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Effect of Aromatherapy on Nausea and Vomiting of Cancer Patients Undergoing Chemotherapy: A Randomized Controlled Trial

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ABSTRACT

Objective(s): The aim of this study is to determine the effectiveness of aromatherapy in reducing nausea and vomiting in adult patients receiving chemotherapy.

Methods: A randomized controlled trial was conducted on 66 patients with cancer undergoing chemotherapy at the Oncology Centre in Al-Kut City, Iraq, from November 7th, 2023, to June 13th, 2024. Patients were selected conveniently and randomly based on the inclusion criteria, and they were randomly assigned into two groups: the inhalation aromatherapy group and the control group. The first group inhaled peppermint oil for 20 minutes, while the control group did not receive any intervention and underwent only routine treatment. The Rhodes Index Scale was used to assess nausea and vomiting. Used SPSS version 26 to analyze the data, applying both descriptive and inferential analysis, and a one-way ANOVA test was used to determine the statistically significant difference between the two trial groups.

Results: The findings revealed that there was a significant difference in the severity of nausea and vomiting in the aromatherapy groups compared to the control group, according to the mean of the aromatherapy group, which was 12.63, with a P value of 0.001.

Conclusion: The Aromatherapy was found to be effective in reducing nausea and vomiting levels when compared to the control group. Therefore, inhalation of aromatherapy is recommended as an effective non pharmacological intervention to reduce nausea and vomiting related to chemotherapy.

Recommendations: The study recommends healthcare professionals, particularly nurses to utilize nonpharmacological techniques such as aromatherapy that have been validated as effective more often for alleviating nausea and vomiting caused by chemotherapy.

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تأثير العلاج العطري على الغثيان والقيئ لمرضى السرطان الخاضعين للعلاج الكيميائي: تجربة عشوائية محكومة

المستخلص

الأهداف: هدفت الدراسة إلى تحديد فاعلية العلاج العطري في تقليل الغثيان والقيء لدى مرضى السرطان الذين يتلقون العلاج الكيميائي.

منهجية البحث: أُجريت دراسة ذو تجربة عشوائية منضبطة على **66** مريضًا بالسرطان يخضعون للعلاج الكيميائي في مركز الأورام في مدينة الكوت بالعراق، خلال الفترة من **7** تشرين الثاني 2023 إلى 13 حزيران 2024. تم اختيار المرضى بشكل عشوائي استنادًا إلى معايير الاختيار وتخصيصهم عشوائيًا إلى مجموعتين: مجموعة العلاج العطري عن طريق التنفس والمجموعة الضابطة. استنشقت المجموعة الأولى زيت النعناع لمدة 20 دقيقة، بينما لم تتلقَّ المجموعة الضابطة أي تداخل. تكونت أداة جمع البيانات من جزأين: الجزء الأول ويتضمن الخصائص الديموغرافية، بينما يتضمن الجزء الثاني مقياس رودس للغثيان والقيء. تم تحليل البيانات باستخدام برنامج SPSS الإصدار **26**، مع تطبيق التحليل الوصفي والاستدلالي.

النتائج: أظهرت النتائج وجود فروق ذات دلالة إحصائية بين المجموعة الضابطة ومجموعة الدراسة حيث أدت التجربة الى قله تكرار وشدة القى والغثيان، وفقًا لمتوسط مجموعة العلاج العطري الذي كان **12.63** مع قيمة احتمالية قدرها 0.001.

الاستنتاجات: وجد ان استخدام العلاج العطري فعال في تقليل مستويات الغثيان والقيء مقارنتا بالمجموعة الضابطة. لذلك يوصى باستنشاق العلاج بالروائح العطرية كطريقة غير دوائية فعالة في تقليل الغثيان والقيء المرتبط بالعلاج الكيميائي.

التوصيات: توصي الدراسة بضرورة استخدام المعنيون في مجال الرعاية الصحية، ولا سيما الممرضون على استخدام التقنيات الغير دوائية التي تم التحقق من فعاليتها بشكل أكبر في تخفيف الغثيان والقيء الناجمين عن العلاج الكيميائي.

