



Original Research

Effect of Massage on Nausea and Vomiting of Patient with Chemotherapy: A Randomized Controlled Trial

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Abstract:

Background: Chemotherapy is adversely associated with nausea and vomiting in most cases. Adherence to this treatment reduces and patients' quality of life and affects it negatively. At present, non-pharmacological therapeutic alternatives are used for management of nausea and vomiting. This can be executed without additional cost or time in the clinical practice arena.

Objective: This study aims to determine the effects of massage therapy in reducing nausea and vomiting symptoms in adult patients undergoing chemotherapy.

Methods: A randomized controlled trial (RCT) was performed on 82 adult patients suffering from cancers, who were undergoing chemotherapy at the Oncology Center, Wasit Governorate, Iraq. the study samples were divided randomly into two groups: Foot massage group: The massage lasted for a total of 20 minutes, with 10 minutes devoted to each foot by using of peppermint oil and the Control group: Did not receive any intervention. The data collection instruments were the Numerical Rating Scale (NRS) and the Rhodes Index Scale.

Results: The findings revealed the distribution and comparison of nausea and vomiting between all groups, in response to all interventions. They showed that there were significant mean differences between the massage groups as compared to the control group at p .000.

Conclusion: The foot massage therapy demonstrated promise in managing chemotherapy-induced nausea and vomiting (CINV). These non-pharmacological approaches have demonstrated significant reductions in the severity of nausea, incidence of vomiting, and overall discomfort associated with CINV compared to routine treatment alone.

Keywords: Foot massage, Chemotherapy, Nausea, Vomiting



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Introduction

Cancer remains the predominant global health issue and ranks among the top causes of mortality worldwide (1). In the Middle East, particularly in Iraq, there has been a notable rise in the occurrence of cancer over the previous decade. Despite extensive study on cancer, it continues to be a significant public health issue that requires attention from researchers (2).

One of the main treatments for cancer is chemotherapy (3,4). Chemotherapy have various side effects, but the common severe effects are nausea and vomiting(5). These adverse effects are troubling symptoms for cancer patients, particularly those undergoing chemotherapy, and have the potential to cause 70 to 80% of patients to reject the most effective chemotherapy treatment (6,7).

Chemotherapy-induced nausea and vomiting (CINV) is the predominant adverse effect experienced by cancer patients undergoing chemotherapy (8,9). Recurrent and intense vomiting can cause a decrease in appetite, resulting in a lack of necessary nutrients, a weakened immune system, disrupted metabolism, and other negative consequences that impact the patient's quality of life and the effectiveness of chemotherapy (10).

Effective control of nausea and vomiting is vital in supporting the treatment of patients receiving chemotherapy since it can possibly diminish the efficacy of the therapy and alter treatment outcomes (10). The severity and duration of these symptoms differ across individuals and can also be affected by the specific chemotherapy medications administered (11).

Nowadays, there is an increasing interest towards complementary and alternative medicine (CAM) especially toward medicinal herbs (12). This concerns the application of easy, risk-free, and efficacious treatment approaches to enhance and maximize quality of life, particularly for cancer patients (13). CAM assist patients in effectively addressing their issues by utilizing treatments that have fewer side effects and lower socio-economic

expenses (14). Massage with aromatherapy have been documented to exert a beneficial impact in alleviating many symptoms including pain, anxiety, exhaustion, nausea, and vomiting (15).

Aromatherapy is one of the CAM methods with a history of several thousand years (16). Aromatherapy uses plant essences from flowers, leaves, and stems to treat various diseases. Essences are volatile oils that can be inhaled, swallowed, or applied topically (17). Approximately 40% of cancer patients in Europe utilize CAM as part of their oncology treatment. Massage interventions in manual supplementary therapies that nurses can use to offer care for patients (18,19).

Research Hypotheses:

Null hypothesis: (H0) There is no significant difference in the reduction of nausea and vomiting between patients undergoing chemotherapy who receive massage therapy when compared to the control group.

Alternative hypothesis: (H1) There is a significant difference in the reduction of nausea and vomiting between patients undergoing chemotherapy who receive massage therapy when compared to the control group.

