Effect of Aromatherapy Massage with Chamomile Oil versus Lavender Oil on Neuropathic Pain and Quality of Life in Diabetic Patients: randomized controlled clinical trial

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Abstract

Background: Diabetic peripheral neuropathy is a common consequence of diabetes. Inadequate pain control in diabetic neuropathy affects patients' quality of life. Aromatherapy has been documented as a safe form of pain relief. **Objective**: investigate the effect of aromatherapy massage with chamomile versus lavender essential oils on diabetes patients' neuropathic pain and quality of life. **Method**: the study was conducted at Alexandria's main university hospital, Egypt. This study comprised a random ample random 120 adults patients were randomized to the study groups at an equal ratio. Over the course of four weeks, three times each week, the intervention groups received either lavender or chamomile aromatherapy massage. Over a period of 6 months, starting from October 2022, the Visual Analog Scale was used for pain assessment and the Neuropathic Pain Effect on Quality-of-Life Questionnaire as a disease specific quality of life assessment tool. **Results**: A total of 115 participants was analyzed .The massage with lavender oil or chamomile oil showed a significant decrease in the pain intensity after two and four weeks as compared to the control ($p<0.01$). In addition, within the groups, the comparison showed a significant effect in the lavender and chamomile groups and no significant within the control group. Furthermore, the intervention groups had a superior improvement in quality of life after four weeks as matched to the control group. **Conclusions**: Lavender or chamomile oil massage is an effective, safe, and simple nursing intervention for pain management and improving diabetic patients' quality of life and painful neuropathy.

Keywords: Pain, Nursing Care, Aromatherapy, Massage, Chamomile, essential oil, lavender, neuropathic pain, diabetic patients, neuropathy, quality of life.

Introduction

Diabetes is an important healthcare problem at alarming levels, with nearly half a billion people diagnosed on a worldwide scale **(Forouhi & Wareham, 2019).** Although there were 463 million known diabetics in 2019, it is projected to reach 578 million by 2030 and close to 700 million by 2045, an increase of 51% **(Cicek & Sendur, 2021).** Diabetes is one of the most common chronic diseases, increases direct medical costs, causes early mortality with complications such as cardiovascular system diseases, renal failure, extremity amputations, vision loss, and nerve damage, and/or causes great economic losses for individuals, families, healthcare systems, and national economies**(Almdal et al., 2014; Deshpande et al., 2008).**

One of the most common diabetic consequences is a series of clinical symptoms brought on by impairment of the peripheral and/or autonomic nervous systems. These diseases, which are also known as various types of neuropathy, affect the nervous system in up to 50% of diabetics and are brought on by widespread and localized nerve injury**(B. C. Callaghan et al., 2015).** One of the most prevalent and painful microvascular consequences is diabetic peripheral neuropathy (DPN) (Feldman et al., 2019). This pathology is present in around 10% of diabetes at the time of diagnosis (Sarfo-Kantanka et al., 2019). DPN has a significant impact on patients by causing falls, increasing pain, and decreasing quality of

life (QoL) (**Pop-Busui et al., 2017)**. Diabetes neuropathy is expected to develop in around 90% of diabetes patients within the next twenty years, and it frequently results in impairment **(Kapoor et al., 2017).**

Medical treatment, lifestyle modifications, and complementary therapies are utilized to enhance the management process and quality of life for diabetes patients because managing their disease is a challenging and complex process (**Khawandanah, 2019;** Şahin et al., 2019). Complementary and alternative therapies are progressively used by nurses in many treatment centers because they are secure, inexpensive, simple, and have little side effect (**Burns et al., 2007; Maddocks-Jennings & Wilkinson, 2004)**. Among the most frequently utilized complementary and alternative therapies are massage therapy and aromatherapy. As a well-known traditional treatment, massage therapy is increasing in popularity since it improves health and well-being **(Moyer et al., 2004).**

Aromatherapy is the use of essential oils taken from herbal sources via diverse approaches to treat illnesses and improve the physical, spiritual, and mental well-being. In aromatherapy, these oils are applied through compress, inhalation, bathing , and massage (**Ali et al., 2015)**. The use of essential oils via massage is a considerably common form of aromatherapy **(Manion & Widder, 2017).** These oils can be derived from various plant parts, such as stems, flowers, and leaves **(Ali et al., 2015).**

