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Damask Rose Aromatherapy and the Anxiety of Endoscopic Candidate Patients: A Clinical Trial

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ABSTRACT

Introduction: Anxiety is one of the common problems among patients before undergoing invasive diagnostic techniques. One of these diagnostic techniques is gastrointestinal endoscopy. Aromatherapy is one of the complementary therapies to reduce anxiety.

Objective: This study aimed to determine the effect of aromatherapy with Damask rose on the anxiety of the patients before undergoing endoscopy.

Materials and Methods: This study is a clinical trial performed on patients referred to the Endoscopy Department of one of the educational and therapeutic centers in Rasht City, Iran, in 2019. The study sample was 70 patients divided into the intervention and control groups. After giving the informed consent form, the samples completed the demographic information questionnaire and Spielberger anxiety questionnaire. The intervention group received aromatherapy with 10% Damask rose essential oil, and the control group received aromatherapy with a placebo for 30 minutes. The anxiety questionnaire was completed again 30 minutes after aromatherapy. The data were analyzed using descriptive and inferential statistics (the paired t-test, Chi-square, independent t-test, and covariance test).

Results: Results showed that the Mean±SD age of participants was 41.05±13.15 years in the intervention (ranged 22-65 years) and 45.82±16.81 years in the control groups. Most participants were female (57.1%). After the intervention, the mean score of anxiety in the aromatherapy group (39.88±11.51) was lower than that in the control group with placebo (49.94±12.30), which was statistically significant (P=0.001).

Conclusion: This study showed that aromatherapy with Damask rose essential oil was effective on pre-endoscopic anxiety of the patients. Since complementary medicine is increasingly practiced in nursing care, Damask rose aromatherapy, because of its low cost, safety and simplicity, can be used as a complementary measure to reduce anxiety in patients before endoscopy. However, more studies with intervention, control, and routine groups are needed to confirm the effectiveness of aromatherapy in endoscopy.

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Highlights

- Aromatherapy is one of the complementary therapies to reduce anxiety.
- Complementary medicine is increasingly practiced in nursing care.
- Results showed that after the intervention, the mean score of anxiety in the aromatherapy group was lower than the control group with placebo.
- Damask rose aromatherapy, due to its low cost, safety and simplicity, can be used as a complementary therapy to reduce anxiety in patients before endoscopy.

Plain Language Summary

Anxiety is one of the common problems among patients before undergoing invasive diagnostic techniques. One of these techniques is gastrointestinal endoscopy. Aromatherapy is one of the complementary therapies to reduce anxiety. This study aimed to determine the effect of aromatherapy essential oil on the anxiety of the patients before endoscopy. This study is a clinical trial performed on patients referred to the Endoscopy Department of the educational and therapeutic center in Rasht City, Iran, 2019. The study sample was 70 patients that were divided into the intervention and control groups. After giving the informed consent form, the patients completed the demographic information questionnaire and anxiety questionnaire. The intervention group received aromatherapy with 10% Damask rose essential oil, and the control group received aromatherapy with a placebo for 30 minutes. The anxiety questionnaire was completed again after aromatherapy. The data were analyzed using descriptive and inferential statistics. Results showed that after the intervention, the mean score of anxiety in the aromatherapy group was lower than the control group with placebo, which was statistically significant. The study results showed that aromatherapy with Damask rose essential oil was effective on pre-endoscopic anxiety in patients. Since complementary medicine is increasingly practiced in nursing care, Damask rose aromatherapy, because of its low cost, safety and simplicity, can be used as a complementary measure to reduce anxiety in patients before endoscopy.

Introduction

Timely diagnosis of gastrointestinal disorders is as vital as early diagnoses of other body organ problems [1]. Upper gastrointestinal endoscopy is one of the main diagnostic tools for evaluating and examining the upper gastrointestinal tract [2]. About 1% of the world's population underwent an endoscopy annually. In Britain, more than 10 people per 1000 individuals have undergone this process, and this number reaches more than 15 in some regions [3]. The endoscopy procedure may cause anxiety, feeling harm, unsafety, and discomfort. Moreover, false beliefs such as pain, choking, or exacerbation of fundamental concerns, such as the possibility of transmission of infection through the endoscope, exacerbate patients' fear and anxiety and decrease their cooperation in the process [2, 4].

