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Effect of Aromatherapy Massage on Neuropathic Pain Among Patients with Type II Diabetes Mellitus

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Abstract: **Background: Neuropathic pain is complex symptom to cope with; it has strong impact on patient life. Its treatment needs combining pharmacological and nonpharmacologic therapies. Aim: Was to evaluate the effect of using aromatherapy massage on neuropathic pain among patients with type II diabetes mellitus. Hypotheses; H_1: The study group who will receive aromatherapy massage will have less neuropathic pain component mean scores than control group who receive only conventional treatment among type II diabetic patients. H_2: The study group who will receive aromatherapy massage will have less neuropathic pain quality mean scores than control group who receive only conventional treatment among type II diabetic patients. Setting: Was conducted at the medical inpatient wards and the outpatient clinic of Diabetes and Endocrine disorders at Kasr EL-Aini Hospital-Cairo University Hospital. Sample: Convenient sample of 60 diabetic patients over consecutive six months. Design: Quasi experimental design simple interrupted time series pre-post-test nonequivalent control group design. Tools: Demographic and medical data form, Douleur Neuropathique Questionnaire, Pain DETECT questionnaire and Neuropathic Pain Questionnaire. Results: The study found that 30 % of both study and control group their age was 60≤70 with mean of age (51.3 ± 11.3) and (55.7 ± 7.9) years respectively. Among study group: There was marked reduction in neuropathic pain components and qualities mean scores after 2nd and 4th weeks of the intervention. Conclusion: Aromatherapy massage is an effective nursing intervention to reduce neuropathic pain among type II diabetic patients. Recommendation: Aromatherapy massage should be included in the nursing management plan among diabetic patients.**

Keywords: **Aromatherapy, diabetes mellitus, massage, neuropathic pain.**

I. INTRODUCTION

Recently, diabetes mellitus (DM) is one of the most prevalent disorders all over the world. According to the International Diabetes Federation (IDF), it was estimated that in 2017 there were 451 million their age ranged between 18–99 years old worldwide(Andrade-Cetto, Cruz, Cabello-Hernández & Cárdenas-Vázquez, 2019). Indeed, Type II DM complications have been increased over the two past decades. These complications are divided into: macrovascular complications; which include major problems as cardiovascular diseases…etc; while the microvascular complications as; retinopathy, nephropathy and neuropathy disorders (World Health Organization, 2016).

Painful diabetic neuropathy is present in up to 25% of diabetic patients (McDonnell et al., 2018).Patients may describe neuropathic pain symptoms as: tingling, prickling, burning, stabbing, pins and needles or electric pain. Also, symptoms as: diminished sensations, allodynia and hyperalgesia may be present. Currently pharmacotherapy is typically limited to intensive glycemic control and symptomatic treatment (Zilliox, 2017).

In fact, pharmacological therapies lead to tremendous adverse effects such as: dizziness, fatigue, ataxia, nausea, vomiting, and delirium….etc. In addition to its high cost (Mu, Weinberg, Moulin & Clarke, 2017). That is why, additional treatment modalities are recommended to be used with complications associated with DM. Dietary supplements, acupuncture, massage, and aromatherapy are the most common used by diabetic patients worldwide (Rhee, Westberg & Harris, 2018). Indeed, aromatherapy as a Complementary Medicine (CM) is very effective therapy for pain management and there are many different types of essential oils used for analgesia, antimicrobial, and antidepressant properties such as: tea tree, lavender, rosemary, eucalyptus…..etc (Jopke, Sanders& White-Traut, 2017). Obviously, combining aromatherapy with different massage techniques increase the efficacy of neuropathic pain management (Vaughan & Carver, 2019). Classical massage consists of following techniques: *effleurage;* defines as gentle movement over the skin, *petrissage;* means squeezing of tissues in a kneading motion, *friction;* is penetrating pressure; applied by the fingertips and *tapotement;* known as strike the tissues rapidly (Bervoets, Luijsterburg, Alessie, Buijs & Verhagen, 2015).