Because of the high density of these oils, they are diluted in vegetable oils, also known as carrier oils, before usage. Lavender, chamomile, eucalyptus, marjoram, jasmine, geranium, mint, and rosemary, are the most commonly used essential oils in aromatherapy. Lavender *(Lavandula angustifolia)*, which belongs to the family of Lamiaceae, is most commonly used. In addition to its bacteriostatic and fungistatic properties, lavender is recognized to have beneficial effects on a variety of conditions such as sleeplessness, burns, pain, stress, anxiety, agitation, and demanding behaviors. Lavender also has no known negative effects **(Hashemi et al., 2015).**

Roman chamomile (**Anthemis nobilis Linn**) which belongs to the Asteracea family, is a precious plant with the opportunity to calm, moderate, and a strong emotion. Chamomile products are now being used to treat a variety of human problems, including hay fever, inflammation, muscle spasms, menstrual disorders, ulcers, sleeplessness, gastrointestinal disorders, wounds, hemorrhoids, and rheumatic pain **(Srivastava et al., 2010).** In addition to its anti-anxiety and stress-relieving properties, it eases depression, worry, and an overactive mind. It is widely used in aromatherapy to treat pain from physical problems, tension, and menstrual cramps by applying it to the lower belly. It has been used to treat eczema, psoriasis, boils, cold sores , and sunburn, as well as to relieve pain from stings, arthritis, and sprains (**Setzer, 2009)**.

There is no contradiction but there is Factors involved may affect product management, ingredients, excessive use or inappropriate use, sensitization/anaphylaxis, and lack of scientific evidence. It is wise to know the adverse effects along with their uses. Some of the studies have shown additional side effects of lavender essential oils like contact dermatitis, acute eczema, and facial dermatitis allergic reaction

Significance of study:

Diabetes mellitus (DM) is an important global health issue. Around 425 million people worldwide are suffering from this disease, and this number is expected to rise to 628 million people by 2045(Yovera-Aldana et al., 2021). Among the complementary and supportive practices used by diabetic individuals, there are cognitive-behavioral approaches, manipulative approaches, energy approaches, alternative medical systems, and biological approaches. One of the most frequently used and most popular practices in biological approaches of complementary and supportive practices is aromatherapy, which is a non-pharmacological application that can be safely applied by nurses

and transferred to clinic. Aromatherapy helps to alleviate health problems and improve quality of life as an inexpensive and non-invasive method(Cicek & Sendur, 2021).

Aromatherapy has numerous therapeutic applications in physical, emotional, and mental disorders (S**ánchez-Vidaña et al., 2017)**. Many essential oils used in aromatherapy have antibacterial, anti-inflammatory, anti-stress, anti-depressive, and immune-boosting properties. In DPN, inadequate pain management reduces patients' QoL; hence, pain control is critical. **(Van Acker et al., 2009).** There are limited clinical studies on the influence of lavender oil on painful diabetic neuropathy; in addition, the absolute effect of chamomile oil on this population has not been evaluated yet.

Aim of the study

This study aimed to assess the efficacy of an aromatherapy message including chamomile essential oil vs. lavender essential oil on neuropathic pain and QoL in diabetes patients as compared to a control group.

Research hypotheses:

H1: participants in the lavender group (LG) and chamomile group (ChG) will experience a higher reduction in pain than participants in the control group (CG).

H2: Participants in the LG and ChG will have better improvement in QoL than participants in the CG.

Methods

Study Design and Setting

A three-arm, open-lab, randomized clinical trial was conducted at the diabetic outpatient clinics of the Main Alexandria University Hospital in Alexandria, Egypt. These clinics provide diagnostic, management and referral services to Alexandria and surrounding governorates. The study was conducted and reported in accordance with the f Multi-Arm Parallel-Group Randomized trial: Extension of the Consolidated Standards of Reporting Trials CONSORT 2010 Statement**(Schulz et al., 2010)**.