Anxiety caused by endoscopy is classified into four groups of sensory disorders (e.g., pain), inappropriate outcomes (e.g., fear of cancer diagnosis), inefficiency (e.g., inadequate information about treatment), and various causes (e.g., fear of a physician) [5]. Anxiety during endoscopy is a severe problem among those referring to gastroenterology clinics and diagnostic and treatment departments. The high anxiety level can lead to failure to perform a complete diagnostic procedure, hard and painful procedure, increased use of analgesics, and a higher possibility of associated outcomes. Studies show that the number of patients who experience anxiety before undergoing endoscopy is alarmingly significant. As such, it is recommended that serious measures be taken to reduce the fear and anxiety of patients [1, 6, 7]. Some studies have estimated the prevalence of anxiety before endoscopy to be between 49% and 60% [8, 9].

In recent years, special attention has been paid to complementary therapies, and nurses in more than 30 countries use complementary therapies, including aromatherapy, in holistic nursing care [10]. Nurses are the most crucial healthcare team members who play an essential role in maintaining health and saving patients' lives. One of the critical roles of nurses is alleviating anxiety

in patients. Nurses take measures to reduce anxiety in patients before diagnostic and therapeutic methods. For instance, they encourage patients to take a deep breath before injection, explain the feelings they might experience during the diagnostic and treatment processes, and provide them with the necessary educations [5, 7].

Moreover, various pharmacological and non-pharmacological methods control and alleviate patients' anxiety [2]. Benzodiazepines and specific serotonin reuptake inhibitors, and tricyclic antidepressants reduce anxiety [11, 12]. In addition to side effects, the application of these drugs results in increased treatment costs, a longer duration of processes, and more personnel to monitor and treat patients [7, 9].

Today, pharmaceutical treatment is no longer the best method of reducing anxiety in patients due to numerous side effects [9]. Despite the production of various anxiolytic drugs, many patients may experience anxiety [2, 11]. Some of the advantages of complementary medicine include cost-effectiveness, simple implementation, non-invasiveness, non-pharmaceutical, and no chemical complications [13].

Aromatherapy is the knowledge of using plant-based extracts to improve health and recovery [5]. It is one of the non-pharmacological treatments that can reduce stress and anxiety. This method affects the senses through smell [14, 15]. In this regard, one of the plants used is the Damask rose plant with the scientific name of Rosa damascena. The pharmaceutical mechanism of the damask rose action is related to its abundance containing phenolic, flavonoid, and terpenes compounds [16]. Phenolic compounds comprise a wide range of pharmaceutical activities, such antioxidant, anti-inflammatory, antidepressant, cleansing, and anti-cancer [17]. Several studies have evaluated the decrease in patients' anxiety using non-pharmaceutical methods. In research by Dehkordi et al., aromatherapy with 2% Damask rose affected the anxiety of patients undergoing hemodialysis [18]. On the other hand, Fazlollahpour et al. reported that aromatherapy with a 4% Damask rose had no impact on the anxiety of open-heart surgery candidates [19]. According to the researcher's work experience in the Internal Diseases ward, patients usually have some degree of anxiety before endoscopy. Now, non-invasive and non-pharmacological approaches have gained popularity in control and reducing anxiety in patients. In this regard, the patients are educated on the importance, procedure, and feeling during the procedure. Also, the sedatives such as Midazolam are used in patients with high anxiety.

Regarding the conflicting results on the impact of complementary therapies in various studies and few studies in the field of effect of aromatherapy with Damask rose on the anxiety of patients undergoing endoscopy, we aimed to determine the effect of aromatherapy with Damask rose on the level of anxiety of patients before an endoscopy.

