**Migration Letters**

Volume: 20, No: S7(2023), pp. 458-469

ISSN: 1741-8984 (Print) ISSN: 1741-8992 (Online)
www.migrationletters.com

# Effectiveness of Foot Massage on Diabetic Patients' Peripheral Neuropathy: A Randomized Controlled Trial

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**Abstract**

*Objective: To determine the effectiveness of foot massage for patients who have diabetic peripheral neuropathy (DPN).*

*Methods: A true experimental study was conducted from November 3, 2022 to May 18, 2023. A probability (simple random) sample of (52) diabetic patients diagnosed with DPN at Al-Hassan Specialized Center for Endocrinology and Diabetes, Karbala, Iraq. The study samples were randomly divided into two groups: Foot massage group which received three sessions per week for two weeks, and the control group that did not receive any intervention. The data collection instrument was the Toronto Clinical Neuropathy score (TCNS). The data were analyzed using SPSS version 26.*

*Results: The decrease in the TCNS level in the intervention group was significant (0.000). In comparison with the control group, there was a significant difference in the foot massage group (0.003) in the post-test. While there was a non-significant difference in comparing the control group in the post-test.*

*Conclusion: Although foot massage is supportive care techniques for diabetic patients with peripheral neuropathy, foot massage was significant effect at the DPN level. This technique has been used to be most useful as supportive care when considering non-pharmacological interventions to improve DPN and prevent complications among diabetes patients.*

***Keywords:*** *Diabetic peripheral neuropathy; DPN; Foot massage; Randomized controlled trial.*

## INTRODUCTION

Diabetes is a metabolic condition that can occur as chronically, characterized by high blood glucose levels [1]. Type-2 diabetes is the most prevalent, typically impacting adults, it occurs when the body develops insulin resistance or is unable to produce enough insulin, and Type-1 diabetes also called (juvenile diabetes) is a chronic condition in which the pancreas does not produce or insufficiently produce insulin for the body [2]. Diabetes mellitus (DM) is one of the most significant health problems; around 425 million people worldwide suffer from diabetes, with the whole number expected to rise to 628 million by 2045 [3]. Prolonged elevation of blood glucose levels can give rise to a range of complications, leading to substantial harm to different bodily regions such as the feet, bones, kidneys, and eyes. These complications are collectively referred to as diabetic complications [4-8]. Neuropathy is a diabetes complication that causes nerve damage throughout the body; approximately half of all diabetic have some form of nerve damage; the most common type of neuropathy is peripheral neuropathy, also known as DPN or

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Diabetic Peripheral Neuropathy [9]. DPN 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 [10]. More than 45% of people with type-2 diabetes and 54% of patients with type-1 diabetes may be asymptomatic [3]. As one of the most common neuropathies of diabetes mellitus, DPN can lead to foot ulceration, amputation, and affect autonomic, motor, and sensory nerve functions [11, 12]. DPN also impacts humanism and economy significantly, 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 [11]. Most people with diabetes can prevent serious foot complications by regular foot care routinely follow up are the best bet for preventing diabetic foot problems [13, 14].

The American Diabetes Association has put forth a declaration stating that diabetes mellitus conditions can be improved and the risks associated with DFU can be decreased through preventive care [15]. Foot massage using reflexology is a known supportive care technique for alleviating physical and emotional symptoms among patients with various diseases [11]. Thai foot massage is a viable alternative treatment for balance performance, ROM of the foot, and the foot sensation in diabetic patients with peripheral neuropathy. In this study, the researcher will evaluate the effectiveness of foot massage for the foot with diabetic peripheral neuropathy [17].

