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Effectiveness of Foot Massage and Range of Motion Exercise on Diabetic Patients' Peripheral Neuropathy: A Randomized Controlled Trial

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ABSTRACT

Objective(s): To determine which interventions: Foot massage, or Range of motion exercise, is most effective for diabetic peripheral neuropathy.

Methods: A true experimental study was conducted from December 2, 2022, to April 25, 2023. A probability (simple random) sample of (77) diabetic patients diagnosed with peripheral neuropathy at Al-Hassan Specialized Center for Endocrinology and Diabetes, Karbala, Iraq. The study samples were randomly divided into three groups: 25 patients in the Foot massage group and 25 patients in the range of motion group, which received three sessions per week for two weeks, while 27 patients in the control group receive the routine care. Data was collected using Toronto Clinical Neuropathy Score to assess diabetic neuropathy. The data were analyzed using SPSS version 26, paired t-test, Analysis of Variance, Pearson correlation, least significant difference, and Friedman's test was used for the analyzing data in the current study.

Results: The decrease in the Toronto Clinical Neuropathy Score level in both intervention groups was significant between the pretest and posttest (0.000). In comparison with the control group, there was a significant difference from the foot massage group (0.001) in the post-test. However, there was a non-significant difference in comparing the range of motion group with the control group in the post-test. According to Friedman's test mean rank, the most effective intervention group was a foot massage, which had the lowest mean.

Conclusion: Although foot massage, and range of motion exercises are all supportive care techniques for diabetic patients with peripheral neuropathy, foot massage was more effective than range of motion exercises, and range of motion exercises were less effective at the peripheral neuropathy level.

Recommendations: These techniques have supportive care when considering non-pharmacological interventions to improve diabetic peripheral neuropathy and prevent complications among diabetes patients.

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فاعلية تدليك القدم و تمارين نطاق الحركة على الاعتلال العصبي المحيطي لدى مرضى السكري: تجربة منضبطة عشوائية

المستخلص

الهدف: تحديد اي من التداخلات: تدليك القدم ، أو تمارين الحركة، هي الاكثر فاعلية لاعتلال الأعصاب المحيطية لمرضى السكري.

المنهجية: دراسة تجريبية حقيقية أجريت الدراسة في الثاني من كانون الأول ٢٠٢٢ إلى ٢٥ نيسان ٢٠٢٣. تم اختيار عينة احتمالية (عشوائية) قوامها (٧٧) مريض سكري تم تشخيصهم بالاعتلال العصبي المحيطي في مركز الحسن التخصصي للغدد الصماء والسكري، كربلاء، العراق. تم تقسيم عينات الدراسة بشكل عشوائي إلى مجموعتين: مجموعة تدليك القدم و مجموعة تمارين نطاق الحركة، كلا المجموعتين تلقت ثلاث جلسات في الأسبوع لمدة أسبوعين. والمجموعة الضابطة التي لم تتلق أي تداخل. كانت أداة جمع البيانات للاعتلال العصبي المحيطي السكري هي مقياس تورونتو للتقييم السريري للاعتلال العصبي السكري. تم تحليل البيانات الاحصائية باستخدام الحقيبة الاحصائية نسخة 26, تم استخدام اختبار t المقترن، تحليل التباين، إرتباط بيرسون, أقل فرق معنوي واختبار فريدمان.

النتائج: كان الانخفاض في مستوى مقياس تورونتو في جميع مجموعات التدخل كبير (٠.٠٠١). بالمقارنة مع المجموعة الضابطة، كان هناك فرق معنوي مع مجموعة تدليك القدم (٠.٠٠١) في الاختبار اللاحق. بينما كان هناك اختلاف غير معنوي في مقارنة مجموعة تمارين نطاق الحركة مع المجموعة الضابطة في الاختبار اللاحق. وفقاً لمتوسط اختبار فريدمان، كانت مجموعة التدخل الأكثر فاعلية هي تدليك القدم ، والتي تمثل أقل متوسط.

الخلاصة: على الرغم من أن تدليك القدم وتمارين نطاق الحركة هما تقنيات رعاية داعمة لمرضى السكري الذين يعانون من الاعتلال العصبي المحيطي، إلا أن تدليك القدم كان أكثر فاعلية من مجموعة تمارين نطاق الحركة، وكانت تمارين نطاق الحركة أقل فاعلية على مستوى الاعتلال العصبي. استخدمت على هذه التقنيات لتكون أكثر فائدة كرعاية داعمة عند النظر في التدخلات غير الدوائية لتحسين الاعتلال العصبي المحيطي السكري والوقاية من المضاعفات لدى مرضى السكري

الكلمات المفتاحية:الاعتلال العصبي المحيطي السكري، تدليك القدم، تمارين نطاق الحركة، تجربة سريرية عشوائية.