الكلمات المفتاحية: العلاج العطري، الغثيان والقيء، مرضى السرطان، العلاج الكيميائي.

Introduction

Chemotherapy, a cornerstone in the treatment of cancer, is frequently associated with significant adverse effects, among which nausea and vomiting are the most distressing for patients [1]. These side effects not only diminish the quality of life but also can lead to non-compliance with treatment regimens, thus potentially impacting the overall effectiveness of cancer therapies [2]. Despite advancements in pharmacological treatments for chemotherapy-induced nausea and vomiting (CINV), a substantial number of patients continue to experience these symptoms, indicating the need for additional supportive care interventions [3].

Aromatherapy, the therapeutic use of essential oils extracted from plants, has been increasingly recognized as a complementary treatment for a variety of medical conditions [4]. Essential oils such as ginger, peppermint, and lavender have been traditionally used for their potential anti-emetic and calming properties [5]. Preliminary studies suggest that aromatherapy may help reduce the severity of nausea and vomiting, providing a non-invasive and low-risk intervention for symptom management in cancer patients [6].

Cancer remains the predominant global health issue and ranks among the primary causes of mortality worldwide [7]. According to the statistics of the Iraqi Ministry of Health, more than 30 thousand cancer patients are currently receiving treatment in the country (IMH, 2022). Each year, there are about 18.1 million new cancer cases worldwide and Approximately 9.6 million people die from cancer annually [8].

The initial interventions for cancer are intricate and may encompass surgical procedures, treatment with chemotherapy, biotherapy and radiotherapy. Treatment options are established according to the tumor stage, its hormone receptor status, the presence of metastases, and the patient's overall state [9].

One of the main treatments for cancer is chemotherapy [10,11]. Approximately 70 to 80% of cancer patients suffer from

chemotherapy-induced nausea and vomiting. Among them, a significant number may choose to postpone or decline future chemotherapy treatments due to their concern of experiencing more episodes of nausea and vomiting, ultimately leading to a complete cessation of all treatments [12].

Pharmaceutical interventions, such as intravascular or oral drugs, can alleviate nausea and vomiting, but they are not necessarily compatible with the medicine being administered and may be linked with adverse effects, allergies, and increased costs [13].

Using complementary and alternative medicine (nonpharmaceutical) is one of the simplest and safest choices, since anti-nausea and vomiting drugs have limited efficacy and potential harmful effects [14]. Some non-pharmacological options for managing nausea and vomiting caused by chemotherapy include aromatherapy, abdominal massage, relaxation techniques, acupuncture treatments, and musical therapy [15,16]. It was shown in a European survey that 35.9% of cancer patients use complementary and alternative medicine [17].

Aromatherapy is one of the complementary and alternative medicine (CAM) methods with a history of several thousand years is a cost-effective alternative to conventional medicine because it is painless, non-invasive, and typically associated with little adverse effects [18]. 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 [19]. Peppermint essential oil is one of the key oils examined in research exploring the impact of aromatherapy on CINV. Peppermint essential oil is well-known for its efficacy in alleviating nausea [20,21].

Nurses play a crucial role in managing and treating nausea and vomiting, setting them apart from other healthcare providers due to their close relationship with patients. They are able to provide guidance on nausea and vomiting management strategies, administer planned treatments, assist patients during their recovery, and evaluate the effectiveness of treatments [22].

Given the promising preliminary evidence, this randomized controlled trial aims to evaluate the effectiveness of aromatherapy in managing chemotherapy-induced nausea and vomiting. By systematically assessing the impact of specific essential oils on nausea and vomiting in chemotherapy patients, this study seeks to contribute to the growing body of evidence supporting integrative oncology practices.

Research Question: Is the aromatherapy more successful in alleviating chemotherapy-induced nausea and vomiting?

Methods

Study Design and Setting

A randomized controlled trial (RCT) was carried out in Iraq at the Oncology Center in Wasit Governorate, a mining to explore the impact aromatherapy on alleviating nausea and vomiting in patients undergoing chemotherapy. Oncology Center, in Wasit Governorate serves as the primary hospital for delivering chemotherapy treatment to cancer patients this study covered individuals who received treatment at this facility.

