

Protocol

The effect of relaxation breathing exercise on chemotherapy induced nausea and vomiting in patients with hematological malignancies

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ABSTRACT

Background: Chemotherapy is widely used in the treatment of hematological malignancies despite it has important and difficult side effects in patients. Chemotherapy induced nausea and vomiting are among the most common side effects in patients and antiemetic drugs may not be always curative. This research aimed to determine the effectiveness of relaxation breathing exercise on managing chemotherapy induced nausea and vomiting in patients with hematological malignancies undergoing chemotherapy.

Methods: A randomized controlled trial design was conducted with a total of selected sixty-eight patients with hematological malignancies (34 intervention and 34 control participants) undergoing chemotherapy hospitalized in the hematology clinic of a training and research hospital. The intervention group implemented relaxation breathing exercise three times a day with a standard treatment protocol and the control group only received routine drug treatment for chemotherapy induced nausea and vomiting. Nausea and vomiting were assessed by filling Rhodes index of nausea vomiting and retching (RINVR) for the first six days after the start of the chemotherapy. Data collection process ended. Data analysis process is in progress.

Conclusions: In this study the effectiveness of relaxation breathing exercise on chemotherapy related nausea and vomiting will be examined in patients with hematological malignancies.

Trial Registration: The study was registered at clinicaltrials.gov.tr (Registration No: NCT07456982).

Keywords: Relaxation breathing exercise, Hematological malignancies, Chemotherapy, Nausea and vomiting

INTRODUCTION

Chemotherapy is still widely used for the treatment of hematological malignancies.¹⁻³ The side effects of chemotherapy occur as a result of decreased immune function. Determining the symptoms that may develop due to chemotherapy and applying individualized healthcare are important in improving the quality of life of the patients.^{4,5} The major side effects of the chemotherapy are nausea and vomiting.^{6,7} Over the last two decades, the incidence of chemotherapy-induced nausea and vomiting (CINV) has increased considerably. 61% of patients taking chemotherapy drugs complain about this situation.⁸ Despite the proper administration of pharmacological

agents, nausea and vomiting remain a clinically important side effect for patients who receive chemotherapy.⁹ Antiemetics commonly used in the treatment of CINV include serotonin (5-HT₃) receptor antagonists, neurokinin-1 receptor antagonists, steroids, dopamine receptor antagonists, or olanzapine. These are used based on the emetogenic effect of the drugs and the patient's type of nausea and vomiting.¹⁰ The drugs may not always be effective in each patient therefore it is difficult for patients with hematological malignancies to cope with it.^{11,12} It will be necessary to manage symptoms based on chemotherapy induced nausea and vomiting. Non-pharmacological methods including breathing exercises, relaxation exercises, acupuncture, reflexology, aromatherapy, music

therapy or herbal treatments are used today to reduce symptoms of CINV.^{12,13} It is also known that non-pharmacological methods are simpler and more cost-effective than pharmacological methods and have no side effects.^{1,11}

There are some types of breathing exercises e.g. pranayama (yogic breathing), diaphragmatic breathing, deep breathing.^{14,15} One of the breathing exercise is relaxation breathing exercise (RBE) which includes relaxation techniques such as consciously stretching and relaxing the muscles with diaphragmatic breathing.^{13,16} Evidence presents to recommend that relaxation technique and diaphragmatic breathing are influential for patients undergoing chemotherapy in reducing the intensity and duration of CINV.¹⁷

It is known that patient's psychological status is a risk factor for CINV.¹⁸ Relaxation therapy involves regular muscle stretching and relaxation with deep breathing to moderate stress and anxiety of the patient and the sensitivity of the digestive system.¹⁹

Nurses play an active role in protecting patients from CINV and improving health. The implementation of chemotherapy by the nurses and the observation of its side effects are the indicators of how important their role is.²⁰ Controlling nausea and vomiting, ensuring fluid-electrolyte balance, and maintaining normal fluid and food intake are the basic goals of patient care.⁹

Furthermore, RBE can be a cost-effective method to reduce CINV and to improve the general condition of patients with hematological malignancies.^{5,13}

If the nurses can learn how to practise the relaxation breathing exercise, they can teach patients RBE for the management of CINV as a nonpharmacological method in the hematology clinics of the hospitals.