Introduction

Diabetes mellitus (DM) is a metabolic condition that occurs chronically and is characterized by high blood glucose levels [(1)]. Type-2 diabetes is the most prevalent, typically impacting adults when the body develops insulin resistance. Type-1 diabetes, also called juvenile diabetes, is a chronic condition in which the pancreas does not produce or insufficiently produces insulin for the body [(2)]. Diabetes mellitus is one of the most significant health problems; around 425 million people worldwide suffer from it, by which the whole number expected to rise to 628 million by 2045[(3)]. When high blood sugar levels are prolonged, many complications can occur and cause significant damage to various parts of the body, including the feet, kidneys, and eyes; this is called diabetic complications [(4)].

Neuropathy is a diabetes complication that causes nerve damage throughout the body. Approximately half of all diabetics have some form of nerve damage and the most common type is peripheral neuropathy, also known as diabetic peripheral neuropathy, or DPN [(5)]. Diabetic peripheral neuropathy prevalence ranges from 21.3 to 34.5% in type-2 diabetes, or T2DM, and from seven to 34.2% in type-1 diabetes, or T1DM [(6)]. More than 45% of people with type-2 diabetes and 54% of patients with type-1 diabetes may be asymptomatic [(3)]. One of the most common neuropathies of diabetes mellitus, DPN can lead to foot ulceration and amputation and affect autonomic, motor, and sensory nerve functions [(7)]. Diabetic peripheral neuropathy also impacts humanism and the economy significantly, as it limits patients' general functioning and ability to sleep, often makes

them feel depressed and anxious, and causes impaired work productivity, which are associated with reduced health-related quality of life [7]. Most people with diabetes can prevent serious foot complications through regular foot care and routinely follow-up, which are considered the best for preventing diabetic foot problems [8].

The American Diabetes Association has put forth a declaration stating that diabetes mellitus conditions can be improved and the risks associated with diabetic foot ulcers (DFU) can be decreased through preventive care. Another professional organization specializing in diabetes has suggested a range of measures for preventing DFU, including controlling blood sugar levels, providing health education, administering pharmacological therapies, engaging in physical exercises, and ensuring proper foot care for patients with diabetes [9]. By utilizing the arch ball roll technique, performing plantar exercises can effectively stimulate the muscles situated on the plantar or sole of the foot. This combination of techniques can induce muscular contractions and compression of blood vessels within the foot, resulting in an increased blood supply to peripheral tissues [9].

The described method leads to the creation of open capillary networks and activates additional insulin receptors, which facilitate the cells entering of blood glucose. Consequently, this process results in a lowered blood glucose level, thereby reducing the likelihood of complications associated with DFU [9]. Flexibility of ankle joints and resistance exercises can help reduce the recurrent neuropathy of the plantar foot in patients with DM, in addition to improving diabetic neuropathy and walking speed [10].
Foot massage using reflexology is a known supportive care technique for alleviating physical and emotional symptoms among patients with various diseases [7].

Thai foot massage is a viable alternative treatment for balance performance, ROM of the foot, and foot sensation in diabetic patients with peripheral neuropathy. Thai massage can help to improve local microcirculation, enhance blood flow rate, correct metabolic disorders, improve the blood circulation of local tissues, increase the body's local pain threshold, enhance joint range of motion, and improve the blood supply and nutrition metabolism of peripheral nerves [11].

Stretching and strengthening in ROM exercises have the potential to enhance the mobility of foot joints and promote a more even distribution of plantar pressure during walking in diabetic patients [13].

The implementation of such exercises can aid in the prevention of diabetic foot complications[13].

This study is not similar to a study that evaluated only foot massage [11], or ROM on DPN [13]. The study compares foot massage and ROM exercises for the patient with diabetic peripheral neuropathy. There is no study that compared foot massage with ROM exercises and measured the extent of improvement in the level of diabetic peripheral neuropathy in Iraq. In addition, this study will compare these variables to find out which of these interventions is best for improving the level of peripheral neuropathy. This study aimed to compare foot massage and ROM exercises for patients with DPN.

Methods

Study Design and Setting

A randomized controlled trial (RCT) was conducted to evaluate the effectiveness of foot massage and ROM exercise on the level of DPN among diabetic patients attending the Al-Hassan Specialization Center for Endocrinology and Diabetes in Karbala.

Sample and Sampling

A simple random sampling of a total sample size of 77 diabetic patients was chosen by random assignment.