Study Sample and Sampling

To ensure a transparent and scientifically grounded randomization process, a simple randomized method was employed to allocate participants (patients with cancer and undergoing chemotherapy). This method assumes every participant has an equal probability of being assigned to any of the groups. The randomization procedure included divide the participants into two groups: aromatherapy group, and control group. For this study, the minimum sample size required for each group was 33 patients. This calculation is based on an 80% confidence level and a 5% margin of error, as

determined by the sample size calculation procedure. All 78 patients in the sample met the criteria for eligibility and willingly agreed to take part in the study. Nevertheless, 12 participants were eliminated from the study due to the specified exclusion criteria. A total of 66 patients who met the inclusion criteria were randomly divided into the control and intervention groups. Study flow diagram is shown in **Figure 1** explaining the recruitment and allocation to study groups.

Randomization Process

The randomization procedure included dividing the participants (with chemotherapy) into two groups: The aromatherapy 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 yellow card represented the aromatherapy group, and the black card symbolized the control group. The two groups were allocated randomly in this manner. In the sample, there were 66 patients. Both the intervention groups and the control group had an equal number of subjects.

Data Collection and Study Instruments

The researcher gathered the data at the oncology center. A total of 66 patients consented to participate in the trial. During a pre-test period, baseline data were collected from patients using a questionnaire of demographic characteristics, clinical characteristics, and the Numerical Rating Scale to evaluate the degree of nausea the patient was experiencing. Each participant required approximately 10-15 minutes to complete the survey. Then, each participant in the intervention group for the aromatherapy group was given inhalation of peppermint oil placement of a cotton spongy that was previously moistened with 2 ml of peppermint oil on the tip of the patient's nostrils for (10) minutes prior to the beginning of the chemotherapy treatment and It lasts for 20 minutes. After 24 hours data on patients' responses to treatment were obtained by researcher via telephone on the day following.

Two tools were used in this study for data collection, in addition to patient's Sociodemographic data. The Numerical Rating Scale (NRS) used to assess the degree of nausea can be broken down into four different levels: a score of 0 shows that there is no nausea at all, a number between 1 and 3 indicates that the nausea is mild, a score between 4 and 6 indicates that the nausea is moderate, and a score between 7 and 10 indicates that the nausea is severe [23,24].

Rhodes Index of Nausea, Vomiting, and Retching self-report assessment tool that developed by Rhodes and McDaniel in (1999) and this tool was adapted and translated into the Arabic language according to review of literature by the researcher to quantify the frequency of nausea and vomiting experienced by patients undergoing chemotherapy an eight-question index makes up the index. Each reaction is given a numerical value between 0 (the least anguish) and 4 (the most anguish) by the index [25,26]. The items' scores were added together to yield a total score ranging from 0 to 32, score of 0: Indicates absence of nausea or vomiting . Scores 1-8: suggest mild nausea and vomiting. Scores 9-16: Reflect a moderate experience with nausea and vomiting .Scores 17-24: Indicate severe nausea and vomiting, with sensations of stimulation .Scores 25-32: represent a severe experience of nausea and vomiting [26].

Blinding

No placebo intervention was applied due to characteristic odor of peppermint essential oil. Therefore, blinding of researchers and patients to study groups could not be achieved.

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. The research protocol received approval from the Iranian Registry of Clinical Trials. IRCT20231027059871N1 at the website https://www.irct.ir/

Statistical Methods

Data were analyzed through the use of the Statistical Package for Social Science (SPSS) Version 26. Descriptive Statistics in terms of Frequency (F), Percentage (%), Mean Score, and Standard deviation served to analyze demographic characteristics. The inferential analysis and one-way ANOVA test was used to determine the statistically significant difference between the two trial groups.

Oil Using

Peppermint essential oil (EO) is derived from the plant of the enduring herb, Mentha piperita L. This plant is highly recognized and significant in the field of medicine, being extensively utilized in many traditional medical practices for its diverse therapeutic advantages. It has been demonstrated that menthol and menthone are included in this. Smells are processed by neurons in the respiratory system, which in turn send signals to the hypothalamus and the limbic system. These properties are particularly effective in targeting the small intestine within the gastrointestinal tract, helping to alleviate symptoms associated with nausea and vomiting [27,28].