## METHODS

A true experimental study was conducted in order to evaluating the effectiveness of foot massage on level of DPN among diabetic patients who attending to Al-Hassan specialization Center for Endocrinology and Diabetes in Karbala. A simple random sample of (52) diabetic patient was chosen. After the approval of Ethical Research Committee, and Nursing Faculty Council/ Baghdad University, the official agreement was offered by Al-Hassan Specialization Center for Endocrinology and Diabetes, and the patients' written consent (official consent) was received from the study participant. Using Toronto Clinical Neuropathy Score (TCNS) for assessing DPN in Diabetic patient**,** this tool is available and published without copyright**.** A total of (52) patients were included in the data analysis. the study sample was divided into three groups: 25 patients in the foot massage group and 27 patients in the control group. The data collection procedure was starts from November 3, 2022 to May 18, 2023 to meet the study objectives. After knowing that the patient has DPN, applied for experimental study that allocated the samples into two groups, including a group that applied Thai foot massage, and a control group that did not receive any intervention, each sample of intervention group take three sessions per week, continues with in two weeks. 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 [17]. 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 [17]. According to the different thresholds in each individual, each thumb pressure was applied until the participant started to feel some discomfort (below-pressure pain threshold) and maintain 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 [17]. While in control Group did not receive any interventions, just pre-test, and then post-test assessments after two weeks such as other groups, and compared with the other groups of the study. Then patients in all groups were evaluated prior to the intervention (post-test assessment) after two weeks by using the TCNS. Using Statistical Package for Social Science (SPSS) version (26) was used for the analyzing data in the current study. The significance level was at $p < 0.05$, at 80% of the confidence level [18].

## RESULTS

Table (1): Demographic Characteristics among the Study Groups of Participants (Total, Massage, Control)

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

| Rating and intervals | Total | | Massage | | Control | |
|---|---|---|---|---|---|---|
| | **M** | **SD** | **M** | **SD** | **M** | SD |
| **Age** | 54.8 | ±6.4 | 55.1 | ±5.5 | 55.9 | ±6.5 |
| **Duration of Diagnosed with DM** | 16.1 | ± 5.9 | 14.6 | ± 3.8 | 19.1 | ±7.3 |
| **HbA1c Level** | 10.3 | ± 2.3 | 9.8 | ± 1.6 | 10.2 | ±2.2 |
| **BMI** | 29.5 | ± 4.5 | 29.2 | ± 4.7 | 30.1 | ±4.2 |
| | | | | | | |
| | **f.** | **%** | **f.** | **%** | **f.** | % |
| **Gender** | | | | | | |
| Male | 32 | 61.5 | 15 | 60 | 17 | 63 |
| Female | 20 | 38.5 | 10 | 40 | 10 | 37 |
| Total | **52** | **100%** | **25** | **100%** | **27** | 100% |
| **Marital Status** | | | | | | |
| Single | 0 | 0 | 0 | 0 | 0 | 0 |
| Married | 49 | 94.2 | 23 | 92 | 26 | 96.3 |
| Divorced | 0 | 0 | 0 | 0 | 0 | 0 |
| Separated | 3 | 5.8 | 2 | 8 | 1 | 3.7 |
| Widow | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | **52** | **100%** | **25** | **100%** | **27** | 100% |
| **Educational Level** | | | | | | |
| Illiterate | 18 | 34.6 | 11 | 44 | 7 | 25.9 |
| Just read and write | 0 | 0 | 0 | 0 | 0 | 0 |
| Primary School | 28 | 53.9 | 12 | 48 | 16 | 59.3 |
| Secondary School | 3 | 5.8 | 0 | 0 | 3 | 11.1 |
| Preparatory School | 1 | 1.9 | 0 | 0 | 1 | 3.7 |
| Diploma | 0 | 0 | 0 | 0 | 0 | 0 |
| Bachelor | 2 | 3.8 | 2 | 8 | 0 | 0 |
| Postgraduate | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | **52** | **100%** | **25** | **100%** | **27** | 100% |
| **Occupation** | | | | | | |
| Employee | 3 | 5.8 | 2 | 8 | 1 | 3.7 |
| Gainer | 8 | 15.4 | 3 | 12 | 5 | 18.5 |
| Unemployed | 22 | 42.3 | 10 | 40 | 12 | 44.4 |
| Housewife | 18 | 34.6 | 9 | 36 | 9 | 33.3 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Retired | 1 | 1.9 | 1 | 4 | 0 | 0 |
| Student | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | **52** | **100%** | **25** | **100%** | **27** | 100% |
| Continue Table (1) ……. | | | | | | |

