

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

"Effect of Massage and Aromatherapy on Nausea and Vomiting of Patient with Chemotherapy: A Randomized Control Trial"

Protocol summary

Study aim

1. To determine the effect of massage on reducing nausea and vomiting of patients with chemotherapy in adults' patients. 2: To determine the effect of aromatherapy on reducing nausea and vomiting of patients with chemotherapy in adults' patients. 3: To determine the effect of massage and aromatherapy on reducing nausea and vomiting of patients with chemotherapy in adults' patients.

Design

Comparative, randomized, controlled clinical trial with a parallel group design of 90 patients.

Settings and conduct

This study was conducted in the oncology centers of Wasit hospitals, where the study included 90 patients who entered the hospital to receive chemotherapy. They were divided into three groups, and a study was conducted on them.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adult patients aged (18 and above) years old diagnosed with cancer undergoing chemotherapy; voluntary participated in the study; read and write; Patients experiencing nausea and vomiting; have no problems communicating and are fully conscious. Exclusion Criteria: Patients who refused to participate in the study; patients with a history of allergy to massage oil or aromatherapy; had any record of respiratory diseases like asthma; patients with a history of psychiatric disorders; impaired vision and skin ulcers.

Intervention groups

Two groups/ massage groups apply foot massage for 15 minute with the use of Peppermint oil and aromatherapy groups inhale aroma for 10 minute

Main outcome variables

Reduced nausea and vomiting intensity caused by chemotherapy for patient with cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231027059871N1**

Registration date: **2024-01-23, 1402/11/03**

Registration timing: **retrospective**

Last update: **2024-01-23, 1402/11/03**

Update count: **0**

Registration date

2024-01-23, 1402/11/03

Registrant information

Name

Karrar Al zubaidy

Name of organization / entity

University of Baghdad/ college of nursing

Country

Iraq

Phone

+964 772 372 7372

Email address

karrar.abd2202m@conursing.uobaghdad.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-20, 1402/09/29

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"Effect of Massage and Aromatherapy on Nausea and Vomiting of Patient with Chemotherapy: A Randomized Control Trial"

Public title

Reducing Nausea and Vomiting in Patient-Related Chemotherapy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients aged 18 and above diagnosed with cancer and undergoing chemotherapy Read and write Patients experiencing nausea and vomiting Have no problems communicating Fully conscious.

Exclusion criteria:

Skin ulcer Patients with a history of psychiatric disorders Respiratory diseases like asthma Patients with a history of allergy to massage oil or aromatherapy Patients who have problems communicating and are unconscious

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to maintain a transparent and scientific-based randomization process, simple randomization will use three cards of different colors in a box for the sample to select one card that represents the group of the study. The yellow card represents the aromatherapy group, the blue card represents the massage group, and the black card represents the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethical Approval Committee, at the College of Nursing

Street address

5, Al-Jamiya District., Gold Street

City

Al-zubaidiya

Postal code

70001

Approval date

2023-11-22, 1402/09/01

Ethics committee reference number

4356/8/1/3/1

Health conditions studied**1****Description of health condition studied**

Chemotherapy Induced Nausea and Vomiting

ICD-10 code

C80.1

ICD-10 code description

Malignant (primary) neoplasm, unspecified

Primary outcomes**1****Description**

Nausea and Vomiting-related Chemotherapy

Timepoint

After 24 hours from intervention

Method of measurement

Rhodes Index Scale Rhodes index of nausea, vomiting and retching (24 hours after chemotherapy)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Massage therapy group: Patients receive regular massage sessions during chemotherapy in the foot area for 15 minutes using peppermint oil.

Category

N/A

2**Description**

Intervention group: Aromatherapy group: All patients were male and female lying in the supine position in the chemotherapy administration unit. Three drops of peppermint oil were placed with a dropper on a sterile gauze that was tied around the participants' collar for inhalation for 10 minutes while taking chemotherapy. After that, the Rhodes Index Scale was measured to evaluate the severity of nausea and vomiting 24 hours after taking the therapeutic dose.

Category

N/A

3

Description

Control group: Patients receive standard chemotherapy care without additional interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology Center

Full name of responsible person

Karrar Hassan Abd al Sada

Street address

5, Al-Dhahab Street., Al-Jamiya neighborhood., Al-Zubaidiyah city,

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Web page address

https://www.irct.ir/user/trial/74188/update/recruitment_center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Baghdad/ College of Nursing

Full name of responsible person

Karrar Hassan Abd AL Sada

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5, Al-Dhahab Street., Al-Jamiya District,

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Web page address

<https://www.irct.ir/user/trial/74188/update/sponsor>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Baghdad/ College of Nursing

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of Baghdad College of Nursing

Full name of responsible person

Karrar Hassan Abd AL Sada

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursing

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Web page address

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Person responsible for scientific inquiries

Contact

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Web page addresshttps://www.irct.ir/user/trial/74188/update/scientific_queries_contact**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Web page addresshttps://www.irct.ir/user/trial/74188/update/data_updater_contact**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The researcher acknowledges that the scientific community has verifiable findings from the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed, reputable journals

When the data will become available and for how long

Once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available

To whom data/document is available

All the related files will be shared with any scientific interested parties.

Under which criteria data/document could be used

It may be used after seeking the author's permission and acknowledging his contribution

From where data/document is obtainable

The author's professional email that will be available with the published manuscript can be used to contact the author. e-Mail: karrarhassan220@gmail.com

What processes are involved for a request to access data/document

N/A

Comments