Sample Size Calculation

A total of 77 patients were included in the data analysis. The study sample was divided into three groups: 25 patients in the foot massage group, 25 patients in the foot ROM exercise group, and 27 patients in the control group ***(see figure 1)***. The minimum sample size in this study was 77 patients, according to the calculation of the minimal sample size based on a confidence level of 80% and a margin of error of 5% [(12)].

Data Collection and Study Instrument

The data collection procedure was starts from (December 2nd, 2022) to (April 25th, 2023) to meet the study objectives. Patients with DPN who were assessed by the Toronto Clinical Neuropathy Score were eligible and allocated into three groups: a foot massage group, a ROM exercises group, and a control group with regular care. Each sample of the intervention group takes three sessions per week and continues for two weeks [(11)]. In the Thai Foot Massage group, in the supine and side-lying positions, pressure was administered to the knee area, lower leg, ankle, and foot of the participants [(11)].

The researcher used their thumb to apply pressure gently and gradually along the three meridian lines on the feet. This approach is referred to as thumb pressing in foot massage, which involves applying pressure gently and gradually along the three meridian lines on the feet [(11)]. According to the different thresholds in each individual, for example, age and gender, each thumb pressure was applied until the participant started to feel some discomfort (below-pressure pain threshold) and maintained the pressure for five to ten seconds at each massage point. During the study, all participants were administered traditional Thai massage for a duration of 25 minutes per session, three times a week, for a total of 2 weeks [(11)]. In the ROM Exercises Group, ROM was combined with plantar exercise every 2 days. The active ROM procedure included exercises such as flexion-extension-adduction-abduction in the hips and toes, flexion-extension of the knees, dorsiflexion and plantar flexion in the ankles, and inversion-eversion of the legs. All participants received 30 minutes per session, three sessions per week for the two weeks [(13)]. The control group did not receive any interventions, just pre-test and post-test assessments after two weeks, as did other groups, and was compared with the other groups in the study. Then every patient in all groups was evaluated after the intervention (post-test assessment) after two weeks by using the TCNS.

Randomization

The study sample was enrolled in the study sequentially. Every two weeks, the researcher enrolled 10–14 patients by random assignment, placing each group with a specific color as follows: the foot massage group with yellow paper, the ROM exercises group with green paper, and the control group with red paper. He put all these papers in a closed envelope for the participant to open and withdraw or select the color that they wanted without knowing that the color represented any of the study groups, and then the intervention was applied to each group separately.

Ethical consideration

The study was approved by the Ethical Research Committee of the College of Nursing Council/University of Baghdad; the official agreement was offered by the Al-Hassan Specialization Center for Endocrinology and Diabetes; and the patients'

written consent was obtained from the study participants.

Data Analysis

Using the Statistical Package for Social Science (SPSS) version (26), The significance level was $p < 0.05$. The mean and standard deviation for the foot bathing group, the foot massage group, the foot ROM group, and the control group were calculated. Paired t-test, independent t-test, Pearson correlation coefficient, analysis of variance (ANOVA), and Friedman's test were used to determine the correlation between variables.