Participants and Sampling

A simple random sampling was used to recruit the required number of participants. Initially 186 diabetic patients with painful diabetic neuropathy were screened for eligibility. Of these, 54 were omitted because they did not match the inclusion requirements, and 12 refused to participate. The remaining 120 patients were randomly assigned to study groups LG, ChG, or CG based on a randomization sequence that was generated using an online randomizer **(*Research Randomizer*, n.d.).**

Following the groups' assignment, two patients in the LG did not attend the appointment due to difficulty getting to the hospital. Three patients (LC, n = 2; and ChG, n = 1) declined to continue in the study and did not disclose any reasons. Thus, 115 patients (LG, n = 36; ChG, n = 39; and CG, n = 40) completed the trial protocol (see Figure 1).

Inclusion criteria:

- Age ≥ 18 years
- Agree to participate in the study.

Exclusion criteria:

- Wounds on the hands or feet, or recent surgery
- Inflammation, ulceration, or blood coagulation disorders
- Peripheral vascular disease
- Pregnancy
- Essential oil allergies
- Usage of aromatherapy or other complementary therapies two weeks before the study or during the study period
- Neuropathic pain on the visual analogue scale (VAS) ≤ or Douleur Neuropathic 4 questionnaire (DN4) score < 3 points.
- Known or confirmed vitamin b deficiency
- Other causes of neuropathic pain.

Sample size calculation

As estimated by Gpower software (version 3.1.9.7), 99 participants will be needed for a 0.05 type 1 error rate and 80% power, with an effect size of 0.0625. The sample size was increased to 120 participants to overcome

the potential dropout rate. Forty participants were assigned to each group.

Tools of the study

Three tools were used for data collection in addition, the Douleur Neuropathic 4 questionnaire (DN4) was used as a screening tool for participant eligibility.

Tool 1: Patients' bio-socio-demographic Characteristics

A form was developed by the researchers for gathering the socio-demographic characteristics (age, gender, and occupation) and clinical data (type and duration of diabetes, current treatment protocol, comorbid diseases, HbA1c level, current use of medication for neuropathy, daytime of intense pain, etc.). These data was gathered through the patient's interview and the review of the patient's medical records.

Tool 2: Douleur Neuropathic 4 questionnaire (DN4)

The DN4 questionnaire consists of four questions and ten neuropathic pain-related items. Two of the questions are dependent on the patient interview, while the other two on the clinical examination. For a total possible score of 10, each question is scored "yes" or "no," with yes receiving a 1 and no receiving a 0. Neuropathic pain was classified as having a cut-off value of 4 points (Bouhassira et al., 2005). DN4 is reliable (α=0.97), sensitive (95%) and specific (96%) measure in identifying neuropathic pain **(Unal-Cevik et al., 2010).**

Tool 3: Visual analog scale (VAS)

It is one of the most widely used self-administered questionnaires for assessing pain severity. Patients were instructed to make a mark on the line at a point that related to the intensity of discomfort they were experiencing at the time. Then pain intensity is graded from zero (no pain) to ten (the worst possible pain) **(Price et al., 1983)**.

Tool 4: Neuropathic Pain Impact on Quality-of-Life Questionnaire (NePIQoL)

This tool was developed by **Poole et al.(2009).** It is a self-reported scale designed to evaluate neuropathic pain and its influence on quality of life. It has 42 questions divided into six categories: personal care, psychological, physical, symptoms, work or social activity, and relationships. The NePIQoL score ranges from 42 to 210. The high score reflects an improved quality of life.

Tools validity and reliability

The tools (NePIQoL and VAS) were translated into Arabic by two separate translators then translated the Arabic version again into English. A team of five experts in medical-surgical nursing tested it for face and content validity to ensure correctness and relevance, and the suggested changes were applied. The NePIQoL and VAS was tested for internal consistency using test – retest reliability with Cronbach's alpha (α=0.848), and (α=0.82) respectively

Preparatory phase:

Administrative approval

A permission letter was directed from the faculty of nursing, Alexandria University to the main university hospital administrative authorities. The hospital administrative authorities granted permission to perform the study.