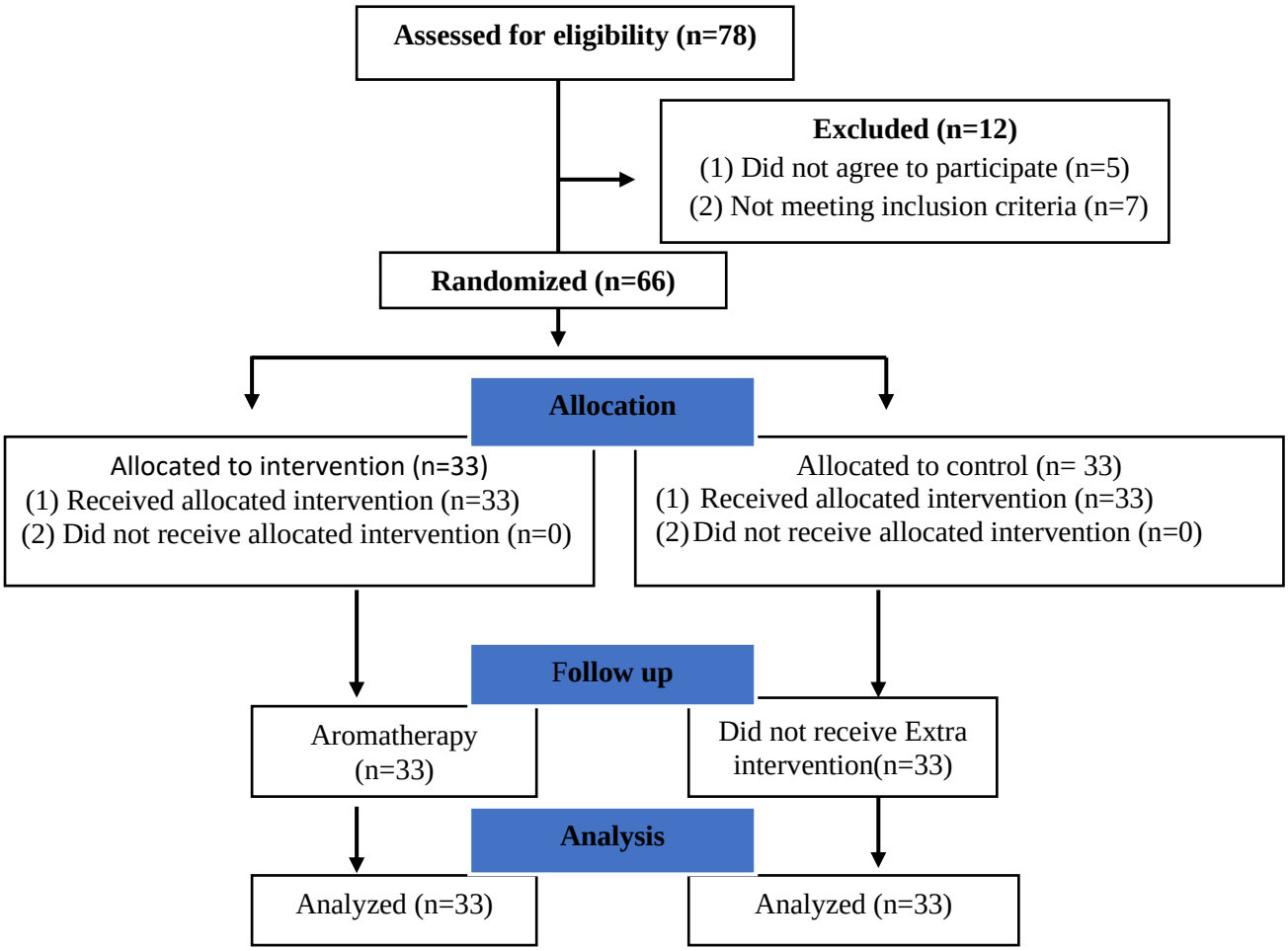

FIGURE 1 Clinical trial flow diagram

Results

Table 1: Socio-Demographic characteristics of patients with cancer in the study and control groups