According to the American Holistic Nurses Association (AHNA) it is expected that the nurse integrates principles and techniques of conventional and complementary practices such as: massage, acupressure, herbal and aromatherapy….etc. which considers within the scope of nursing practice in order to achieve holistic and integrative nursing care (AHNA, 2016). Thus, it was important to conduct such a study to evaluate the effect of using aromatherapy massage on neuropathic pain among patients with type II DM.

Significance of the study

The International Diabetes Federation (2017) reported that the number of people affected by type II diabetes in Africa is expected to rise from 14.2 million 34.2 million by 2040. Actually, Egypt is the 8th of the top 10 countries for the number of patients with type II DM, there are 8.2 million predicted to double to 16.7 million by 2045 (Khalil et al., 2018). In fact, the worldwide trend for use of complementary medicine in DM which has been increased with prevalence ranging between 30-57% (Candar, Demirci, Baran& Akpınar, 2018). Considering using complementary medicine by type II diabetic patients is growing with prevalence ranging between 17.0 to 72.8% (Yıldırım & Marakoğlu, 2018).

Therefore, this study by using techniques of CM expected to be useful for nursing regarding how to apply aromatherapy massage to decrease diabetic patients' neuropathic pain. In addition, it is hoped that, this study will generate attention for further researches in this area. Also, provides nurses with a wide base of knowledge, skills and attitude regarding safe and effective use of CM. As well as, widen the scope of nursing practice and adding different techniques of CM to the basic nursing curriculum and nursing programmes. The main aim of the current study is to evaluate the effect of aromatherapy massage on neuropathic pain among patients with type II DM.

Research hypotheses;

H_1: The study group who will receive aromatherapy massage will have less neuropathic pain component mean scores than control group who receive only conventional treatment among type II diabetic patients.

H_2: The study group who will receive aromatherapy massage will have less neuropathic pain quality mean scores than control group who receive only conventional treatment among type II diabetic patients.

II. SUBJECT AND METHODS

Research Design

A quasi experimental design simple interrupted time series pre-posttest nonequivalent control group (Wood & Haber, 2017).

Setting

Medical inpatient wards as well as at the outpatient clinic of Diabetes and Endocrine disorders at Kasr EL-Aini Hospital-affiliated to Cairo University Hospital.

Sample

A convenient sample with total number of 60 patients with type II DM. The inclusion criteria were; age ≥ 18 years, did not receive any CM currently and Douleur Neuropathique Questionnaire (DN4) score was ≥4. While, the exclusion

criteria were; hypersensitivity to essential oils to be used, hand or foot wound or previous related surgery, skin irritation, ulceration or active infection, pregnancy, using current topical preparation. Patients were divided randomly into two equal groups, 30 patients for each group. Data collection was over six consecutive months starting from July 2018 to the end of January 2019.

Data collection tools:

1: Demographic and medical data form was developed by the researchers and consists of two parts: **Part I:** Patient's demographic data which covers items related to age, gender, marital status, level of education …..etc. **Part II:** Medical data pertinent to medical diagnosis, current medications ……etc.

2: Douleur Neuropathique Questionnaire (DN4): it was developed by French neuropathic pain group to distinguish nociceptive pain from neuropathic pain and it consists of ten items; characteristics of pain burning, painful and electric ……etc; hypoesthesia to touch and pricking; friction. Each question is scored to be; yes or no, yes scored 1 and no scored 0, with a total possible score of ten and cut off value, *with ≥4 points denoting neuropathic pain.* Its reliability for English version using cronbach's alpha coefficient = 0.97 (Unal-Cevik, Sarioglu-Ay, & Evcik, 2010). Furthermore, this tool was translated into Arabic version by Terkawi et al., (2017) and analyzed its reliability as cronbach's alpha=0.67.