Ethical Considerations

Before beginning the study, the study protocol was approved by the Research Ethics Committee, Faculty of Nursing, Alexandria University, Egypt (IRB00013620, SN: 2022-9-42) After explaining the purpose of the study, each study participant provided written informed consent. Participants' data was kept confidential, and the privacy of the study participants was maintained. The participants were advised that their participation was voluntary, and they could withdraw from the study at any time.

Essential oils preparation

Chamomile and lavender were obtained from the faculty of agriculture and prepared at the faculty of pharmacy at Alexandria University. They were prepared by collecting freshly picked flowers and exposing them to hydrodistillation in a Clevengers apparatus for

3 hours for the extraction of the volatile oil. The oils were dried over anhydrous sodium sulphate. The coconut oil was used as carrier oil. The prepared oils were kept in dark-colored, glass, light-proof bottles and stored in a refrigerator at 4C. The oils were removed from the refrigerator 30 minutes before they were used to reach room temperature.

Pilot study

Before beginning the main study, a pilot study with 12 participants was conducted to determine its clarity, feasibility, and usefulness. No modification based on the pilot were required. These participants were not included in the actual study.

Field Work

The researcher collected the data two days a week 6 months, between October 2022 and March 2023. Recruited participants were invited to a separate room that is quiet and ventilated at outpatient clinics.

During the initial interview with the participants, baseline data was gathered using the patients' socio-demographic characteristics and clinical data, VAS, and NePIQoL. Following the baseline assessment, the intervention protocols were applied to the LG and the ChG. Participants were re-evaluated at week 2 using the VAS and at week 4 using the VAS and NePIQoL.

Essential oil Massage protocol (intervention groups)

Each participant in the intervention groups received the same massage protocol: 12 sessions in the form of three sessions a week for four weeks. The massage was done by rubbing 5 ml of treatment oils.

- For a foot massage, the patient was seated in the supine position, and the researcher sat on a chair opposite the patient's feet. Rubbing with the oil was performed from the toes to the ankle.
- For hand massage, the researcher and the participant were set face-to-face. Massage was started from the palm towards the wrist, beginning at the dorsal surface.

Each treatment lasted between 20 and 30 minutes, depending on the body part affected. Patients were allowed to continue their medications as long as they had been on stable doses for at least 30 days since entering the study.

Control group

The control group received the routine care, which is the use of analgesics for pain control.

Statistical Analysis

IBM SPSS version 22.0 was used to analyze the data. The Shapiro-Wilk test was used to validate the normality assumption. Frequencies and percentages were computed for categorical variables. For parametric variables such as age and diabetes duration, the mean and standard deviation (SD) were calculated. The median, 25th, and 75th quartiles were determined for abnormally distributed data such as the VAS, NePIQoL, BMI, and HbA1c level scores. The Fisher exact test was used to compare the baseline qualitative variables between the study groups. The Kruskal-Wallis test was used to compare the BMI, HbA1c, VAS, and NePIQoL scores between the study groups. The Friedman's test was used to examine how the VAS and NePIQoL ratings changed between the study groups over time. If the Kruskal-Wallis or Friedman tests revealed statistical significance, the Bonferroni adjustment technique was applied for multiple comparisons. The statistical significance level was set at $p < 0.05$ for all tests.