Many studies have been conducted on breathing exercises with cancer patients. Some of them demonstrated that breathing exercises reduced the level of pain, anxiety and depression, increased inspiratory capacity and quality of life in cancer patients.^{21,22} Few studies showed that relaxing and breathing exercises had a positive effect on CINV.¹⁷

Nevertheless they are limited to determine the relationship between CINV and relaxation breathing exercise. The study aims to evaluate the effectiveness of relaxation breathing exercise to administrate CINV in patients with hematological malignancies undergoing chemotherapy.

Null hypothesis

Relaxing breathing exercise does not affect chemotherapy-induced nausea, vomiting, and retching in patients with hematological malignancies.

METHODS

Study design

The research was designed as a randomized controlled study including experimental and control groups. It was conducted between January 2024 and September 2025 with patients who were hospitalized in the hematology clinics of a university training and research hospital in Istanbul, Turkey. The participants were randomly assigned and the number of the participants in each group were equal. Consolidate standards of reporting trials (CONSORT) recommendations were followed.

Setting

The research was conducted in the hematology clinics of a university training and research hospital in Istanbul, Turkey. Hospitalized patients with hematological malignancies who underwent chemotherapy were included in the research. Hematology patients apply to the hematology polyclinics in the hospital and then patients who are diagnosed with hematological malignancies such as leukemia, lymphoma or multiple myeloma and will receive chemotherapy are hospitalized. The researcher planned to help patients to cope with nausea and vomiting while they were receiving chemotherapy in this study. Before the chemotherapy had been started, the relaxation breathing exercise training was provided to the hospitalized patients in their rooms who agreed to participate in the study. After training a guidebook about relaxation breathing exercise was given to the patients so that they would not forget how to implement the intervention

Selection criteria

Inclusion criteria were patients: aged 18 years or over with hematological malignancies, undergoing chemotherapy, and not having any communication problems (able to read, write and speak Turkish).

Exclusion criteria of the study were patients: having psychiatric and mental problems, receiving radiotherapy concurrent with chemotherapy, having respiratory distress, having central nervous system involvement, having grade 3 or grade 4 nausea and vomiting. Because patients having these conditions are unable to implement RBE properly.

Intervention

Administration of the RBE

There are three stages of the relaxation breathing exercise.

Preliminary exercise

Participants lie comfortably on their backs in the bed and focus on the lower abdomen. They place their left ankles over their right knees and then place their right ankles over

their left knees. They draw both knees toward their abdomens.

Relaxation breathing

Participants relax while breathing deeply through their noses and letting them out through their mouths slowly. They count to four and breathe in deeply, they hold their breathe while counting to four, and breathe out while counting to eight.

Ending exercise

Participants stretch their arms and legs and then loosen them. They relax the muscles concerned with their faces, shoulders and eyebrows by keeping their mind clear.

Outcomes

The results of the study are the effect of the measurements taken daily for six days by using Index of Rhodes nausea vomiting and retching after the chemotherapy has been started.

Participant timeline

The researcher had attended a course on breathing coaching and got the certificate priorly. The patients with hematological malignancies hospitalized who were going to receive chemotherapy and the health team were informed about the aim and procedure of the study. After the written consent was obtained from the patients who

met the inclusion criteria, the experimental and the control groups were formed according to the randomization method. Before chemotherapy, the patient information form was requested to be filled out by all participants in both experimental and control groups in a face-to-face interview. The patients in the intervention group were trained about the application of the relaxation breathing exercise by the researcher before starting chemotherapy. The training lasted 20 minutes. After training, a guideline about RBE was given to each patient in the intervention group. When chemotherapy was started, the researcher wanted him/her to perform the RBE correctly and effectively and to fill RINVR once a day specially at the same time for six days. Each RBE session lasted ten minutes, three times a day (in the mornings, afternoons and nights) took 30 minutes in total everyday. Nausea and vomiting were followed up for 6 days after the chemotherapy had been started because CINV typically presents over a 6-day period after starting chemotherapy.^{23,24} The patients in the intervention group were monitored by the researcher while they were doing the exercise. On the other side, the control group filled RINVR once a day for the first six days after the chemotherapy had been started. No intervention was performed on the patients in the control group, they were just followed up in the standard procedure.

Implementation of the study

The CONSORT flow diagram of the research is demonstrated in Figure 1.