Variable	Groups	Aromatherapy group		Control group	
		F.	**%**	F.	**%**
Age	Mean ± SD	49.9	13.5	48.9	19.4
Sex	Male	20	60.6	22	66.7
	Female	13	39.4	11	33.3
Residence	Urban	18	54.5	23	69.7
	Rural	15	45.5	10	30.3
Marital Status	Single	4	12.1	3	9.1
	Married	22	66.7	22	66.7
	Divorced/separated	2	6.1	0	0
	Widow	5	15.2	8	24.2
Employment status	Employee	7	21.2	7	21.2
	Free work	10	30.3	7	21.2
	Housewife	13	39.4	8	24.2
	Retired	2	6.1	8	24.2
	Student	1	3	3	9.1
Educational level	Read and write	7	21.2	7	21.2
	Primary	7	21.2	9	27.3
	Intermediate	3	9.1	2	6.1
	Preparatory	8	24.2	5	15.2
	Diploma	4	12.1	3	9.1
	Bachelor	4	12.1	7	21.2

F.= frequency**, % =** percentages

Table (1) indicates that the mean age of the aroma group was 49.9 years and 48.9 years for the control group. Most of the aroma group were females including 60.6 percent and 66.7 percent for the control group. Most of the study sample were living in urban area for all groups as 54.5, and 69.7. Also, most of the study sample were married, including 66.7 for aroma and control groups respectively. In relation to work, the significant level of participant 39.4 for the aroma group were housewife, and 24.2 of the control group were retired.

Table 2: Clinical data of patients with cancer

Variable	Groups	Aroma group		Control group	
		F	%	F	%
Type of disease (cancer)	Breast	6	18.2	5	15.2
	Lung			1	3
	Colon	4	12.1	4	12.1
	Stomach	1	3	1	3
	Pancreatic				
	Bladder	10	30.3	6	18.2
	Intestinal	2	6.1	2	6.1
	Blood	2	6.1	4	12.1
	Others	8	24.2	10	30.3
Stage of the cancer	First			1	3
	Second	7	21.2	5	15.2
	Third	9	27.3	8	24.2
	Fourth	5	15.2	5	15.2
	Not classified	12	36.4	14	42.4
Duration of chemotherapy	Minimum/Maximum	0	4	0	3
	Mean/ SD	1.54	.97	1.72	.45
Feeling nausea after getting chemotherapy	Yes	31	93.9	30	90.9
	No	2	6.1	3	9.1
	No	33	100	33	97
Nausea and vomiting scale score	Minimum/ Maximum	2	10	2	6
	Mean SD	6.09	2.09	2.12	.69

F.= frequency**, % =** percentages

Table (2) shows that 30% percent of the aroma group have bladder cancer, and 18.2 percent of the control group have bladder cancer. The highest percent in all groups have third stage of cancer with 27.3% in aroma group, and 24.2% in control groups. The mean duration of chemotherapy of all groups was below 2 years of therapy. Most of the aroma group 93.9%, and control group 90.9% were suffering from nausea, and the mean of the nausea score was 6.09 for aroma group, and 2.12 for the control group respectively.

Table 3. Comparison of Rhodes scale of nausea and vomiting for groups**.**

No.	Rhodes scale of NV score	Aroma group		Control group		F test	Sig.
		F.	Mean	F.	Mean		P value
1	**Mild**	7	12.63	6	2.24	103.6	0.001
2	**Moderate**	18		13			
3	**Severe**	8		14			

F.= frequency**, % =** percentages**, M=** mean**, SD =** Standard deviation, P value= 0.001

Table (3) presented the distribution and comparison between all groups about nausea and vomiting in response to all interventions, in which there was a significant difference with aroma groups than control group according to the mean of the aroma therapy group was 12.63, with P value= 0.001

Discussion

Distribution of the study sample according to their medical records, regarding type of cancer, the findings of the current study discovered that the highest percentage of patients in both aroma and control groups have bladder cancer, This result was slightly greater than that reported by the study sample in study group is (19%), and the control group (17%) [29]. The majority of the patients in the aroma group and control group have third stage of cancer about, The findings of our study were consistent with the study in India that reported the third stage of cancer [30]. 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 [31]. Most of the aroma group and control group were suffering from nausea, The findings of this study are consistent with the study that reported the majority 90.24% of the control group and 97.5% of the experiment group exhibited symptoms of NVR after to chemotherapy treatment [30]. The average nausea score for both the aroma group and the control group is high. This finding supported by study in Iran to evaluate the effects of aromatherapy using sour lemon on nausea in patients undergoing chemotherapy [31].