Methodology

Trial Design

A randomized RCT was conducted to assess the viability and initial impact of aroma therapy, applied through foot massage, on the occurrence and intensity of acute nausea and vomiting caused by chemotherapy. The Oncology Center, in the Wasit Governorate in Iraq, conducted the study.

Setting and Data collection

The Oncology Center, in the Wasit Governorate served as the primary hospital for delivering chemotherapy treatment to cancer patients. This study covered individuals who received treatment at this facility. Patients from various cities in Iraq, who were diagnosed with cancer, were admitted to these facilities to specifically undergo chemotherapy treatment. The administrators

formally endorsed the approval letters for data collection.

The researcher gathered the data from the Oncology Center. A total of 82 patients consented to participate in the trial. Data gathering commenced from December 26, 2023 to February 6, 2024. The study sample was selected and classified into two groups: experimental groups and a control group, using probability sampling methods. We collected baseline data from patients during a pre-test period using a questionnaire of demographic characteristics, clinical characteristics, and the Numerical Rating Scale, to evaluate the degree of nausea the patient was experiencing.

Participants

The data for this study were collected at the Oncology Center in Al-Kut City, Iraq. In relation to the inclusion criteria, they were categorized as follows: (1) Chemotherapy patients who were adults (18 and above), both male and female, diagnosed with cancer. (2) Patients who did not

have any physical or mental disabilities, such as, those who were not paralyzed, and who did not have conditions that prevented leg massage, such as, open wounds, fractures, strains, sprains, or deep vein thrombosis. With regard to the exclusion criteria, the following were followed: (1) Patients who did not read and write. (2) Patients who had problems communicating or were unconscious. (3) Patients had allergies to plants and perfumes; (4) Patients with mental state disorder; (5) Patients with leg edema or ulcer; olfactory disorder. In addition, individuals, who were unable to finish the entire session, were not included as participants. All 82 patients in the sample satisfied the requirements for eligibility and voluntarily consented to take part in the trial. However, the specified exclusion criteria eliminated 12 participants from the study. We randomly divided 70vpatients, who met the inclusion criteria into “control” and “intervention” participant groups. A study flow diagram is illustrated in Figure 1, presenting the recruitment and allocation of groups in the trial.