| Rating and intervals | Total | | Massage | | Control | |
|---|---|---|---|---|---|---|
| | **f.** | **%** | **f.** | **%** | **f.** | % |
| **Residence** | | | | | | |
| Rural | 16 | 30.8 | 9 | 36 | 7 | 25.9 |
| City | 36 | 69.2 | 16 | 64 | 20 | 74.1 |
| **Total** | **52** | **100%** | **25** | **100%** | **27** | 100% |
| **Other Chronic Diseases** | | | | | | |
| No | 22 | 42.3 | 10 | 40 | 12 | 44.4 |
| HTN | 21 | 40.4 | 13 | 52 | 8 | 29.6 |
| IHD | 0 | 0 | 0 | 0 | 0 | 0 |
| HTN and IHD | 9 | 17.3 | 2 | 8 | 7 | 25.9 |
| HTN, IHD, and Asthma | 0 | 0 | 0 | 0 | 0 | 0 |
| HTN and Arrhythmia | 0 | 0 | 0 | 0 | 0 | 0 |
| HTN, Asthma and Arrhythmia | 0 | 0 | 0 | 0 | 0 | 0 |
| **Smoking** | | | | | | |
| No | 39 | 75 | 19 | 76 | 20 | 74.1 |
| Yes | 13 | 25 | 6 | 24 | 7 | 25.9 |
| **Total** | **52** | **100%** | **25** | **100%** | **27** | 100% |

**f. = Number of frequencies, % = percentage**

Regarding the demographic information in Table 1, show that the mean patient age in the study was (54.8) years with a SD of (± 6.4) years, as well as the large mean of age in the study groups was in control group that represent (55.9) years with (SD ± 6.5) years. The mean duration of being diagnosed with DM was (16.1) years with a SD of (± 5.9) years, while the control group was the large mean among groups that represent (19.1) years with SD (± 7.3) years. The mean HbA1c level was (10.3) with a SD of (± 2.3), the control group was the large mean of HbA1c that represent (10.2) with SD (± 2.2). The mean BMI of study groups that was (29.5) with SD (± 4.5), while the control group was the large BMI was represent (30.1) with SD (± 4.2). The percent of (61.5%) of the study participants were male, and the majority of the patients (94.2%) were married. More than half of the study samples (53.9%) were primary school graduates. Less than half of the female study samples (34.6%) were housewives, while male occupation was unemployed nearly to half that represents (42.3%). The majority of study participants were residents of the city that represented them (69.2%). About (40.4%) of the patients have HTN. Finally, the most of the study participants (75%) were non-smokers.

Table (2): Level of DPN by Groups of Intervention

| Measure | Intervention group | | Mean | SD | t | Sig. |
|---|---|---|---|---|---|---|
| Level of DPN | **Foot Massage** | **Pre-test** | 14.320 | ±2.996 | 12.741 | **0.000** |
| | | **Post-test** | 11.680 | ±3.363 | | |
| | **Control** | **Pre-test** | 14.629 | ±3.498 | - 1.162 | 0.256 |
| | | **Post-test** | 14.777 | ±3.662 | | |

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

Table 2 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 represents 14.320 ± 2.996, and the post-test was 15.880 ± 2.278. The intervention group showed a significant effect for which the p-value was (0.000 < 0.05). While the control group was no positive change between pre-test that represent 14.629 ± 3.498, and post-test that represents 14.777 ± 3.662, with non-significant effect (p-value = 0.256 > 0.05).

Table (3): 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** | **Massage** | 0.26963 | 0.80788 | 0.739 |
| Post-test | **Control** | **Massage** | 3.05778* | 0.87507 | **0.001** |

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

Table 3 shows the level of DPN by comparing mean in intervention group with control group. There is non-significant difference between the massage group in pre-test with control group. In the post-test there is a significant difference between foot massage with control group (p-value = 0.003 < 0.05).

Table (4): Correlation of Some Demographic Variables with Intervention Groups

| Demographics | Bathing Group | Massage Group | Control Group |
|---|---|---|---|
| Age | 0.280 | **0.000** | 0.110 |
| Duration of diagnosed with DM | 0.074 | **0.000** | 0.058 |
| HbA1c Level | 0.052 | 0.101 | 0.181 |
| BMI | 0.112 | 0.256 | 0.094 |

NS: Non-significant at P >0.05, S: Significant at P < 0.05

Table 5 shows there is a significant relationship between age and the massage group that was represented (p-value = 0.000 < 0.05). The duration of being diagnosed with DM shows a significantly positive correlation regarding the foot massage group that represents (p-value = 0.000 < 0.05). On the other hand, there are non-significant correlations among other demographic characteristics and intervention groups.