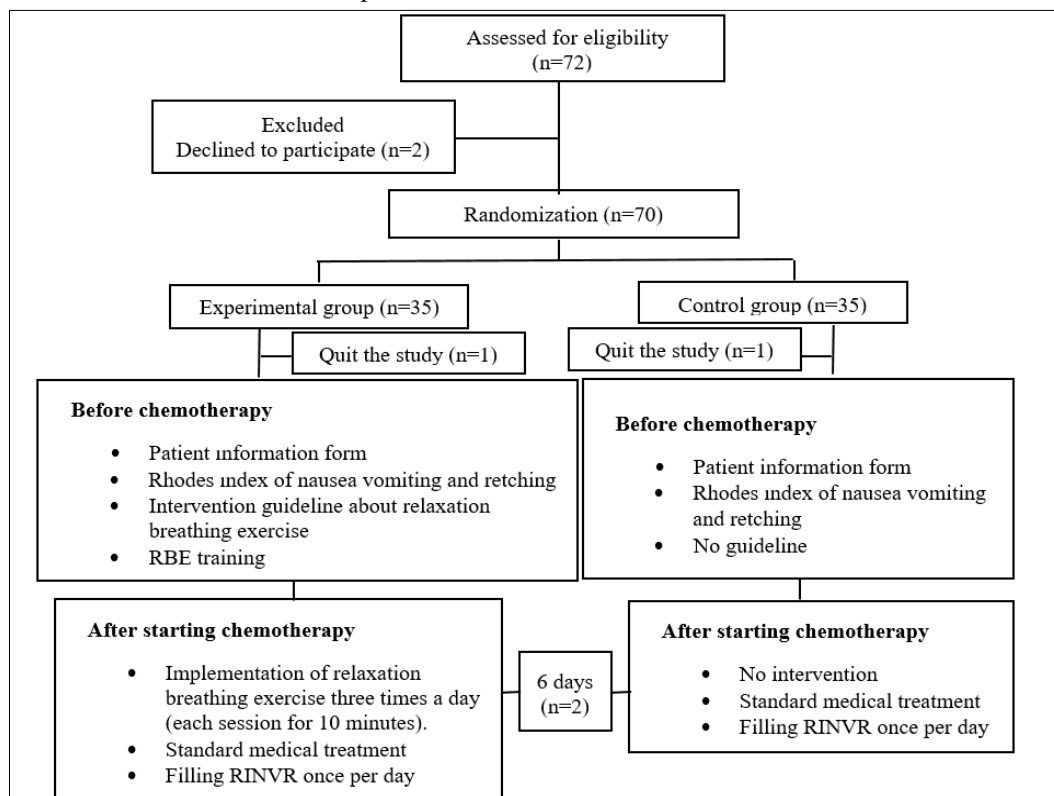


Figure 1: Flowchart of the study.

Sample size

Power analysis was performed using G*Power version 3.1.9.2. The sample size was determined to set a difference between the nausea and vomiting scores of two independent groups for six days after chemotherapy (β =type II error, power of 0.80) with a significance level of 0.05 and an effect size of 0.80 ($d=0.8$). It is calculated that there should be at least 26 participants in each group. Considering drop-out rate of participants such as deterioration of general condition or quitting the study, 74 patients were included in the study. The sample of the study consisted of 34 patients in the intervention group and 34 patients in the control group, totally 68 hospitalized patients with hematological malignancies receiving chemotherapy.

Randomization

While creating the intervention and control groups, patients were randomized according to their hospitalization order. The initial group was determined by coin tossing. Heads was determined as the experimental group, tails as the control group, and if the coin toss came up heads, the first patient was assigned to the experimental group, the second patient admitted to the control group, and the third patient to the experimental group one to one and so on. A coin was tossed and it came up heads first. So first patient was assigned to the experimental group, second patient was assigned to the control group and the third one to the experimental group and proceeded in this way. This process continued until all participants in the sample were assigned to the groups so that at the end of the assignment process, equal numbers of subjects were placed in both groups.²⁵ Coin tossing was used to keep the number of participants in both groups balanced and to reduce bias. It is also a simple and an easy technique. All of the participants in the study were blinded to the randomization method. On the other hand, blinding could not be used for the researchers due to the property of the RBE intervention. The intervention was explained to the patients and the RBE guidelines were given to them.