Materials and Methods

This clinical trial study was performed in Rasht City, Iran, in 2019. The number of samples was determined based on a 5% Type I error (α) and 80% test power (1-β) and study of Tahmasbi 35 participants per group. According to this on the effect of aromatherapy on anxiety in patients undergoing coronary angiography, the Mean±SD of anxiety of Spielberger was 44.27±4.54 in the intervention group and 47.83±4.35 in the control group after the intervention [13].

The inclusion criteria were being ≥18 years old; undergoing gastrointestinal endoscopy for the first time; not having emergency endoscopy or active mental and anxious diseases; not having a history of eczema and allergies, chronic headaches, and severe emotional stress around the time of endoscopy; lacking the impaired sense of smell and use of anxiolytics drugs based on the patient›s medical records; and obtaining a history from the patient. The exclusion criteria included feeling acute pain during the study.

The study data were collected with a demographic questionnaire and Spielberger state-trait anxiety inventory (STAI), which is a valid and standard tool [20]. STAI has 20 items and is scored based on a 4-point Likert-type scale. For positive questions (questions 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20) the options are 4= very low, 3= low, 2= high, and 1= very high and in negative questions (questions 3, 4, 6, 7, 9, 12, 13, 14, 17, and 18) the options are 1= very low, 2= low, 3= high, and 4= very high. The final score range of STAI is 20-80, where a higher score indicates a greater anxiety level [20]. The Cronbach alpha of STAI has been reported 0.91 [20, 21].

In the present study, to determine the reliability of the Spielberger anxiety instrument, a pilot study was performed with 20 endoscopic candidate patients out of 70 study samples based on the inclusion and exclusion criteria. Then the reliability of the instrument was 0.7 with the Cronbach alpha test. This value indicates the appropriate reliability of the tool.

After receiving the necessary permissions, the researcher referred to the research setting (Endoscopy Ward at one of the educational and therapeutic centers in Rasht). The researcher explained the research objectives to the patients and obtained their informed consent.

The samples were selected by convenience sampling method (the samples that were referred daily for endoscopy, 7-10 patients per day, in the research environment and met the inclusion criteria). The patients in the two groups were completely unaware of the other group and their differences (single-blind study). Random allocation of the participants was carried out using the lottery. In this way, after selecting the eligible patients, a lottery container containing two folded papers with numbers 1 and 2 was given to the patient to draw a number randomly, and the number indicated the group in which the sample was placed (No. 1 intervention group and No. 2 placebo group). After completing the number of samples in one group (for example, 35 people in the intervention group), the samples were collected by the same lottery method for the remaining group (placebo) until the end of sampling.

After completing the questionnaires, the intervention process was performed 1 h before the endoscopy procedure in the endoscopy ward in the intervention group. It involved adding two drops of 10% Damask rose oil extract on a cotton ball, attaching it to the patient's collar using a safety pin, and asking the patient to breathe normally for 30 minutes. Various studies have reported that the aroma affects the anxiety level 15-30 minutes after inhalation [17, 22].

Rose oil is obtained from Rosa damascena species from Kashan farms in the center of Iran. This essential oil is extracted by a hydro-distillation method at laboratory temperature 25°C by Tabib Daru Company, and the solution with 100% concentration and pale yellow color was the same color as placebo solution, and it was converted to a concentration of 10% by an expert in the laboratory based on another study [23] about aromatherapy with rose Damask.

Based on the opinion of a gastroenterologist, who was the consultant of the present research project and the expert of Tabib Daru Company, a placebo was selected for the control group. Therefore, in this study, unscented soybean oil was used, which in appearance and color was similar to rose Damask essential oil but without its properties.

In the control group, two drops of placebo were used, similar to the intervention group. Patients in the two groups were in separate ward rooms. These rooms were in the same condition in terms of size, light, temperature, humidity, ventilation, etc., and both rooms were in the endoscopic section and had no connection. The control group had no relationship with Damask rose extract. The study was single-blind, and the samples did not know whether they were in the intervention or control group (Figure 1). Also, due to different physical and mental conditions in hospitalized and outpatient patients, only outpatients were included in the study.

Ultimately, the STAI was completed by all participants 30 minutes after the intervention. A researcher read the questionnaire for all patients, and the patient's response was marked. The obtained data were analyzed in SPSS v. 21 with descriptive and inferential (the paired t-test, independent t-test, Chi-square, and covariance test) statistics.