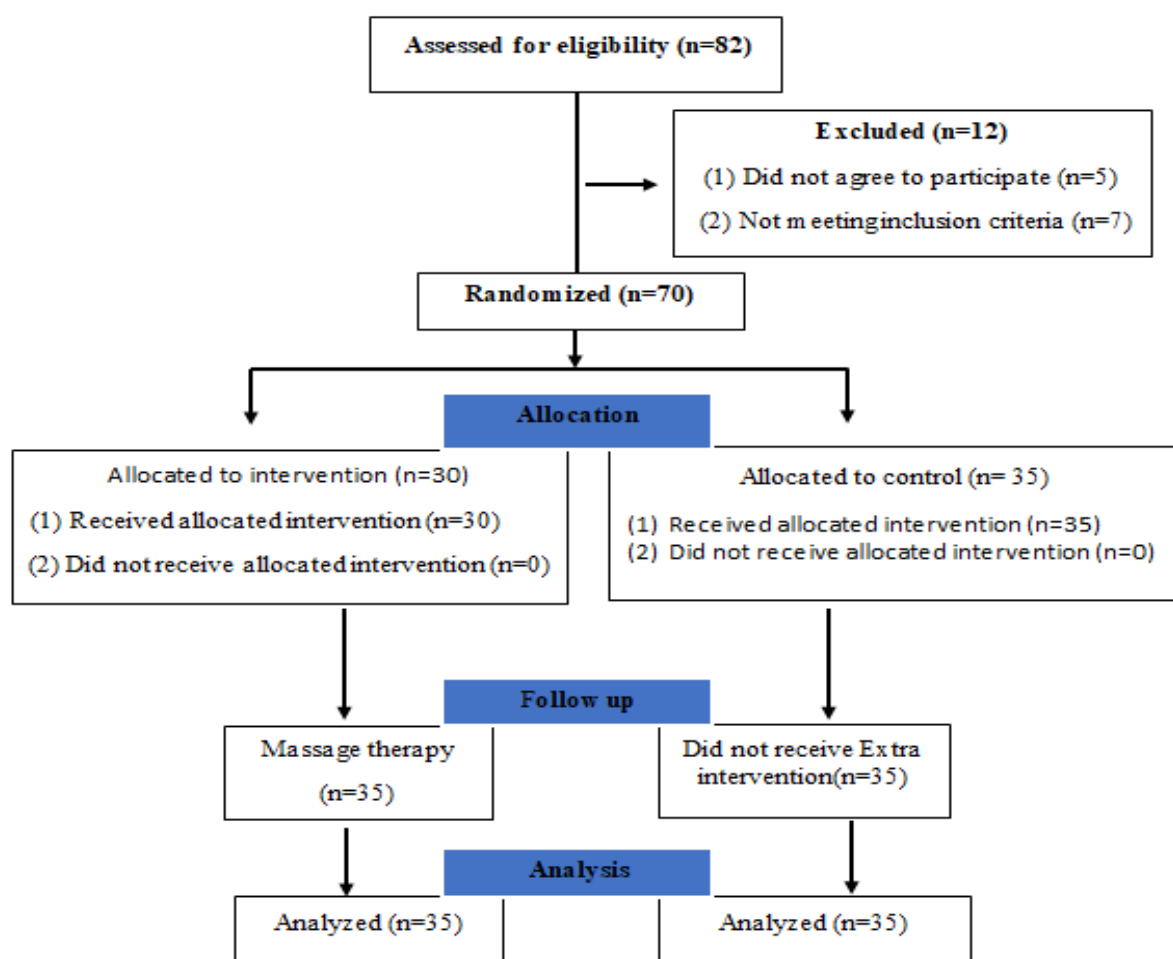


Figure 1 Clinical Trial Flow Diagram

Materials and methods

Interventions

The main investigator (PI) gave the participants in the massage group foot massages using the Swedish massage techniques, specifically on the dorsum of the foot, effleurage on the top of the foot, and massage of the toes. The massage lasted for a total of 20 minutes, with 10 minutes dedicated to the treatment of each foot specifically.

Four milliliters of peppermint essential oil were in the treatment room. However, the control group did not receive any intervention. Each participant required approximately 25–30 minutes to complete the intervention. The researcher obtained data on the patients' responses to treatment via telephone the day following chemotherapy, and the principal investigator recorded the data on the questionnaire portion after 24 hours, to assess the patients' response to the interventions.

Sample size calculation

The sample size was calculated by applying the G Power software version 3.1.9.7 by setting the alpha (α) to 0.05, the power (β) to 0.80, and the effect size to 0.5. For each group, a minimum sample size of 35 was required. The study included a total of 82 participants, equally allocated between three groups: The massage, aroma therapy, and control groups (see Figure 1) (20).

Randomization

To ensure a transparent and scientifically grounded randomization process, a simple randomized method was employed to allocate participants (individuals with cancer and undergoing chemotherapy) to the massage therapy, and control groups. This method assumes every respondent has an equal probability of being assigned to any of the groups. The randomization procedure included dividing the participants (with chemotherapy) into two groups: The massage group, and the control group, by giving two cards of different colors in a box to the sample to select one card that represents the study group. The blue

card represented the massage group and the black card symbolized the control group. The two groups were allocated randomly in this manner. In the sample, there were 70 patients. Both the intervention groups and the control group had an equal number of subjects.

Tools of the study

Part 1: Demographic and clinical characteristics of patients with chemotherapy (age, gender, level of education, occupation, educational level, address, marital status, monthly income, cancer site, stage of disease, chemotherapy treatment period, feeling nauseous).

Part 2: The Numerical Rating Scale (NRS) was originally used to assess the state-of-life conditions of the cancer patients in the 1970s (21). We could categorize the degree of nausea into four distinct levels: A score of 0 would show that there was no nausea at all; a number between 1 and 3 would indicate that the nausea was mild; a score between 4 and 6 indicated that the nausea was moderate; and a score between 7 and 10 indicated that the nausea was severe (22).