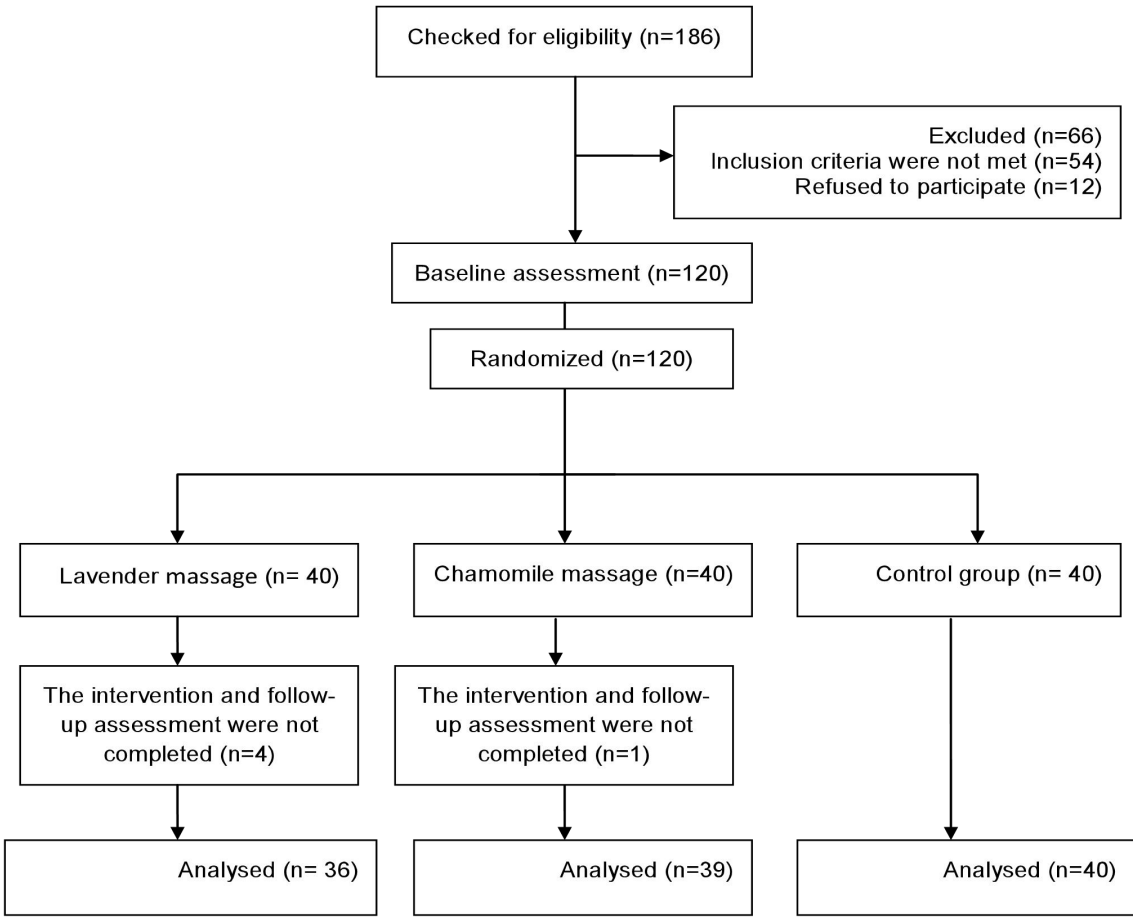

Figure 1: Flow diagram of the Study

Results

Bio-socio-demographic Characteristics of the Study Participants

Data from **Table 1** shows that the LG had a mean age of 48.44 ±11.58, the ChG had a mean age of 42.69 ±15.17, and the CG had a mean age of 43.47±14.11. More than half of the LG and ChG participants, and half of the CG participants, were male. When clinical characteristics were assessed, it was discovered that more than half of the participants in each group had insulin-dependent diabetes mellitus. For the LG, ChG, and CG, the mean diabetes duration was 18.75 ± 7.0 years, 18.64 ± 7.25 years, and 18.8 ± 7.51 years, respectively. In three groups, more than half of the participants were using insulin. Also, the majority of participants in the study groups had at least one comorbid condition.

Additionally, **Table 1** shows that the LG, ChG, and CG had median HbA1c values of 7.65%, 7.6%, and 7.51%, respectively. In all groups, more than half of the patients (LG = 58.3%, ChG = 71.8%, and CG = 70.0%) had neuropathic pain symptoms in their hands. The majority of patients in three groups (LG = 77.8%, ChG = 87.2%, and CG = 77.5%) stated that no neuropathic pain medication had been taken. Regarding the smoking status, approximately half of the ChG and the CG were active smokers, and 47.2% of the LG were non-smokers. For the LG, ChG, and CG, the median BMI was 28.29, 38.39, and 27.69, respectively. Furthermore, no statistically significant

differences in socio-demographic and clinical data were found across the groups ($p > 0.05$).