3: Pain DETECT questionnaire; was developed by Rainer Freynhagen and colleagues at 2006 (Gudala, Ghai, & Bansal, 2017) for measuring neuropathic pain components and it consists of nine items: seven sensory symptom items, including burning, tingling, or prickling sensations…..etc, that are graded from 0 to 5 on a Likert-type scale. One item on pain course graded from _1 to +1. One item on pain radiation graded from 0 for no radiation to +2 for radiating pain. The total score calculated from -1 to 38. Pain DETECT questionnaire has good internal consistency (Cronbach's alpha > 0.83) (De Andrés, et al., 2012). As well as after translation into Arabic by the researchers; its reliability was re-established by the researchers as cronbach's alpha= 0.85

4: Neuropathic Pain Questionnaire (NPQ); it was developed by Krause & Backonja at 2003 for measuring neuropathic pain qualities and it consists of twelve items graded on a scale from 0 to 100.The patient response to the NPQ items are weighted and then used to calculate a total score after multiplied it by the coefficient factors and the scores which were below 0 suggested nociceptive, rather than neuropathic pain and the scores which were 0 or above indicated neuropathic pain. NPQ has excellent internal consistency (chronbach's alpha = 0.95) (Krause & Backonja, 2003). As well as after translation into Arabic by the researchers; its reliability was re-conducted by the researchers as cronbach's alpha= 0.94.

Tools Validity and reliability:

Content validity of the translated Arabic version of the study tools was reviewed by juries of experts. As well as the reliability test was re-performed by the researchers for the translated versions into Arabic.

Pilot study:

A pilot study was conducted on ten subjects to test feasibility and clarity of the study and to ensure clarity of the developed study tools, as well as to determine the time required to fulfill the data collection tools.

Ethical Consideration:

Approval was obtained from the Research and Ethics committee of Faculty of Nursing, Cairo University. Also an official permission was obtained from the inpatient medical departments and diabetes outpatient clinic at Kaser EL-Aini Hospital. As well as, the current study was conducted according to the Helsinki Declaration.

Procedure:

Preparatory phase: Initially; using DN4; patients who had *≥4 points denoting neuropathic pain* was enrolled in the study. 1st reading (pre intervention) for demographic, pain DETECT questionnaire and NPQ for study and control groups. Aromatherapy recipe was referenced based on Metin, Donmez, Izgu, Ozdemir & Arslan, (2017) also, prepared under supervision of the pharmacognosy professor of the current study. Aromatherapy recipe was: blending three essential oils: rosemary, eucalyptus and lavender at a ratio of 2:2:1 and mixed with the sun flower oil as carrier oil. The blended oils were stored in 30-mL light proof and air tight glass bottles.

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Implementation phase: The control group was taking routine hospital management/conventional treatment of neuropathic pain. The study group was taking routine hospital management in addition to the aromatherapy massage. Initially, to ensure the safety measures regarding the used aromatherapy essential oils, patch test was conducted for the study group (Lawless, 2013). Aromatherapy massage was applied firstly to the feet 0.5 ml for each foot starting from left to the right; then 0.5 ml for each hand in the order of: efflurage, petrissage, friction then tapotement ended with efflurage for both feet and hands. Aromatherapy massage was applied three times weekly; over one month/patient. Each session took around 30 minutes.

Evaluation phase was conducted at second and fourth week for study group (after 15 min of aromatherapy massage sessions) and for control group.

Data Analysis:

Collected data was analyzed using statistical package for the social science (SPSS) program, version 23, by using descriptive statistics as frequency and percentage mean and standard deviation. Inferential statistics as paired t-test, independent t-test, ANOVA test and chi-square test. Level of significance was adopted at $p \leq 0.05$.