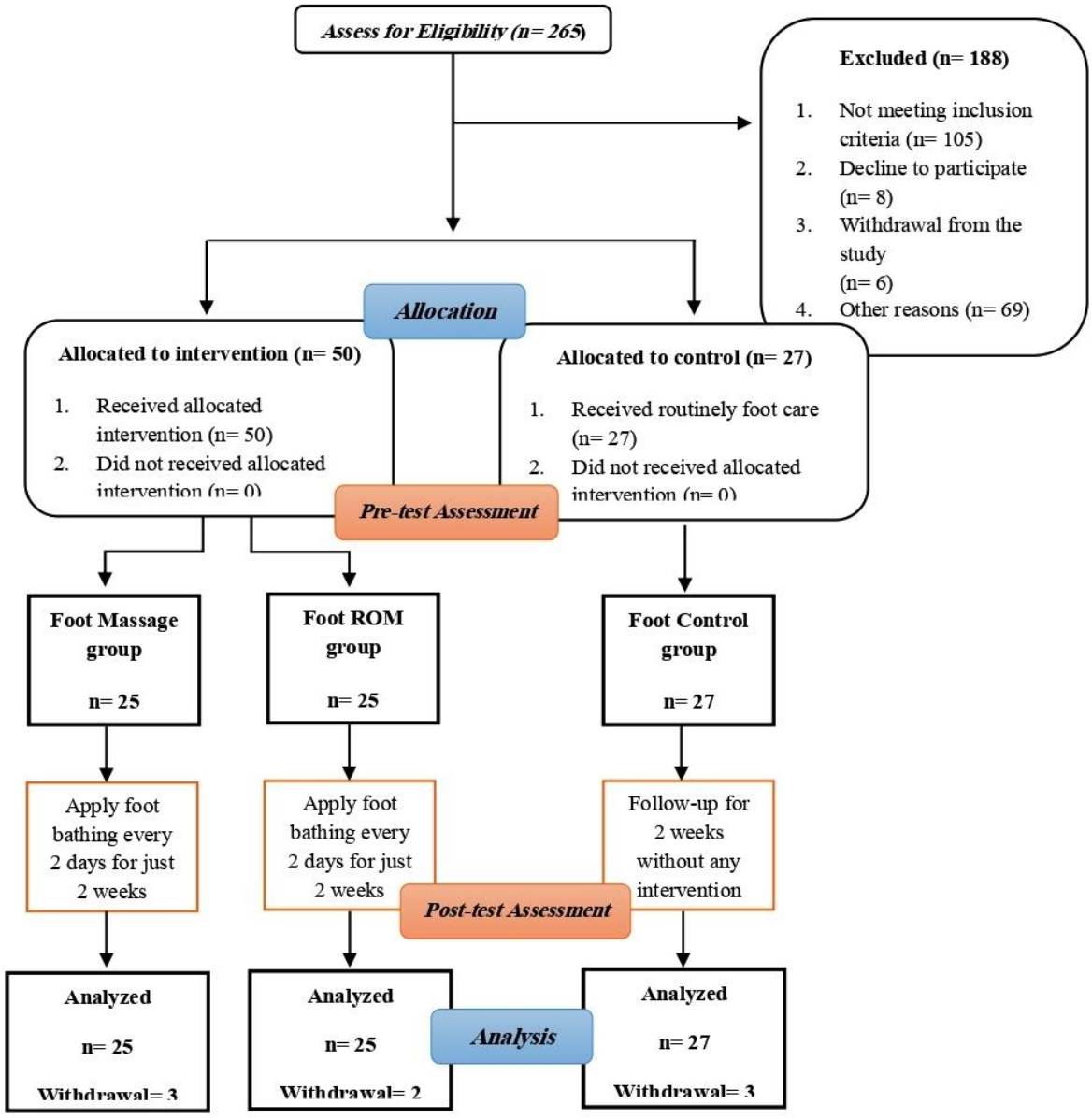

Figure 1 Clinical trial flow diagram

Results

Table 1. Mean and Standard Deviation of Socio-demographic and Clinical Characteristics of the Study Groups

Item	Total	Massage	ROM	Control
	M ± SD	**M ± SD**	**M ± SD**	**M ± SD**
Age	54.9 ± 6.3	55.04 ± 5.6	54.7 ± 7.7	**55.8 ± 6.4**
Duration of Diagnosed with DM (years)	16.04 ± 5.8	14.5 ± 3.9	14.3 ± 3.9	**19.2 ± 7.4**
HbA1c Level	10.1 ± 2.2	9.9 ± 1.5	10.6 ± 2.7	**10.01 ± 2.1**
BMI	29.1 ± 4.3	29.3 ± 4.8	27.3 ± 3.4	**30.01 ± 4.1**

M ± SD= Mean± Standard deviation.

Table 2. Socio-demographic and Clinical Characteristics of the Study Groups

Item	f.	%	f.	%	f.	%	f.	%
sex								
Male	36	46.8	10	40	16	64	10	**37**
Female	41	53.2	15	60	9	36	17	**63**
Marital Status								
Married	73	94.8	23	92	24	96	26	**96.3**
Separated	4	5.2	2	8	1	4	1	**3.7**
Educational Level								
Illiterate	22	28.6	11	44	4	16	7	**25.9**
Just read and write	0	0	0	0	0	0	0	**0**
Primary School	42	54.5	12	48	14	56	16	**59.3**
Secondary School	3	3.9	0	0	0	0	3	**11.1**
Preparatory School	6	7.8	0	0	5	20	1	**3.7**
Diploma	2	2.6	0	0	2	8	0	**0**
Bachelor	2	2.6	2	8	0	0	0	**0**
Occupation								
Employee	4	5.2	2	8	1	4	1	**3.7**
Gainer	12	15.6	3	12	4	16	5	**18.5**
Unemployed	26	33.8	10	40	4	16	12	**44.4**
Housewife	32	41.5	9	36	14	56	9	**33.3**
Retired	3	3.9	1	4	2	8	0	**0**
Residence								
Rural	21	27.3	9	36	5	20	7	**25.9**
City	56	72.7	16	64	20	80	20	**74.1**
Other Chronic Diseases								
No	29	37.7	10	40	7	28	12	**44.4**
HTN	31	40.2	13	52	10	40	8	**29.6**
IHD	1	1.3	0	0	1	4	0	**0**
HTN and IHD	15	19.5	2	8	6	24	7	**25.9**
HTN and Arrhythmia	1	1.3	0	0	1	4	0	**0**
Smoking								
No	55	71.4	19	76	16	64	20	**74.1**
Yes	22	28.6	6	24	9	36	7	**25.9**

M= Mean**, SD**= Standard Deviation**, f.** = frequencies**, %** = percentage.

