as their multiplicity and chronicity. This result is in harmony with that of **Briganti et al. (2018)** in Brazil, which showed a significant prevalence of depressive symptoms among individuals with diabetic foot ulcers.

After the implementation of the psychological intervention, significant improvements were shown in patients' scores of depression symptoms in all its elements. Thus, at the post-implementation phase, only around two-fifth of them were having moderate or severe depression symptoms. Such improvement was due to a reduction in anxiety symptoms as well as the effect of the study intervention, which was found to be the main negative predictor of the depression score. The effectiveness of psychological intervention could be attributed to its content as well as process, where active participation and adult learning principles were applied, in addition to the practical element of the intervention. These findings revealed improvements in the studied patients' anxiety and depression symptoms after the implementation of psychological intervention, thus leading to acceptance of the set research hypothesis.

In line with our findings, a randomized clinical trial done by, **(Chen et al., 2020)** in China reported improvement in diabetic foot patients' depression symptoms following an intensive patient education program. Similarly, **Pereira et al., (2023)**, who studied "Stress reduction interventions for patients with chronic diabetic foot ulcers" reported significant improvements in depression, anxiety, and ulcer grades after implementation of the program.

Concerning a number of factors that could have affected the depression scores of the patients in the present study, however, only the urban residence had an independent significant effect in the multivariate analysis. These results are congruent with a study conducted in Ethiopia by **Asefa et al. (2020)**, which revealed that diabetic patients from urban areas had a significantly higher prevalence of depression. This result is similar to **Şahin and Cingil, (2020)** study in Turkey, which demonstrated that the place of residence, whether urban or rural, had a significant influence on the psychological status of patients with DM.

Meanwhile, the results of the present study revealed a statistically significant, strong positive correlation between the studied patients' anxiety and depression scores. Moreover, the pre-post improvements of the anxiety and depression scores were positively correlated. The findings indicate that the improvement in one of the two symptoms is positively reflected in the other one. In line with this, a study of type I and type II diabetes in Australia reported about the correlation of anxiety and depression as well as associated factors among these patients **(Nefs et al., 2019).**

Conclusion

According to the results of the current study, it can be concluded that the implementation of the psychological interventions for patients with diabetic foot ulcers was effective in improving their depression and anxiety symptoms, with improvements in their ulcer grades. A significant positive, strong correlation was

found between patients' depression and anxiety scores.

Recommendations

In the light of the current study findings, the following recommendations are advised:

- The developed psychological interventions regarding foot ulcer care should be applied in the study settings as well as in similar diabetic care centers, and its materials should be made available in all diabetes clinics.
- The psychological state of any patient with diabetes, especially those suffering from diabetic foot, should be closely and regularly monitored through simple assessment tools.
- The nurses providing care to diabetic patients, particularly with diabetic foot, should be able to provide psychological support and counseling for anxiety and depression symptoms.
- Further research is needed to measure the long-term effect of such psychological intervention on depression and anxiety, as well as on ulcer grades.

Limitations of the study:

- The sample size was relatively small, thus limiting the generalizability of the result. despite the observation of numerous significant relationships.

-The study was conducted in just one governorate. Therefore, our findings are difficult to generalize to the whole population of Egypt.

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