III. RESULTS

(1) Demographic characteristics of patients among the studied patients

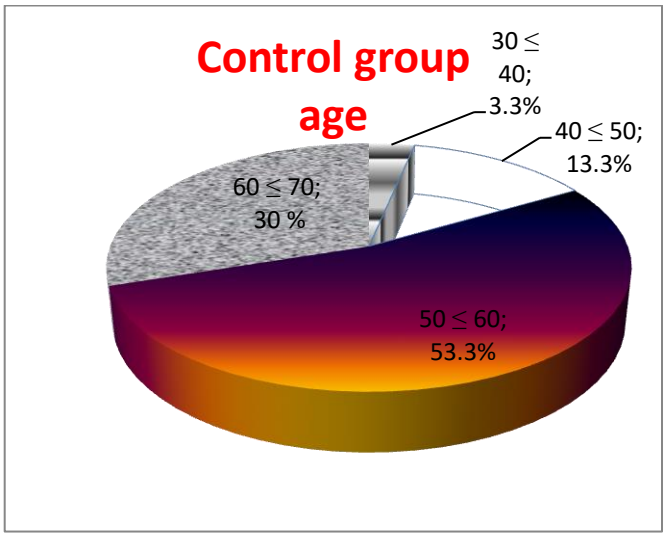

Figure 1

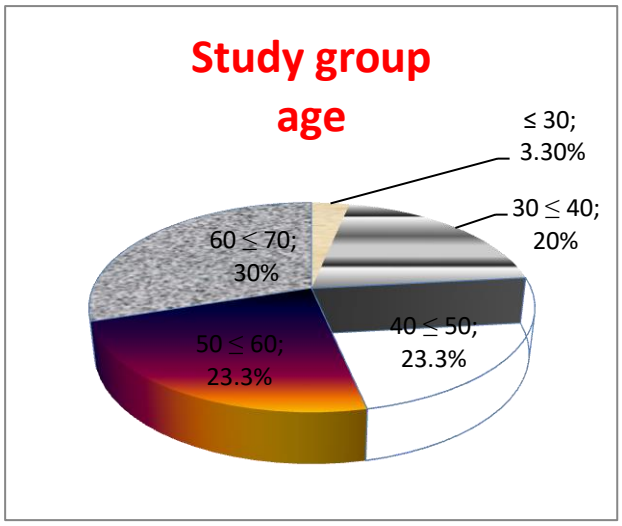

Figure 2

Figure 1 and 2 illustrated that, 30 % of both study and control group their age was 60 ≤ 70 with mean of age (51.3 ± 11.3) and (55.7 ± 7.9) years respectively. As well as there was no statistical significant difference between both groups as (T test =1.77; P = 0.08).

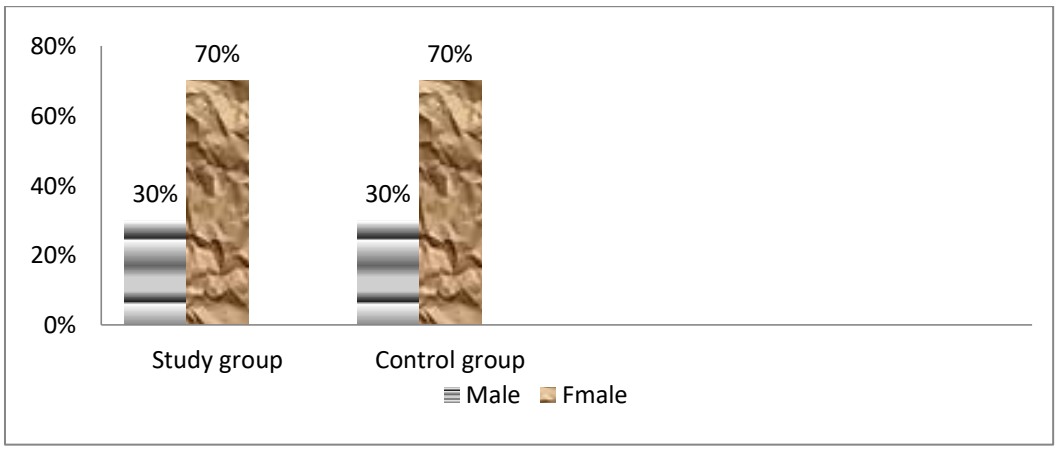

Figure 3: Gender of study and control group

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From figure (3) it was observed that, 70% of the both groups study and control were females.
In addition, it was found that, 86.7%, 70% were married. 33.3%, 70% can read and write and 50%, 56.7% worked as housewives for study and control groups respectively.