Table (6): Differences of Some Demographic Variables with Intervention Groups

| Demographics | Massage Group | | | Control Group | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | **value[a]** | **df** | **P-value** | **value[a]** | **df** | **P-value** |
| Gender | 8.47 | 11 | 0.231 | 8.56 | 12 | 0.279 |
| Marital status | 15.94 | 11 | 0.067 | 8.30 | 12 | 0.567 |
| Educational level | 22.02 | 22 | 0.154 | 31.06 | 36 | 0.356 |
| Occupation | 34.176 | 44 | 0.317 | 33.33 | 36 | 0.356 |
| Residence | 12.84 | 11 | 0.212 | 7.73 | 12 | 0.433 |
| Smoking | 11.11 | 11 | **0.029** | 11.20 | 12 | 0.558 |
| Other chronic diseases | 29.28 | 22 | **0.000** | 30.61 | 24 | 0.298 |

Value[a]= Pearson Chi-square, df= degree of freedom, P-value = Probability value, NS: Non-significant at P >0.05, S: Significant at P < 0.05

Table 6 shows differences in some demographic variables between the intervention groups. In this table, there is a significant difference between smoking and massage group (p-value = 0.029 < 0.05), as well as other chronic diseases with massage group (p-value = 0.000 < 0.05). On the other hand, there are non-significant differences among other demographic characteristics and intervention groups.

## DISCUSSION

The data analysis findings showed the distribution of samples according to demographic characteristics, which revealed that the mean total age of intervention group was 55.1 with SD±5.5 years. This result was slightly lower than that the study reported that the mean age of participants was 57.7±6.4 years, another study that showed mean age of the study samples was 67.7 ±7 [17-19]. The majority of patients with diabetic peripheral neuropathy were elderly, with an age above 50 years, as most type 2 diabetes mellitus cases occur between the ages of 36 and 65 years [22]. 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 [23]. The total mean duration of being diagnosed with DM was 16.1 years, with a SD of 5.9 years. Our result was slightly higher than that reported the study's findings revealed that the mean duration of diagnosed with DM among participants was 14.5 ±8.88 years [24]. Patients with diabetic peripheral neuropathy typically experience a longer duration of diabetes, increasing the likelihood of developing neuropathy, which can occur within ten years of a diabetic diagnosis [18].The total mean HbA1c level was 10.3 with a SD of 2.3, the massage group was 9.8 with SD ±1.6, while the control group was 10.2±2.2. Our result was consistent with the study reported the intervention group had a higher HbA1c level 9.3 with SD± 2.9 than the control group 8.2 ± 2.2 [21]. The high HbA1c levels are associated with DPN, as well as a good indicator for the development of DPN in patients with T2DM [25]. The mean BMI of the massage group was 29.2 kg/m$^2$ with a SD ±4.2, The findings of our study were 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 30.1 kg/m$^2$ with a SD ± 4.2. Their

control group also had a higher BMI of 32.04±7.09 kg/m$^2$, consistent with our results [24]. The average BMI of the sample is high since obesity is associated with diabetes and is considered a risk factor for developing it [26].

This study shows the most of study samples were male that represent 61.5%, The findings of this study are not consistent with the study that showed the study participants were female, representing 71.4% of the sample [27]. The result shows the majority of the patients (94.2%) were married. The findings are consistent with the study that found the majority of participants were married, representing 80% of the sample [28]. As the age average of the study samples mean was 54.9 years old, it was expected that most of them were married. More than half of the study samples (53.9%) were primary school graduates. According to the study demonstrated that 52.6% of the sample had completed primary school [29]. More than three quarter of the study sample were housewives or unemployed that represent (76.9%), The findings of this study are consistent with the study that reported the majority of participants were unemployed, comprising 46.4% of the sample [27]. The most of study participants were residents of the city that represented them (69.2%). The findings of our 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 [28].