Table 1 shows that the large mean age in the study groups was in the control group, which represents 55.8 years. The mean duration of being diagnosed with DM in the control group was 19.2 years. The large mean of HbA1c represents 10.6. The control group had a large BMI. Table 2 indicates that the majority of the study participants were female, and the majority of the patients were married. More than half of the study samples were primary school graduates. Nearly half of the female study samples were housewives, while the most common male occupation was unemployed. The majority of study participants were residents of the city. Less than half of the patients have HTN. Finally, most of the study participants were non-smokers.

Table 3. Level of DPN by Foot Massage, ROM, and Control Group

Measure	Intervention group		Mean ± SD	t	Sig.
Level of DPN	**Foot Massage**	**Pre-test**	14.31 ±2.99	12.74	**0.001***
		Post-test	11.67 ±3.36		
	Foot ROM	**Pre-test**	15.87 ±2.27	5.33	**0.001***
		Post-test	14.41 ±2.66		
	Control	**Pre-test**	14.61 ±3.49	- 1.16	0.256*
		Post-test	14.76 ±3.66		

M = Mean**, SD =** Standard Deviation**, P-value =** Probability value**, NS=** Non-significant at P >0.05**, Sig=** Significant at P < 0.05.

Table 3 shows the level of DPN by groups of interventions. The foot massage group of intervention based on mean difference and SD between pre-test and post-test was the pre-test (mean ± SD 14.31 ± 2.99) and the post-test (mean ± SD 15.87 ± 2.27). The foot ROM pre-test represents (mean ± SD 11.67 ± 3.36), and the pre-test represents (mean ± SD 14.41 ± 2.66). All intervention groups showed a significant effect, for which the p-value was 0.000 < 0.05. While the control group showed no positive change between the pre-test (mean ± SD 14.61 ± 3.49) and post-test of the control group (mean ± SD 14.76 ± 3.66) with a non-significant p-value of 0.256.

Table 4. Level of DPN by Comparing Mean in Intervention Groups with Control Group

Dependent Variable	(I) Grouping	(J) Grouping	Mean Difference (I-J)	Std. Error	Sig.
Pre-test	**Control**	**ROM**	-1.250-	0.807	0.125
		Massage	0.269	0.807	0.739
Post-test	**Control**	**ROM**	0.377	0.875	0.667
		Massage	3.057*	0.875	**0.001**

P = Probability value**, NS=** Non-significant at P >0.05**, Sig=** Significant at P < 0.05.

Table 4 shows that there is a significant statistical difference between foot massage and the control group (P = 0.001) in the post-test. While there is a non-significant difference in comparing foot ROM with the control group (p = 0.667). There is no significant difference between the study groups (massage and ROM) in the pre-test compared to the control group.

Table 5. The Mean Rank of the TCSS among Foot Massage, ROM, and Control Group

Ranks		Chi-square	df	Sig.
	Mean Rank	61.86	7	**0.001***
Foot Massage; TCSS	2.81			
Foot ROM; TCSS	4.55			
Control; TCSS	5.05			

df= Degree of freedom**, P value=** 0.001.

Table 5 shows the mean of the TCSS among groups of intervention. According to the mean rank of TCSS, the most effective intervention group was foot massage, with a little difference in mean rank of 2.81 and a relatively large difference of up to double between foot massage and foot ROM. There is a significant difference among all study groups, with a p-value of 0.000 < 0.05. According to the mean rank of TCSS, there is a little difference in the mean rank between ROM and the control group.

Table 6. Correlation of Socio-demographic Variables with Intervention Groups

Demographics	Massage Group	ROM Group	Control Group
Age	0.001*	0.042	0.111
Duration of diagnosed with DM	0.001*	0.186	0.059
HbA1c Level	0.102**	0.188	0.182
BMI	0.257	0.696	0.095

******Non-significant at P >0.05, *****: Significant at P < 0.05.

Table 6 shows there is a significant relationship between age and the massage group (p = 0.001) and the ROM group (p = 0.042). The duration of being diagnosed with DM shows a significantly positive correlation regarding the foot massage group (p = 0.001). On the other hand, there are no significant correlations among other socio-demographic characteristics and intervention groups.