(2) Medical data among the studied participants

Table (1): Frequency and percentage distribution of medical data among the studied participants (n = 60)

Medical data	Study Group=30		Control Group=30	
	No	%	No	%
Anti-diabetic medication				
-Insulin only	17	56.7 %	9	30 %
-Metformin only	8	26.7 %	16	53.3 %
-Both insulin and metformin	5	16.7 %	5	16.7 %
Analgesics				
-Yes	14	46.7 %	17	56.7 %
-No	16	53.3 %	13	43.4 %
X ± SD	**0.66 ± 0.84**		**0.83 ± 0.91**	
Vitamin. B12				
-Yes	18	60 %	22	73.3 %
-No	12	40 %	8	26.7 %
X ± SD	**0.60 ± 0.49**		**0.73 ± 0.44**	

Table (1) showed that, 56.7 %, 30% of patients took insulin only, while 26.7 %, 53.3 % received oral metformin only among both study and control group respectively. On the other hand, 16.7 % of both groups took both insulin and metformin as their anti diabetic medication. In addition, 46.7%, 56.7% of study and control groups administered analgesics with X ± SD (0.66 ± 0.84), (0.83 ± 0.91) respectively. Also, 60%, 73.3% received vitamin B12 supplementations with X± SD (0.60 ± 0.49), (0.73 ± 0.44) for study and control respectively.

Table (2): Compare of mean scores for Study and Control Groups regarding neuropathic pain components

Neuropathic pain component	Study group	Control group	T- test	P- value
	Mean± SD	Mean± SD		
1st reading	28.3 ± 5.8	25.7 ± 4.7	1.88	0.064
2nd reading	19.3 ± 5.4	25.1 ± 4.6	4.53	0.000**
3rd reading	12 ± 3.7	26.4 ± 3.9	14.4	0.000**

P≤ 0.05

Table (2) it was observed that; the highest statistically significant difference between study and control groups was during the 3rd readings as T=14.4, at P value= 0.000**.

Table (3): Mean of differences over the three readings among study and control groups regarding neuropathic pain components.

Pain component	Study group			Control group		
	1st reading	2nd reading	3rd reading	1st reading	2nd reading	3rd reading
1st reading		12.47 P= 0.000**	16.72 P= 0.000**		2.31 P= 0.028	1.35 P= 0.18
2nd reading			8.68 P= 0.000**			3.25 P= 0.003
ANOVA	F= 47.13		P= 0.000**	F= 0.45		P= 0.7

P≤ 0.05

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Table (3) illustrated that, there was mean of difference among study's group neuropathic pain components over the three readings. Between 1st & 2nd, 2nd & 3rd, 1st & 3rd which equal 12.47, 8.68, 16.72 respectively. On the other hand, there was mean of difference among control's group between 1st & 2nd, 2nd & 3rd only which equal 2.31, 3.25 respectively. In addition, there was statistically significance difference of neuropathic pain components within patients of the both study group and control groups F=47.13, F=0.45 respectively.

Table (4): Compare of mean scores for Study and Control Groups regarding neuropathic pain qualities

Neuropathic pain quality	Study group Mean± SD	Control group Mean± SD	T- test	P- value
1st reading	729 ± 126.7	727.3 ± 124.5	0.051	0.95
2nd reading	555.3 ± 158.2	739.6 ± 124.1	5.02	0.000**
3rd reading	306.3 ± 132.8	814 ± 92	17.20	0.000**

P≤ 0.05

Table (4) it was showed that; the highest statistical significant difference between study and control groups was during the 3rd readings as T= 17.20, at P value= 0.000**.

Table (5): Mean of differences over the three readings among study and control groups regarding neuropathic pain qualities.