Effect of aromatherapy massage on neuropathic pain: within and between groups' comparisons

According to **Table 2**, the LG's median VAS scores were 6.0 at baseline, 4.0 at weeks 2, and 3.0 at week 4. The ChG had baseline values of 6.0 and 3.0 at weeks 2 and 4. The CG had a baseline of 7.0, a week 2 of 6.0, and a week 4 of 6. At the baseline, comparisons of median VAS scores among the study groups found no statistically significant variations in the median pain scores among the study groups. When compared to the CG at weeks 2 and 4, there was a significant reduction in pain severity in both the LG and ChG.

When comparing VAS median scores within study groups, while there is a substantial time impact in both the LG and ChG, there is statistically insignificant change in the CG across time. As a result, compared to the baseline and week 2, the VAS score in the intervention groups was significantly better in week 4 (**Table 2**, $p < 0.01$).

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Effect of aromatherapy massage on the Quality of Life score: within and between groups' comparisons

The LG's median QoL scores were 110 at baseline and 117 at week 4. The ChG had baseline scores of 111 and 119 at week 4. The baseline for the CG was 108, with a 109 median score at week 4. There were no statistically significant variations in the three research groups' baseline QoL scores. At weeks 2 and 4, both the LG and ChG had significantly decreased QoL scores compared to the CG ($p < 0.01$), but not between the LG and ChG (Table 3).

In comparing the QoL score within the study groups, there were statistically significant differences between the scores measured at the baseline and week 4 in the LG and the ChG. However, no statistically significant difference existed within the CG (Table 3, $p < 0.01$).

Adverse Effects of Aromatherapy Massage

During the trial, no adverse effects from chamomile or lavender were identified by the researchers. Furthermore, no adverse effects were reported by the patients during the treatment period

Table 1: Socio-demographic and Clinical Characteristics of the study Participants

Characteristics	LG (n=36)		Ch G (n=39)		CG (n=40)		Test statistic	p
Age (X ± *SD*)	48.44±11.58		42.69 ±15.17		43.47 ±14.11		1.903 a	0.154
	n	**%**	**n**	**%**	**n**	**%**		
Gender								
Female	14	38.9	16	41.0	20	50.0	1.098[b]	0.595
Male	22	61.1	23	59.0	20	50.0		
Occupation								
Housewife	1	2.8	3	7.7	0	0		
hand work	14	38.9	24	61.5	17	42.5	9.569 [b]	0.111
Employed	16	44.4	10	25.6	19	47.5		
Did not work or retired	5	13.9	2	5.1	4	10.0		
Type of diabetes								
IDDM	19	52.8	24	61.5	22	55.0	0.665 [b]	0.749
NIDDM	17	47.2	15	38.5	18	45.0		
Diabetes duration (X ± *SD*)	18.75 (7.0)		18.46 (7.25)		18.8 (7.51)		0.25[a]	0.975
Current treatment protocol								
Only OADs	9	25.0	8	20.5	4	10.0		
Only Insulin	24	66.7	26	66.7	23	57.5	9.231 [b]	0.052
OADs and Insulin	3	8.3	5	12.8	13	32.5		
Co-morbidity								
Yes	28	77.8	26	66.7	25	62.5	2.182 [b]	0.349
No	8	22.2	13	33.3	15	37.5		
HbA1c value Median, (Q1-Q3)	7.65 (7.23-7.99)		7.6 (6.9-7.9)		7.51 (6.88-8.2)		0.49 [c]	0.794
Site of neuropathic pain								
Hand	21	58.3	28	71.8	28	70.0		
Feet	3	8.3	1	2.6	4	10.0	3.65 [b]	0.448
Hand and feet	12	33.3	10	25.6	8	20.0		
Day time of intense pain								
Early morning	16	44.4	14	35.9	13	32.5		
Afternoon	8	22.2	19	48.7	12	30.0	8.655 [b]	0.069
Night	12	33.3	6	15.4	15	37.5		
Use of medication for neuropathic pain								
Yes	8	22.2	5	12.8	9	22.5	1.575 [b]	0.483
No	28	77.8	34	87.2	31	77.5		
Smoking status								
Active smoker	10	27.8	22	56.4	21	52.5		
Non-smoker	17	47.2	11	28.2	13	32.5	7.314 [b]	0.118
Quitter	9	25.0	6	15.4	6	15.0		
Body mass index Median, Q1-Q3)	28.29 (24.4-32.15)		38.39 (25.53-30.84)		27.697 (25.35-29.41)		0.49 [c]	0.783

LG: Lavender group, **ChG:** Chamomile group, **CG**: Control group, IDDM: insulin dependent diabetes mellitus, NIDDM: non- insulin dependent diabetes mellitus [a] One-way ANOVA, [b] Fisher exact test, [c] Kruskal Wallis Test, level of significance $p \leq 0.05$.

