

# 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,

**City**

Zubaidiyah city

**Postal code**

7723727372

**Phone**

+964 772 372 7372

**Fax**

**Email**

karrar.abd2202m@conursing.uobaghdad.edu.iq

**Web page address**

[https://www.irct.ir/user/trial/74188/update/recruitment\\_center](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

**Street address**

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

**City**

AL Zubaidiyah

**Postal code**

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**Email**

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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

**Street address**

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

**City**

Al -Zubaidiyah

**Province**

Wasit

**Postal code**

70001

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**Web page address**

[https://www.irct.ir/user/trial/74188/update/public\\_inquiries\\_contact](https://www.irct.ir/user/trial/74188/update/public_inquiries_contact)

**Person responsible for scientific 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**

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**Web page address**[https://www.irct.ir/user/trial/74188/update/scientific\\_queries\\_contact](https://www.irct.ir/user/trial/74188/update/scientific_queries_contact)**Person responsible for updating data****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**

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**Email**

karrar.abd2202m@conursing.uobaghdad.edu.iq

**Web page address**[https://www.irct.ir/user/trial/74188/update/data\\_updater\\_contact](https://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**