Table 7. Differences of Socio-demographic Variables with Intervention Groups

Demographics	Massage Group			ROM Group			Control Group		
	value	df	P-value	value	df	P-value	value	df	P-value
Gender	8.48	11	0.232	10.39	11	**0.039**	8.57	12	0.278
Marital status	15.95	11	0.068	11.98	11	0.338	8.31	12	0.569
Educational level	22.03	22	0.155	34.64	33	0.309	31.07	36	0.357
Occupation	34.18	44	0.318	42.12	44	0.241	33.44	36	0.355
Residence	12.85	11	0.213	12.51	11	0.511	7.74	12	0.434
Smoking	11.12	11	**0.003**	16.47	11	**0.018**	11.21	12	0.557
Other chronic diseases	29.29	22	**0.001**	65.89	66	0.268	30.62	24	0.297

df= degree of freedom**, Value=** Pearson Correlation**, P=** Probability value**, S=** Significant at P < 0.05**, NS=** Non-significant at P >0.05**.**

Table 7 shows differences in some socio-demographic variables between the intervention groups. In this table, there is a significant difference between smoking and the massage group (p = 0.003), as well as with the ROM group that represents (p = 0.018); other chronic diseases with the massage group (p = 0.001); and gender with the ROM group that represents (p = 0.039). On the other hand, there are non-significant differences among other socio-demographic characteristics and intervention groups.

Discussion

Socio-demographic characteristics

The study results revealed that the mean total age of intervention groups was 54.9±6.3 years. This result was slightly lower than the study's report that the mean age of participants was 57.7 ± 6.4 years [11]. The majority of patients with DPN were elderly, with an age above 50 years, as most type 2 diabetes mellitus cases occur between the ages of 36 and 65 years [14]. The longer the duration of diabetes, the more likely neuropathy is to develop, with potential onset occurring within the first 10 years following a diabetes diagnosis [15]. The mean duration of being diagnosed with DM was 16.04 years, with a SD of 5.8 years. Our result was slightly higher than that reported. The study's findings revealed that the mean duration of being diagnosed with DM among participants was 14.5 ±8.8 years [16]. Patients with DPN typically experience a longer duration of diabetes, increasing the likelihood of developing neuropathy, which can occur within ten years of a diabetic diagnosis [15]. The mean HbA1c level was 10.1 with a SD of 2.2, and the ROM group had the largest mean of HbA1c at 10.6 with a SD of ±2.7. this study result is consistent with the study report that the intervention group had a higher HbA1c level (9.3 ± 2.9) than the control group (8.2 ± 2.2) (13). The high HbA1c levels are associated with DPN and are a good indicator for the development of DPN in patients with T2DM [17]. The mean BMI of the study groups was 29.1 kg/m2, with a SD of ±4.3. The finding of this study is consistent with the study reported. The mean BMI in their study was reported as 28.9 ±4.34 kg/m^2, which is similar to our control group's BMI of 30.01 kg/m^2 with a SD ± 4.1. Their control group also had a higher BMI of 32.04±7.09 kg/m^2, consistent with our results [16]. The average BMI of the sample is high since obesity is associated with diabetes and is considered a risk factor for developing it [18].

This study shows approximately half of the study participants were female, which represents 53.2%. The findings of this study are consistent with the study that showed the study participants were female, representing 71.4% of the sample [19]. The result shows that the majority of the patients (94.8%) were married. This finding is consistent with the study that found the majority of participants were married, representing 80% of the sample [20]. As the average age of the study samples was 54.9 years old, it was expected that most of them were married. This study shows that more than half of the study samples (54.5%) were primary school graduates. According to the study, 52.6% of the sample had completed primary school [21]. This study shows that three-quarters of the study sample were housewives or unemployed, which represents 75.3%. The findings of this study are consistent with the study that reported the majority of participants were unemployed, comprising 46.4% of the sample [19]. The majority of study participants were residents of the city, which represented 72.7%. The findings of this study are not congruent with the study that revealed the majority of the sample resided in rural areas, accounting for 64.3% of the participants [20]. Also, the majority of this study participants have other chronic diseases with DM, which represents 71%; about 40.2% of them have HTN. According to the study, the majority of the study participants had a systemic disease with DM, accounting for 57.9%, while approximately 45% of them had hypertension [21]. The pathogenesis of arrhythmias is attributed to structural alterations that arise in diabetes, which impair the customary arrangement of the heart. Individuals diagnosed with T2DM face a 10% higher likelihood of developing coronary artery disease (CAD), a 53% increased risk of myocardial infarction (MI), a 58% greater probability of experiencing a stroke, and a 112% elevated risk of heart failure. Hence,

T2DM represents a significant risk factor for CVD and its associated complications [22]. Approximately three-quarters of the participants in this study-71.4%-were non-smokers, and a quarter of the samples-28.6%-were smokers. This result is consistent with the study that revealed the majority of participants were non-smokers, which represents 76.3% of the sample [21].