Table 2: Effects of Aromatherapy Massage on Neuropathic Pain Severity

Measurement time	LG (*n*=36)	ChG (n=39)	CG (n=40)	Test statistica	*p*	Difference[b]
	Median (Q1-Q3)	Median (Q1-Q3)	Median (Q1-Q3)			
Baseline	6.0 (5.0-7.0)	6.0 (5.0-7.0)	7.0 (5.0-7.0)	3.358	0.187	-
Week 2	4.0 (3.0-4.0)	3.0 (3.0-5.0)	6.0 (5.0-7.0)	57.639	**0.00**	LG-CG, ChG-CG
Week 4	3.0 (3.0-3.75)	3.0 (2.0-3.0)	6.5 (5.0-7.0)	71.965	**0.00**	LG-CG, ChG-CG
Test statistic[c]	-66.157	-71.41	-5.167			
P	**0.00**	**0.00**	0.076	-	-	-
Difference	**Test statistic[d], p**					
T0-T1	Z=5.223,p=0.00	Z=5.553,p=0.00				
T0-T2	Z=5.302,p=0.00	Z=5.478,p=0.00	-	-	-	-
T1-T2	Z=4.064,p=0.00	Z=3.929,p=0.00				

LG: Lavender group, **ChG:** Chamomile group, **CG**: Control group $\mathbf{T_0}$: Baseline, $\mathbf{T_1}$: Week 2, $\mathbf{T_2}$: Week 4,[a] Kruskal Wallis Test, [b]Mann Whitney *U* Test with Bonferroni correction, [c] Friedman Test, [d]Wilcoxon Signed Rank Test with Bonferroni correction, level of significance $p \leq 0.05$.

Table 3: Effects of Aromatherapy Massage on the Quality of Life score

Measurement time	LG (*n*=36)	ChG (n=39)	CG (n=40)	Test statistic[a]	*p*	Difference[b]
	Median (Q1-Q3)	Median (Q1-Q3)	Median (Q1-Q3)			
Baseline	110 (106-115)	111 (106-115)	108 (105-114.7)	0.795	0.672	-
Week 4	117 (115-125)	119 (114-124)	109 (106-114)	33.245	0.00	LG-CG, ChG-CG
Test statistic[c]	-5.235	-5.119	-1.167	-	-	-
P	**0.00**	0.00	0.243			

LG: Lavender group, **ChG:** Chamomile group, **CG**: Control group, [a] Kruskal Wallis Test, [b]Mann Whitney *U* Test with Bonferroni correction, [c]Wilcoxon Signed Rank Test, level of significance $p \leq 0.05$.

Discussion

This randomized, open-lab study aimed to compare the efficacy of aromatherapy massage with chamomile or lavender essential oils on diabetes patients' neuropathic pain and quality of life. The study result proved the effectiveness of both the massage with lavender and the massage with chamomile oil in decreasing the mean pain score at 2 and 4 weeks of follow-up, while no improvement was reported in the control group, thus the study hypotheses were accepted.

These effects can be explained by the synergic effects of both aromatherapy and massage. Massage improves parasympathetic activity while decreasing cortisol levels. It also reduces nerve irritation while raising dopamine and serotonin levels, resulting in relaxation **(Rafii et al., 2019).**

Aromatherapy massage involves the absorption of aromatic oils into the bloodstream through the skin, influencing the limbic system to produce therapeutic effects such as antispasmodic, sedative, and anti-inflammatory effects **(Rafii et al., 2019).** Linalool and linalyl acetate, the components of the lavender herbal, have been documented as parasympathetic nervous system stimulant. Linalool is recognized as a sedative, whilst linalyl acetate

is classified as a narcotic **(Wotman et al., 2017).** Chamomile also has anti-inflammatory and analgesic properties due to the chamazulene component **(Sah et al., 2022).**

These findings are consistent with prior research on the effect of aromatherapy on neuropathic pain. **Rivaz et al. (2021)** reported the efficiency of lavender oil on pain intensity in DPN after the second and fourth weeks. **Gok Metin et al. (2017)** reported that a combination of five aromas (chamomile, lavender, geranium, rosemary, and eucalyptus,) was effective in reducing uncomfortable DPN after 4 weeks; however, these combinations had an insignificant effect at the 2-week follow-up.