Results

In this study, the Mean±SD age of the patients was 41.05±13.15 years in the intervention (ranged 22-65 years) and 45.82±16.81 years in control groups (ranged 18-76 years), and there was no significant difference between the two groups in this regard based on results of independent t-test. Other samples' demographic characteristics were shown in Table 1.

According to the results, no significant difference was found between the Mean±SD anxiety of patients in the intervention (44.91±13.58) and control (50.45±11.62) groups before aromatherapy. However, the Mean±SD anxiety decreased in the Damask rose group (39.88±11.51), compared to the placebo group (49.94±12.30), showing a significant difference (P=0.001) in this regard (Table 2).

Similarly, the paired t-test demonstrated a significant difference between the Mean±SD anxiety before and after the Damask rose aromatherapy process, in a way that the Mean±SD anxiety of the intervention group decreased from 44.91±13.58) to 39.88±11.51 after the intervention (P=0.006).

Because of significant differences in hospitalization history between the two study groups, a covariance test was used to evaluate the effect of the inpatient variable. Due to the significance of the covariance table, a suitable model has been obtained. But there was no interaction between the factor variable (aromatherapy) and the intervening variable (hospitalization history) (P=0.19, Eta=0.02, df=1, F=1.73), so it seems that these two variables did not affect post-intervention anxiety (Table 3).

Table 1. Patients' demographic characteristics

Variables		No. (%)	No. (%)		Sig.*
			Experimental	Placebo	
Gender	Female	40 (57.1)	24 (68.6)	16 (45.7)	0.090
	Male	30 (42.9)	11 (31.4)	19 (54.3)	
Marriage	Single	16 (22.9)	11 (31.4)	5 (14.3)	0.102
	Married	52 (74.3)	24 (68.6)	28 (80.0)	
	Widow or divorced	2 (2.9)	0 (0.0)	2 (5.7)	
Education	Under the diploma	34 (48.6)	14 (40)	20 (57.1)	0.086
	Diploma	18 (25.7)	11 (31.4)	7 (20.0)	
	Academic	18 (25.7)	10 (28.6)	8 (22.9)	
Job	Housewife	26 (37.1)	14 (40.0)	12 (34.3)	0.522
	Employee	10 (14.3)	6 (17.1)	4 (11.4)	
	Worker	6 (8.6)	1 (2.9)	5 (14.3)	
	Self-employed	22 (31.4)	11 (31.4)	11 (31.4)	
	Unemployed	6 (8.6)	3 (8.6)	3 (8.6)	
Signs & Symptoms	Pain	42 (60.0)	20 (57.1)	22 (62.9)	0.081
	Heart burn	20 (28.6)	9 (25.7)	11 (31.4)	
	Other	8 (11.4)	6 (17.2)	2 (5.7)	
Hospitalization history	Yes	31 (44.3)	9 (25.7)	22(62.9)	0.002
	No	39 (55.7)	26 (74.3)	13 (37.1)	
Smoking	Yes	9 (12.9)	5 (14.3)	4 (11.4)	0.721
	No	61 (87.1)	30 (85.7)	31 (88.6)	

* Chi-square test.

Discussion

This study aimed to evaluate the effect of aromatherapy with Damask rose extract on the anxiety levels in candidate patients for an endoscopy. According to the results, aromatherapy with the Damask rose extract significantly decreased anxiety in patients before the endoscopy process. In this regard, our findings are in line with the results obtained by Dehkordi et al., who reported a decrease in the anxiety of patients undergoing hemodialysis after aromatherapy with Damask rose extract [18]. In that study, once the patient was connected to the dialysis machine, a piece of cloth smeared with three drops of the 2% Damask rose oil was attached to the patient's collar, and the patient was asked to breathe normally. The intervention was decided to last 1 h [18]. In another study by Tazakori et al., aromatherapy with oral Damask rose extract (drink 15 drops of Damask rose extract in water every 8 hours up to three times) significantly reduced patients' anxiety before angiography [24]. Also, in the study of Barati et al., the intervention group had three drops of rose water at a concentration of 25% each night before sleeping (in front of their noses for 15 to 20 minutes) and also 15-20 minutes before beginning dialysis sessions (for 4 weeks) [23]. They reported the significant effect of Damask rose aromatherapy on the anxiety of patients undergoing hemodialysis [23]. Another research evaluated the effect