Part 3: V. Rhodes and R. McDaniel, devised the Rhodes Index Scale, also known as the Index of Nausea, Vomiting, and Retching (INVR), in 1999, to specifically quantify the frequency of nausea and vomiting experienced by patients undergoing chemotherapy. The index consisted of eight questions. The index assigned a numerical value between 0 (the least anguish) and 4 (the most anguish) to each reaction (23,24). We added the scores of the items together to get a total score that ranged from 0 to 32.

Ethical Considerations

The study protocol received approval from the Institutional Review Board (IRB) in the College of Nursing Council at the University of Baghdad in Iraq. Furthermore, the necessary authorizations were acquired from the (Oncology Center in Wasit Health Directorate) to gather the data. The participants were provided with a written informed consent form, which they were required to sign in order to indicate their voluntary permission to participate in this study. This study

was conducted in accordance with the principles outlined in the Declaration of Helsinki, and the research protocol received approval from the Iranian Registry of Clinical Trials. IRCT20231027059871N1.

Statistical Methods

A statistical program such as SPSS (Statistical Package for Social Science) version 26. was used to analyze the data through descriptive data analysis that included frequencies, percentages, mean and SD as well as inferential analysis, F test.

Results of the study

Table 1: The Distribution of the Study Samples according to their Demographic characteristics.

Variable	Groups	Massage group		Control group	
		Freq.	%	Freq.	%
Age	Mean $\pm$ SD	44.09	13	48.9	19.4
Sex	Male	20	60.6	22	66.7
	Female	13	39.4	11	33.3
Residence	Urban	25	75.8	23	69.7
	Rural	8	24.2	10	30.3
Marital Status	Single	3	9.1	3	9.1
	Married	26	78.8	22	66.7
	Divorced/separated	1	3	0	0
	Widow	3	9.1	8	24.2
Job	Employee	10	30.3	7	21.2
	Free work	10	30.3	7	21.2
	Housewife	9	27.3	8	24.2
	Retired	2	6.1	8	24.2
	Student	2	6.1	3	9.1
Monthly income	300000 – 600000	16	48.5	16	48.5
	601000 – 900000	14	42.4	14	42.4
	900000 and more	3	9.1	3	9.1
Educational level	Read and write	5	15.2	7	21.2
	Primary	4	12.1	9	27.3
	Intermediate	5	15.2	2	6.1
	Preparatory	6	18.2	5	15.2
	Diploma	5	15.2	3	9.1
	Bachelor	8	24.2	7	21.2

Freq. = frequency, % = percentages

Results in table 1. presented that the mean age of the massage group was 44.09 years old and 48.9 years for the control group. In addition, most of

the study sample were females including 60.6 percent for the massage group, and 66.7 percent for the control group. Moreover, most of the

study sample were living in urban area for all groups as 75.8 and 69.7 respectively. Also, most of the study sample were married, including 78.8 for massage group, and 66.7 control groups. In relation to work, the significant level of

participant 30.3 of the massage group were employed and 24.2 of the control group were retired. Related to education level, 24.2 of the massage group have bachelors' degree, 24.2 and 27.3 of the control group have primary degree.

Table 2: Distribution of the Patients according to the Medical Information.

Variable	Groups	massage group		Control group	
		freq.	%	Freq.	%
Type of disease (cancer)	Breast	4	12.1	5	15.2
	Lung			1	3
	Colon	7	21.2	4	12.1
	Stomach	2	6.1	1	3
	Pancreatic	2	6.1		
	Bladder	3	9.1	6	18.2
	Intestinal			2	6.1
	Blood	3	9.1	4	12.1
	Others	12	36.4	10	30.3
Stage of the cancer	First			1	3
	Second	4	12.1	5	15.2
	Third	9	27.3	8	24.2
	Fourth	6	18.2	5	15.2
	Not classified	14	42.4	14	42.4
Duration of chemotherapy	Minimum/Maximum	0	3	0	3
	Mean/ SD	1.9	.9	1.72	.45
Fear from chemotherapy	Yes	9	27.3	9	27.3
	No	24	72.7	24	72.7
Feeling nausea after getting chemotherapy	Yes	31	93.9	30	90.9
	No	2	6.1	3	9.1
Nausea and vomiting scale score	Minimum/ Maximum	3	10	2	6
	Mean SD	6.72	1.98	2.12	.69