Data collection

It was conducted between January 2024 and September 2025 with patients who were hospitalized in the hematology clinics of a university training and research hospital in Istanbul.

Data collection instruments

Patient information form

Patient Information Form includes both sociodemographic and disease-related characteristics of the patients. Questions about sociodemographic characteristics of patient consists of age, gender, marital status, education status, working status, income status, smoking and alcohol consumption. The other questions concerned disease were

the diagnose of the illness, emetogenicity level of the chemotherapy regimens received by the patients and status of previous undergoing chemotherapy.

Rhodes index of nausea vomiting and retching (RINVR)

RINVR is a Likert-type scale first developed by Rhodes in USA, 1999 and is used worldwide. The scale assesses the number, duration and severity of nausea, vomiting and retching experienced within a period of 24 hours after undergoing chemotherapy.²⁶ It had been adapted into Turkish for validity and reliability by Genç and Tan in a study and the Cronbach's alpha coefficient had been found to be 0.95 and varied between 0.81 and 0.95 for the subgroups.²⁰ The scale is divided into three sub-dimensions: nausea, vomiting and retching, consisting of a total of 8 items, three items for nausea, three items for vomiting and two items for retching. There are five levels for each item and are scored between 0 and 4, respectively. "0" is not present at all, "1" is mild, "2" is moderate, "3" is high and "4" is very serious and unbearable. A minimum score of 0 and a maximum score of 32 are calculated for nausea, vomiting and retching. The higher the score for each dimension, the more severe the degree of nausea, vomiting and retching. Items 1, 3, 6 and 7 should be reversed to score RINVR. All items need to be summed together to calculate the total score.

Data analysis

Data were entered into the statistical program by the researcher. The data analysis of the research will be performed in the computer environment by using statistical package for the social sciences (SPSS), and the results will be evaluated at a confidence interval of 95%, and significance at $p<0.05$ level. Parametric or nonparametric tests will be conducted based on how data is distributed.

Harms

No unwanted or unexpected effects were occurred on the participants. The researcher followed up with the patients face to face or video calls on the phone.

Auditing

The patient compliance was ensured by the researcher in the study. The survey was prepared and the questions of the survey were asked to the patients face to face and completed by the researcher. A guidebook was printed to inform patients about the procedure.

Ethical consideration

The research was approved by Marmara University, Faculty of Medicine Ethics Committee in Turkey (Protocol No:09.2020.1036). Written permissions were obtained first from the Research and Development Department of Marmara University Training and Research

Hospital and then from the Provincial Health Directorate (Decision No: 2022/09). A consent form including patient's rights and responsibilities was obtained from the patients who were explained and want to participate in the study.

Ancillary

No participants were charged and no budget was received from anyone or any institution for the research.

Dissemination policy

The results of the research are planned to be shared through publication in an international peer-reviewed scientific journal.

DISCUSSION

Due to the nausea and vomiting induced by the chemotherapy, patients are at risk of life, threatening conditions such as dehydration, fluid-electrolyte imbalance, and malnutrition.²³ Therefore, optimizing treatment effectiveness will be necessary to improve quality of life and survival.²⁷ Complementary and alternative therapies are one of the important approaches. These treatments can be applied as standalone therapies or as part of other standard therapies for cancer patients.²⁸ Relaxation breathing exercise is included among complementary and alternative therapies.²⁹

Ulger and Yagli (2010) concluded that yogic breathing exercise help to relax and reduce stress, assist cancer patients in performing daily and routine activities, and improve the quality of life in cancer patients.³⁰ One study highlighted that breathing exercise performed on breast cancer patients who experienced chemotherapy-induced nausea and vomiting can help them manage their symptoms on their own.¹⁷ Therefore, training patients on relaxation breathing exercise to reduce chemotherapy-induced nausea and vomiting is important for alleviating or eliminating the distress caused by nausea and vomiting and improving patients' functional status.

CONCLUSION

This research is the first trial examining the effect of the relaxation breathing exercise on CINV in patients with hematological malignancies. The study suggests that RBE intervention, can alleviate CINV, prevent malnutrition and provide quality of life in patients undergoing chemotherapy. The data will be an evidence in clinical oncology nursing. It will help the other researchers to pave the way related to this topic.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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