When distribution and comparison between all groups about nausea and vomiting in response to all interventions. In total, the study's results revealed a significant reduction in post chemotherapy nausea for patients treated with Peppermint essential oil aromatherapy compared to the control group according to their mean and p value = 0.001. According to previous studies our study's findings align with earlier research, which showed a notable disparity in nausea and vomiting scores among the participants who received cardamom aromatherapy. The difference was statistically significant (p-value = 0.001) before and after the intervention [32]. Another study showed that peppermint aromatherapy significantly affected chemotherapy-induced acute nausea and vomiting with a p-value of 0.001 ($\alpha<0.05$) [31]. The results of the current study were supported by the study conducted in Turkey is a quasi-randomized controlled pilot study evaluated the feasibility and preliminary effects of massage and inhalation aromatherapies on chemotherapy-induced acute nausea/vomiting show the incidence of

nausea and retching was significantly lower in the massage group than in the inhalation and control groups (P <.001) [33]. Another study in Iran aimed to determine the effect of peppermint extract on the severity of nausea, vomiting, and anorexia in patients with breast cancer undergoing chemotherapy this study showed there was a significant difference between the 2 groups at 24 and 48 hours after the chemotherapy (P < .05), so that the mean score of the severity of nausea, vomiting, and anorexia in the experimental group was lower than in the control group (P < .05) [34].

According to the present study, implementing inhalation aromatherapy sessions had succeeded in reducing chemotherapy-induced nausea and vomiting in patients with cancer. After the implementation sessions, there was a significant difference in the Rhodes Index for nausea, vomiting scale among the study group compared to the control group.

Limitations

The fact that the study is new and the first in Iraq poses many challenges. The first is the difficulty of obtaining patients' consent to participate. The sampling was conducted from a single clinic, which may limit the generalizability of the findings to a broader population. Some patients did not continue to follow up on receiving aromatherapy.

Conclusion

The study findings showed a notable decrease in post chemotherapy nausea and vomiting among patient who received peppermint oil aromatherapy in comparison with the control group. Aromatherapy by inhalation were effective in reducing nausea and vomiting in patients with cancer treating by chemotherapy.

The findings of this study contribute to the growing body of evidence supporting the use of integrative oncology practices. By systematically assessing the impact of specific essential oils on CINV, this research provides a foundation for further exploration and validation of aromatherapy's efficacy in clinical settings. Future studies should aim to elucidate the mechanisms underlying the therapeutic effects of aromatherapy and identify optimal administration methods and dosages.

Recommendations

Based on the findings of this study, several recommendations can be made to further explore and integrate aromatherapy into the management of chemotherapy-induced nausea and vomiting (CINV):

1. **Clinical Implementation:**

Healthcare providers should consider incorporating aromatherapy as a complementary therapy for managing CINV in cancer patients. Essential oils such as ginger, peppermint, and lavender, known for their anti-emetic and calming properties, can be used to enhance patient comfort and improve treatment adherence.

2. **Education and Training:**

Medical and nursing staff should receive training on the safe and effective use of aromatherapy. This includes understanding the properties of different essential oils, appropriate administration methods, and potential contraindications.

3. **Standardized Protocols:**

Development and implementation of standardized protocols for aromatherapy use in oncology settings are recommended. These protocols should include guidelines on oil selection, dosage, administration methods, and monitoring of patient responses.

4. **Policy Development:**

Advocate for the inclusion of complementary therapies like aromatherapy in national cancer care guidelines and policies. This will ensure that patients have access to a wide range of supportive care options to manage the side effects of chemotherapy.

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