Pain Quality	Study group			Control group		
	1st reading	**2nd reading**	**3rd reading**	**1st reading**	**2nd reading**	**3rd reading**
1st reading		13.40 P= 0.000**	18.10 P= 0.000**		1.79 P= 0.08	6.06 P= 0.000**
2nd reading			9.79 P= 0.000**			6.05 P= 0.000**
ANOVA	F=38.64		P=0.000**	F= 3.32		P= 0.02

P≤ 0.05

Table (5) there was mean of difference among study's group neuropathic pain quality over the three readings. Between 1st & 2nd, 2nd & 3rd, 1st & 3rd which equal 13.40, 9.79, 18.10 respectively. On the other hand, there was mean of difference among control's group between 2nd & 3rd, 1st & 3rd only which equal 6.05, 6.06 respectively. In addition, there was statistically significance difference of neuropathic pain quality within patients of the both study group and control groups F=38.64, F=3.32 respectively.

Table (6) Chi-relation between neuropathic pain components and neuropathic pain qualities over the three readings.

Pain component	Study group Pain quality		
	1st reading	**2nd reading**	**3rd reading**
1st reading	X^2= 26.66 P= 0.9		
2nd reading		X^2 = 21.30 P= 0.000**	
3rd reading			X^2 = 24.23 P= 0.000**
Pain component	**Control group** **Pain quality**		
	1st reading	**2nd reading**	**3rd reading**
1st reading	X^2 = 21.09 P= 0.1		
2nd reading		X^2 = 20.31 P= 0.1	
3rd reading			X^2= 15.13 P= 0.9

P≤ 0.05

Table (6) showed that there was highly significant association between neuropathic pain components and qualities during 2nd and 3rd readings as (X^2 = 21.30, p= 0.000**) and (X^2 = 24.23, p= 0.000**) respectively only among study group. While, there was not any association between neuropathic pain components and qualities over the three readings among control group as (X^2 = 21.09, p= 0.1), (X^2 = 20.31, p= 0.1) and (X^2 =15.13, p=0.9) respectively.

IV. DISCUSSION

Neuropathic pain is the most restless complication of DM. Aromatherapy massage had an effective role in reducing neuropathic pain components and its qualities. Therefore, discussion of the current study presented in the following sequence: **Section l**, Represented the demographic and medical data. **Section II,** answered the research two hypothesis related to neuropathic pain components and its qualities.

Section l, regarding the age; it was found that, almost the studied sample allocated in the middle age (40- 60) years; which might reflect negative sign as DM neuropathy prevalence drawback which appeared in earlier age group than expected. Previous study conducted by Udall et al., (2019) on patients with painful diabetic neuropathy had the same findings. While, a study carried out by Amour et al., (2019) has different result which found that the majority of patients with painful diabetic neuropathy their age were over sixty. Furthermore, it was found that, most of both study and control patients were females, the majority were married, can read and write and more than half of them were housewives. These findings are congruent with the results of previous study conducted by Tosun, Zincir & Eliş, (2019) which concluded that, majority of their studied sample were females, married, housewives with education level of elementary and lower level. While, a study by VanDenKerkhof et al., (2016) found diverse result that, the majority of the studied patients were male, had a university degree and working full time as well as part time. According to the current research findings, the researchers interpreted these results as; female diabetic patients who were experiencing neuropathic pain need more information and awareness to be raised about early detection of DM neuropathic symptoms, how to deal with their pain, mange their daily activities and other complications which could result from neuropathic pain as diminished sensation, diabetic foot…etc.

Concerning, anti diabetic medications regarding the current study found that, more than half of both study and control groups took only one type of anti diabetic medications. Similar findings reported by Karki, Nagila, Dhakal & Chhetri, (2019); Young et al., (2018) which revealed that the majority of their studied sample received only one type of anti diabetic medications. However another study reported by Ismail, Fares & Abd-Alrhman, (2019) revealed that; the majority of the studied sample received combination of insulin and oral anti diabetic medications. Regarding, analgesics it was found that, half of both study and control groups obtained analgesics. These results were supported by the findings of previous studies done by Meisinger et al., (2018) which revealed that patients with neuropathic pain received one type of analgesic or more. In addition, it was found that more than two third of both study and control groups received vitamin B12, which is in the same line with Solomon, (2016) who showed that more than two third of the studied patients was treated with vitamin B12. It was clear that study and control groups were homogenous as the researchers were conscious about that to achieve equality between the studied groups.