Also, this table shows the most of study participants have other chronic diseases with DM, which represents 57.7%; about 40.4% of them have HTN. According to study that represent the majority of the study participants had a systemic disease with DM, accounting for 57.9%, while approximately 45% of them had hypertension [29]. 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 ramifications [30, 31]. Approximately three-quarters of the study participants (75%) were non-smokers, and a quarter of the samples (25%) 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 [29]. The foot massage pre-test was (Mean ± SD 14.320 ± 2.996) and the post-test was (Mean ± SD 15.880 ± 2.278), 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 14.629 ± 3.498) and post-test that represented (Mean ± SD 14.777 ± 3.662) 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 [29]. This improvement may be referred to the positive effect of reflexology on increasing nerve stimulation and blood circulation [29].

The level of DPN by comparing mean in intervention group with control group. Massage pre-test was (Mean ± SD 14.320 ± 2.996) and the post-test was (Mean ± SD 15.880 ± 2.278), as well as foot massage groups showed a significant difference between pre-test and post-test that the p-value was (0.000 < 0.05), While the control group was no positive change between pre-test that represent (Mean ± SD 14.629 ± 3.498) and post-test that represents (Mean ± SD 14.777 ± 3.662) with non-significant effect (p-value = 0.256 > 0.05). This study indicated that the foot massage group demonstrated a significant improvement in all study measures between pre-test and post-test, with a p-value of 0.001 < 0.05 [29]. According to previous studies, massage therapy can be a non-invasive and non-pharmacological method to provide nursing care for DM patients with DPN [17, 32]. In our 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 improve peripheral tissue

perfusion by dilating superficial blood vessels and can increasing blood flow to peripheral limbs that experience slowed perfusion in Diabetic patient with DPN. Additionally, foot massage therapy can stimulate lower extremity sensory pathways improve the balance of ROM [17, 32]. Massaging certain points on the foot help to stimulate the pancreas to produce insulin, which is important in the management of DM. Moreover, foot massage provides a relaxation effect and is popular for its benefits for blood circulation [33]. 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 of peripheral extremities [34].

The result shows there is a significant relationship between age, Duration of diagnosed with DM and the massage group that was represented (p-value = 0.000 < 0.05), On the other hand, there are non-significant correlations among other. Our study found results consistent with the study that showed a significant difference in age between groups (p: 0.003 < 0.05), but no significant difference in other variables [35]. The biomolecular basis of age-related microvascular dysfunction and chronic diseases that cause peripheral vascular diseases leads to decreased blood flow to the limbs [36]. 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 [37]. Smoking has significant difference with massage group (p-value = 0.029 < 0.05). 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 improving mood. 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 [38]. Smoking can have negative effects on blood flow properties by altering certain hematology parameters. This includes increasing hematocrit, whole blood, and plasma viscosity [39]. However, massage can have a positive impact on blood circulation by causing changes in tissue pressure that lead to increased capillary flow rate and decreased blood viscosity [39]. This promotes blood flow and can help remove blood stasis, leading to increased tissue blood flow [40].

In our study that the other chronic diseases have significant difference with massage group (p-value = 0.000 < 0.05). DPN is linked to challenges in managing hypertension in patients with T2DM. Elevated systolic blood pressure is also associated with DPN, even in non-hypertensive patients with diabetes [41]. Self-administered foot reflexology may have a positive impact on T2DM patients with hypertension, as it has been found to lower blood pressure [42]. However, no significant differences were observed among other demographic characteristics or intervention group [42].

## LIMITATIONS

Some female patients withdrew from the study due to social or religious norms because massage 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 therapy has a significant effect on reducing of DPN level. Foot massage was significant effectiveness at the DPN level among patients with T2DM. 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 such as foot ulcers and amputation.

## RECOMMENDATIONS

It is necessary to recommended for provide training to nurses and other health care providers for the application foot Massage to patients and their relatives by evaluating the using of the application in daily life. Applying a foot massage in diabetic foot centers three times a week. Diabetic patients should be urged in the diabetic centers that these interventions are non-pharmacological, free of cost, and can be done at home, but their benefits are great in preventing the progression of peripheral neuropathy and reducing its complications such as foot ulcers and amputation.

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