Moreover, according to **Heydari et al. (2016)**, for three months, a topical therapy of Citrullus colocynthis taken twice daily resulted in less pain in DPN. Likewise, **Mohammed et al. (2019)** verified that after the second and fourth weeks, applying a mixture of the three aromas (eucalyptus, lavender and rosemary) decreased neuropathy pain in diabetes. Similarly, z**gu et al. (2019)** showed that a mix of chamomile, mint, and rosemary had a beneficial effect on chemotherapy-induced painful neuropathy in cancer patients for six weeks.

Various studies have reported the effectiveness of aromatherapy, including chamomile and lavender oils, in reducing pain intensity in diverse patient populations. According to **Shoara et al. (2015)**, topical application of chamomile oil can reduce analgesic demand in patients with knee osteoarthritis. In a randomized cross-over study, **Zargaran et al. (2018)** reported that rubbing oleogel chamomile in the forehead and temporal areas, as well as behind the ears, resulted in a significant reduction of migraine without aura after 30 minutes of application. Additionally, the finding is supported by **Abolfazli et al. (2021) and Shirzad-Siboni et al. (2022),** who reported that chamomile oil application reduced the severity of low back pain. Furthermore, chamomile was effective in improving the functional status and decreasing the symptoms' severity in patients with mild, moderate **(Hashempur et al., 2017)**, and severe **(Hashempur et al., 2015)** carpal tunnel syndrome.

Diabetes neuropathy has a substantial impact on QoL. Indeed, diabetic neuropathy patients have lower QoL than non-neuropathic persons, and this difference began years before and was maintained for years following their neuropathy diagnosis **(B. Callaghan et al., 2015)**. Furthermore, painful diabetic neuropathy is especially detrimental to QoL **(Van Acker et al., 2009)**.

The findings of this study proved the effectiveness of the massage with chamomile or lavender oil applied three times a week for four weeks in increasing the QoL of patients with painful DPN as compared to the control . These findings are in concurrence with the findings reported by **Rivaz et al. (2021)** and **Gok Metin et al. (2017)**, who reported that aromatherapy massage resulted in a significant increase in QoL in diabetic patients at four weeks of follow-up. In diabetic patients, **Nasiri Lari et al. (2020)** reported that inhalation of lavender helped reduce sleeplessness and improve QoL. Furthermore, a study investigated the effects of massage or aromatherapy massage and concluded that the latter improved QoL levels in breast cancer patients **(Ovayolu et al., 2014)**. Additional study investigating the benefits of massage and relaxation therapies on type 2 diabetics found that the former improved QoL **(Wändell et al., 2012)**.

Conclusion and Recommendations

Based on the study findings, it was concluded that both lavender and chamomile aromatic oil massage can be used to alleviate painful DPN. It was also determined that massage with these oils improves the QoL of patients with painful DPN. Considering the harmful effects of neuropathic pain on the health and QoL of patients with DM, the side effects of the frequently used anti-inflammatory drugs (corticosteroids) and analgesics (NSAIDs), and the nurses' fundamental role in alleviating pain and enhancing the QoL of these

patients. It is recommended that this simple and safe nursing intervention can be applied to manage neuropathic pain in this population. More research is needed comparing the effects of these oils over a longer period to evaluate the sustainability of their effects. In addition, comparing these oils with other aromatic oils is needed when considering different routes, such as inhalation.

Study strengths and limitations

The main strength of this randomized controlled design is its capacity to control for nonspecific therapeutic effects using the control group. This study has several drawbacks as well. First, there was a lack of blinding, which might have resulted in bias, as well as the subjective self-report character of the outcome measures.

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