Freq. = frequency, % = percentages

Table 2. presented the distribution of the study sample according to their medical records, in which 21.2 percent of the massage group have

colon cancer and 18.2 percent of the control group have bladder cancer also. The highest percent in all groups have third stage of cancer about 27.3 in

massage and 24.2 in control groups. The mean duration of chemotherapy of all groups was below 2 years of therapy. Most of the massage group 93.9 and control group 90.9 were suffering from

nausea, and the mean of the nausea score was 6.72 for massage group and 2.12 for the control group respectively.

Table 3 Comparison of rod scale of nausea and vomiting using F-test among all groups.

No.	Rod scale of NV score	Massage group		Control group		F test	Sig. P value
		Freq	Mean	Freq	Mean		
1	Mild	6	11.3	6	2.24	103.6	.000
2	Moderate	24		13			
3	Severe	3		14			

M= mean, SD = Standard deviation.

Table 3 presented the distribution and comparison between groups about nausea and vomiting in response to all interventions, in which there was a significant difference with massage than control group according to their mean and p value = .000.

Discussion

Distribution of the study sample according to their medical records, in which 21.2 percent of the massage group have colon cancer and 18.2 percent of the control group have bladder cancer also, This result was slightly greater than that reported by the study sample in study group is colon cancer (19%), and the control group (17%) (25). All groups have third stage of cancer about 27.3 in massage and 24.2 in control groups, The findings of our study were consistent with the study reported the third stage of cancer in massage group 36.58 and control group 36.58 (26). The mean duration of chemotherapy of all groups was below 2 years of therapy, This finding contradicts a study that the mean duration is 40.04 months for study group and the mean duration is 35.32 months for the control group (27). The mean of the nausea score was 6.72 for massage group and 2.12 for the control group. Our study found results consistent with the study that showed the Mean of nausea at the first day for the chemotherapy in the experimental group was 5.72 and for the control group 5.52 (27).

when distribution and comparison between groups about nausea and vomiting in response to all interventions the result shows there was a significant difference between massage and the control group according to their mean and p value = .000. The results of this study are consistent with a previous study that found a significant disparity in nausea and vomiting scores among participants who received cardamom aroma therapy. The difference was statistically significant (p -value = 0.001) before and after the intervention (28). Another study supporting the findings showed that peppermint aroma therapy significantly affected CINV, with a p -value of 0.001 ($\alpha < 0.05$) (29). Furthermore, our study's findings align with a previous research, which indicated that both massage and inhalation aroma therapies resulted in the reduction of nausea and retching, compared to the control group. Furthermore, the occurrence of nausea and retching was notably reduced in the massage group compared to the inhalation and control groups ($p > .001$) (30). In addition, the study showed a reduction of nausea, pain, and fatigue in patients with breast cancer on chemotherapy, following administration of inhalation and massage aroma therapy (31). Massage enhances blood circulation and oxygen absorption by locally activating the musculoskeletal system. It also promotes relaxation and relief by stimulating

the limbic system, possibly reducing the intensity of nausea (26)

Limitations

Several patients opted out of the trial due to societal or religious restrictions, as the massage required the exposure of certain body parts. Some patients did not continue follow-up and also closed communication tools at the time of their follow-up.

Conclusion

It can be concluded that massage therapy show promise in managing chemotherapy-induced nausea and vomiting (CINV). These non-pharmacological approaches have demonstrated significant reductions in the severity of nausea, the incidence of vomiting, and overall discomfort associated with CINV compared to routine treatment alone. Specifically, the studies highlight that massage therapy, when combined with aromatherapy, can lead to a decrease in nausea severity and incidence of vomiting among patients undergoing chemotherapy.

Recommendation

In-service training programs and antiemetic administration protocols should be updated to include the use of non-pharmacological techniques (Aromatherapy) to control nausea and vomiting during chemotherapy administration. More research is needed to confirm these findings and explore the effectiveness of aromatherapy in other settings and populations.

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