Intervention results

Foot Massage: The foot massage pre-test was (mean ± SD= 14.31 ± 2.99) and the post-test was (mean ± SD= 11.67 ± 3.36), as well as foot massage groups showed a significant difference between pre-test and post-test that was p-value: 0.000 < 0.05, while the control group showed no positive change between the pre-test that represented (mean ± SD= 14.61 ± 3.49) and post-test that represented (mean ± SD= 14.76 ± 3.66) with a non-significant effect p-value: 0.256 > 0.05. This result is consistent with the study that revealed a significant improvement in all measures of the study between the pre-test and post-test in the foot massage group (p-value: 0.001 < 0.05[21]. This improvement may be referred to as the positive effect of reflexology on increasing nerve stimulation and blood circulation [21].

Range of Motion Exercise:

The foot ROM pre-test represents (mean ± SD= 15.87 ± 2.27) and the post-test represents (mean ± SD= 14.41 ± 2.66), which showed a significant difference between pre-test and post-test (p 0.000), while the control group showed no positive change between the pre-test that represents (mean ± SD= 14.61 ± 3.49) and post-test that represents (mean ± SD= 14.76 ± 3.66) with a non-significant effect (p-value: 0.256 > 0.05). This study result was consistent with what the study reported. The results of this study showed a significant difference between the pre-test and post-test of the monofilament test in the intervention group (p = 0.000), while no significant difference was observed in the control group (p = 0.50) [13].

The level of DPN by comparing mean in intervention groups with control: Massage pre-test was (mean ± SD 14.31 ± 2.99) and the post-test was (mean ± SD = 11.67 ± 3.36), as well as foot massage groups showed a significant difference between pre-test and post-test that was (p = 0.000), while the control group showed no positive change between pre-test that represents (mean ± SD= 14.61 ± 3.49) and post-test that represents (mean ±SD = 14.76 ± 3.66) with a non-significant effect (p= 0.256). This study result is consistent with the study that indicated the foot massage group demonstrated a significant improvement in all study measures between pre-test and post-test (p=0.001)[21]. According to previous studies, massage therapy can be a non-invasive and non-pharmacological method to provide nursing care for DM patients with DPN [11][23]. In this study, we applied gentle pressure to the feet during foot massage therapy to increase and improve blood flow to body tissues, which supports the optimal function of nerve cells and reduces DPN symptoms. Massage therapy also improves peripheral tissue perfusion by dilating superficial blood vessels and increasing blood flow to peripheral limbs that experience slowed perfusion in diabetic patients with DPN. Additionally, foot massage therapy can stimulate lower extremity sensory pathways and improve the balance of ROM [11][23]. Massaging certain points on the foot helps stimulate the pancreas to produce insulin, which is important in the management of DM. Moreover, foot massage provides a relaxing effect and is popular for its benefits for blood circulation [24]. The circulatory system is responsible for transporting substances, such as oxygen, nutrients, electrolytes, hormones, carbon dioxide, and waste substances, from one part of the body to another, and massage therapy

can affect blood flow throughout the body. The diabetic foot spa can improve blood circulation to peripheral extremities [25].

Also, this study shows there is no significant difference between the foot ROM group in the pre-test and the control group (p = 0.125). In the post-test, there is a significant difference between foot massage and the control group (p = 0.001). On the other hand, there is a non-significant difference in comparing foot ROM with the control group (p = 0.667). The ROM had a non-significant difference with control because this type of exercise may need longer than 2 weeks to clarify the best effect. As a result, many studies that conducted their research involved more than 3 weeks of follow-up, up to 12 weeks. Most of the studies used 8 weeks of follow-up to implement their study programs [26][27][28]. According to the study that used long-term follow-ups of up to 6 months, the maximum period in all the studies [29].

Comparing the effectiveness of foot massage and ROM exercise on the level of DPN: According to the mean rank of TCSS, the most effective intervention was foot massage, which represented the least mean of 2.81; next came foot ROM, with a little difference in mean rank of 4.55. As well, the result shows a relatively large difference of up to double between massage and foot ROM. There is a significant difference among all study groups (foot massage, ROM, and control group) with a p-value of 0.000. Also, there is a little difference in the mean rank between the ROM and the control group.