Section II, In fact, there was highly reduction in the mean level scores of both neuropathic pain components and qualities in the study group over the 2nd and 3rd readings compared to 1st reading. In contrast, there was increasing in the mean level scores of neuropathic pain components and qualities among the control group over the 2nd and 3rd reading compared to 1st reading. Furthermore, this study illustrated that there was statistical significant differences between study and control groups over the 3rd readings regarding both neuropathic pain components and qualities. The results of the current study was similar to those from a study by Metin, Donmez, Izgu, Ozdemir& Arslan, (2017) which reported that, there was statistical significant difference among study and control groups neuropathic pain mean scores after using aromatherapy massage on patients with diabetic neuropathic pain. As well as, study group neuropathic pain level decreased after intervention while pain in the control group increased.

In addition it was found that, there was significant difference between study group pain components comparing to control group; which was over the three readings. And inspite the fact that; the control group had differences of pain component between 1st & 2nd, 2nd & 3rd; but, it was a minor progress comparing to the study group as it was improved more significantly. Furthermore, it was observed that, there was significant difference between study group pain qualities comparing to control group. Regarding the study group this difference was between patients over the three readings.

While among the control group this difference was between patients but; only over 2nd & 3rd, 1st & 3rd; which again highlighted that improvement among study group was significantly greater than the control group. This result was in harmony with findings reported by Heydari, Homayouni, Hashempur & Shams, (2015) which was conducted on diabetic patients with neuropathic pain and revealed that; there was mean of differences among study group patients' neuropathic pain quality along the study period after using natural remedies of *Citrullus Colocynthis* fruit extract. As well as, according to Lakhan, Sheafer& Tepper, (2016) it was confirmed that aromatherapy should be considered as safe pain management technique. Furthermore; this finding is in accordance with results of previous study done by Chao et al., (2019) as it was found that there was statistical difference between both study and control group using natural technique as; acupuncture for diabetic neuropathic pain.

Additionally; there was highly significant association between neuropathic pain components and qualities over 2nd and 3rd readings among the study group; while there was not any association over the three readings among control group. Actually, this result reflects the strong bound between neuropathic pain components and its quality. Indeed, the current research might be considered as one of the initial nursing research which reported that bounding. But other researches as Nathan et al., (2017) found a relation between Mindfulness-based stress reduction and only neuropathic pain qualities.

Based on the current findings; the researchers pointed out that, both study and control groups who received their diabetic medications beside different types of analgesics and vitamin B12; still having different degrees of neuropathic pain. So that, there is a significant need for additional non-pharmacological interventions to be used alongside with the pharmacological treatment. Indeed, the researchers found that, the used essential oils; contain substances of analgesic effect that influence the improvement of parasympathetic response which enhanced by massage techniques; that interact with sensory fibers in the skin and influence pain transmission as well. Also massage induces warming effect which improves blood circulation. So, these results supported the effect of aromatherapy massage in reducing neuropathic pain components and pain qualities among patients with type II diabetes mellitus.

V. CONCLUSION

In summary, aromatherapy massage significantly reduced neuropathic pain component and pain quality among patients with DM after two and four weeks of intervention. Therefore, based on the current research findings aromatherapy massage considered safe and easy applied method for pain management among patients with type II DM.

VI. RECOMMENDATIONS

1. Aromatherapy and massage should be applied as nursing intervention to manage neuropathic pain component and quality among diabetic patients.
2. Application of this study in different setting of patients with DM.
3. Replication this study on larger sample of patients with DM.

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