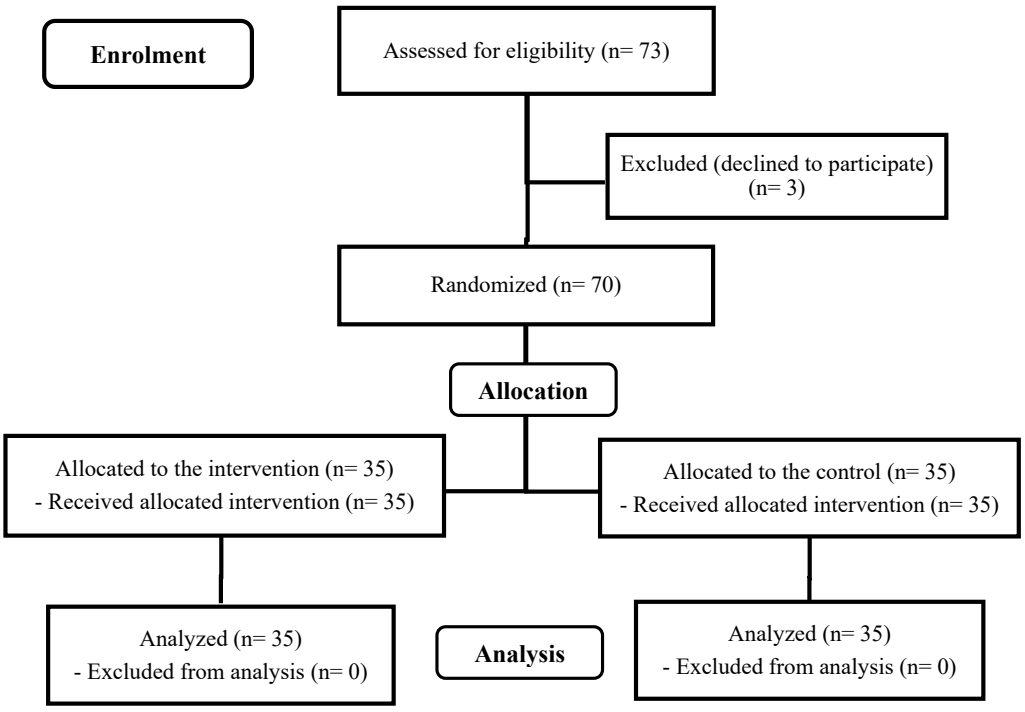

Figure 1. CONSORT flow diagram for the study

of aromatherapy with 1% rose essential oil inhaled for 10 minutes, and at the same time, a foot bath with rose essential oil with 40°C water was performed for 10 minutes on active pregnancy anxiety in primiparous women [22]. They reported a significantly lower anxiety level in the test group than the control group [22].

Consistent with our findings, most studies have indicated the positive effect of aromatherapy with Damask rose extract on patients' anxiety undergoing invasive diagnostic and therapeutic procedures. The pharmaceutical performance of the Damask rose is related to its phenolic compounds [16]. The compounds comprise a wide range of pharmaceutical activities; for example, they reduce depression, sadness, stress, anxiety, and tension [24], which justifies aromatherapy effect with rose on patients' anxiety. The results of this study are in line with similar studies that confirmed the effect of aromatherapy with rose Damask on reducing anxiety. Therefore, researchers can conduct further studies and perform systematic review and meta-analysis studies to provide more effective nursing care in this area.

However, previous studies did not examine anxiety in endoscopy, and the procedures in these studies were very diverse. Also, invasive procedures such as endoscopy, angiography, hemodialysis, and surgery are very different in terms of how to perform, duration of the procedure, the extent and severity of invasiveness, and the type of disease of the samples under study. Therefore, further studies on the effect of rose aromatherapy on anxiety in endoscopic patients are recommended to confirm the present study results.