The study result shows there is a significant relationship between age, duration of being diagnosed with DM, and the massage group that was represented (p = 0.001). On the other hand, there are non-significant correlations among others. This study is consistent with the study that showed a significant difference in age between groups (p = 0.003) but no significant difference in other variables [30]. The biomolecular basis of age-related microvascular dysfunction and chronic diseases that cause peripheral vascular diseases leads to decreased blood flow to the limbs [31]. Massage causes a dynamic change in tissue pressure, increasing capillary flow rate, decreasing blood apparent viscosity, and promoting blood circulation to increase tissue blood flow and remove blood stasis [32].

This study shows there was a significant correlation between ROM group and age (p = 0.042). This result was not consistent with a study that reported no significant difference in age between the intervention and control groups (p = 0.220) [36]. Feet exercises are among the recommended activities for patients with DM, as they can improve blood circulation and prevent injuries, particularly in the lower extremities [33]. The objective of diabetic foot exercises was to improve and strengthen the small, calf, and thigh muscles, overcome joint motion limitations experienced, enhance blood circulation, and improve nutrient transport to tissues for individuals with DM. Therefore, it is critical to explore the impacts of foot exercise and care on peripheral vascular status in patients with DM [34]. The researcher further suggests that this finding may be due to both neuromuscular and mechanical declines that contribute to the age-related loss of joint and muscle strength and function [35].

The correlations and differences among study groups and sociodemographic characteristics. This study found a significant difference between participants sex and the ROM group (p = 0.039). This result is not consistent with the study that revealed that the intervention group did not differ significantly in terms of gender (p = 1.000) [36]. The age-related decline in joints and muscle strength and function affects females more than males, while men spend more time exercising than women [35].

Smoking has a significant difference with the massage group (p= 0.003), and smoking has a significant difference with the ROM group (p = 0.018). Smoking has been linked to an increased risk of DPN in patients with DM and may exacerbate the onset and healing of diabetic foot ulcerations. This is due to the negative effects smoking has on peripheral sensory, autonomic, and motor neuropathy, as well as impaired vasodilation and increased vasoconstriction, which can cause tissue hypoxia and hinder healing. Stress has been found to be a significant risk factor for smoking, and self-massage and resistance exercise training have been proposed as effective adjunct treatments for adults attempting to quit smoking by reducing anxiety, cravings, withdrawal symptoms, and mood [37]. Preliminary evidence also suggests that massage therapy may be beneficial in decreasing tobacco use, and research is needed to determine its effectiveness in pregnant populations [37].

Smoking can have negative effects on blood flow properties by altering certain hematology parameters. This includes increasing hematocrit, whole blood, and plasma viscosity [38]. However, massage can have a positive impact on blood circulation by causing changes in tissue pressure that lead to an increased capillary flow rate and decreased blood viscosity [38]. This promotes blood flow and can help remove blood stasis, leading to increased tissue blood flow [32].

This study results show the other chronic diseases have a significant difference with the massage group (p= 0.001). Diabetic peripheral neuropathy is linked to challenges in managing hypertension in patients with T2DM [39]. Elevated systolic blood pressure is also associated with DPN, even in non-hypertensive patients with diabetes [39]. Self-administered foot reflexology may have a positive impact on T2DM patients with hypertension, as it has been found to lower blood pressure [40]. However, no significant differences were observed among other demographic characteristics or intervention groups [40].

Limitations of the study

Some female patients withdrew from the study due to social or religious norms because massage as well as ROM exercises should expose a part of the body above the knee joint. Some patients did not continue to follow up with the diabetes center, and they also closed the tools of communication at the appointed time for their follow-up.

Conclusion

The result of our study indicates that foot massage and foot ROM exercise therapy have a significant effect on reducing DPN levels. Although foot massage and foot ROM exercise are all supportive care techniques for diabetic patients with DPN, foot massage was more effective than the ROM group at the DPN level. These techniques were found to be more useful as supportive care when considering non-pharmacologic interventions for improving peripheral neuropathy and preventing complications in diabetic patients.

Recommendations and Implications

It is necessary to recommend providing training to nurses and other health care providers for the application of foot massage and ROM exercise to patients and their relatives by evaluating the use of the application in daily life. Scheduling DPN patients for foot massage and ROM exercise sessions in diabetic foot centers three times a week continuously. Patients should be urged in the diabetic centers that these interventions are non-pharmacological, cost-free, and can be done at home, but their benefits are great in preventing the development of DPN and reducing its complications, such as foot ulcers and amputations. Additional studies conducted by taking enough time (more than 2 weeks) and engaging a physiotherapist in

the study are recommended to ensure the effectiveness of foot ROM exercise can be confirmed.

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