The present study results were in contrast to Fazlollahpour- Rokni study. The results of their study indicated no

Table 2. Determine the difference of anxiety in the two study groups before and after the intervention

Anxiety	Groups	No.	Mean±SD	Std. Error Mean	Sig.*
Before the intervention	Damask rose	35	44.9143±13.58280	2.29591	0.07
	placebo	35	50.4571±11.62994	1.96582	
After the intervention	Damask rose	35	39.8857±11.51667	1.94667	0.001
	placebo	35	49.9429±12.30720	2.08030	

* t-test.

Table 3. Analysis of covariance to evaluate the effect of hospitalization history on the anxiety score after aromatherapy in the intervention and control groups

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	2677.27	3	892.42	6.73	0.0001	0.23
Group (intervention+control)	936.07	1	936.07	7.05	0.010	0.09
Hospitalization history	593.89	1	593.89	4.47	0.04	0.06
Group hospitalization history	230.29	1	230.29	1.73	0.19	0.02
Error	8752.21	66	132.60			
Corrected total	11429.48	69				

effect of aromatherapy with Damask rose extract on the anxiety of patients undergoing coronary artery bypass surgery. In their study, the experimental group inhaled three drops of 4% rose essential oil for 10 min 1 night and 1 h before surgery [19]. This inconsistency might be due to different research samples and the aggressiveness of the medical procedures. For instance, Fazlollahpour et al. evaluated anxiety in patients undergoing open-heart surgery, while in the present study it was on endoscopic patients who might experience less severe mental and physical issues due to the low aggressiveness endoscopy than the surgical procedure. In addition, the ineffectiveness of aromatherapy with Damask rose extract might be due to the severity of anxiety and extreme stress levels in patients undergoing open-heart surgery.

Our results showed that the hospitalization history in our two study groups had a statistically significant difference, but the samples of the two groups were under endoscopy for the first time according to the inclusion criteria, and accordingly, the main variable was endoscopic anxiety, not hospitalization anxiety.

One of the limitations of this study is the lack of a double-blinding process because of the type and nature of the intervention. Another study limitation was the difference in the duration of the disease and the history of hospitalization in patients, which could affect the anxiety score after the intervention. This limitation was controlled using the analysis of covariance.

It is suggested that further experimental studies in this field be designed by controlling the known interfering factors in this study. Also, because the present study did not have a routine group, we recommend that another study be performed with three groups of intervention, control, and routine on the effect of aromatherapy on anxiety before endoscopy.

It is also recommended that the effect of aromatherapy with Damask rose extract be studied in patients undergoing invasive diagnostic methods and surgeries based on different anxiety levels of samples. Our findings confirmed the positive effect of aromatherapy with Damask rose extract on patients' anxiety before the endoscopy. Given the decrease of anxiety in these individuals, it seems that this extract can be used before invasive procedures. In addition, the application of the Damask rose extract prevents unwanted complications of chemical drugs. Since complementary medicine is increasingly practiced in nursing care, aromatherapy with Damask rose extract can reduce anxiety in patients before an endoscopy and can be applied as a complementary method to alleviate anxiety in patients.

Ethical Considerations

Compliance with ethical guidelines

This study was part of the proposal approved by the Deputy of Research and Technology of Guilan University of Medical Sciences (Code: IRCT20180303038934N1) in Iran Clinical Trials Registration Center (Ethics Code: IR.GUMS.REC.2017.462).

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Authors' contributions

Conceptualization: Maryam Mirzaee Jirdehi and Arezoo Monfared; Methodology, writing the original draft, funding acquisition, resources, and supervision: All authors; Investigation: Maryam Mirzaee Jirdehi and Arezoo Monfared; Editing and review: Maryam Mirzaee Jir-

dehi, Arezoo Monfared, Friborz Mansour Ghanaei and Ehsan Kazemnezhad Leili.

Conflict of interest

The authors declared no conflict of interest.

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