

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The influence of massage therapy on depression, anxiety and severity of nausea and vomiting in patient with breast cancer undergoing chemotherapy

Protocol summary

Summary

This study evaluates the effects of massage therapy on anxiety, depression, nausea and vomiting in patients with breast cancer undergoing chemotherapy. Subjects and Methods: This study was a clinical trial of 34 patients with breast cancer chemotherapy regimen TAC. After initial assessment of patients to make sure that they have some degree of depression and anxiety and have had nausea and vomiting during previous chemotherapy, patients randomly divided into intervention and control groups. Intervention group had three sessions of Stroke and Kneading back massage in addition to the usual care they received. Control group only received their usual care. Baseline information was gathered on the first day for both groups. 24 hours after each massage the following questionnaires were filled for the patients: the Beck Depression Inventory, Anxiety Spill Burger questionnaire, VAS (Visual Analogue Scale) and a form to record the number of vomitings were completed.

Keywords: breast cancer, massage, anxiety, depression, nausea, vomiting, chemotherapy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903244138N2**

Registration date: **2010-10-06, 1389/07/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-06, 1389/07/14

Registrant information

Name

Somaieh Bosak

Name of organization / entity

medical science university

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

pro vice chancellor for research

Expected recruitment start date

2009-12-14, 1388/09/23

Expected recruitment end date

2010-05-05, 1389/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The influence of massage therapy on depression, anxiety and severity of nausea and vomiting in patient with breast cancer undergoing chemotherapy

Public title

The influence of massage therapy on depression, anxiety and severity of nausea and vomiting in patient with breast cancer undergoing chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria 1 - All patients received at least one cycle of chemotherapy. 2 - had some degree of anxiety

and depression. 3 -complaining from nausea and vomiting after chemotherapy. 4. All the patients to receive ACTAXOL regimen. 5. be fluent in Farsi. Exclusion criteria 1 - any disease or condition that cause nausea and vomiting, such as intestinal obstruction, metastasis to the gastrointestinal tract and central nervous system, etc. 2 - Patients with chronic history of mental problems (such as chronic depression and anxiety, and use of antipsychotics). 3 -Patients who are using psychiatric drugs. 4 - use of chemotherapy with radiotherapy. 5 - use of other methods of alternative medicine or herbal treatments to control nausea and vomiting, depression and anxiety during the study. 6 - Ill patients that are unable to answer questions. 7. Any tumors, ulcers, burns, skin lesion in the lumbar area that may interfere with proper conduction of the massage

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 34

Randomization (investigator's opinion)

Randomized

Randomization description

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

Jondishapour medical university of Ahwaz

Street address

Central department, Ahwaz university of medical sciences, Golestan

City

Ahwaz

Postal code

Approval date

empty

Ethics committee reference number

8/20/484/پ

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

anxiety

Timepoint

24 hour

Method of measurement

Spillburger Anxiety questionnaire

2

Description

depression

Timepoint

24 hour

Method of measurement

Beck depression questionnaire

Secondary outcomes

1

Description

nausea

Timepoint

24 hour

Method of measurement

VAS questionnaire

2

Description

vomitting

Timepoint

24 hour

Method of measurement

form of number of vomiting

Intervention groups

1

Description

Control group: Standard care including antiemetic regimen Ketryl and Dexamethasone

Category

Treatment - Drugs

2

Description

Intervention group: standard care including antiemetic regimen Ketryl and Dexamethasone in addition to 3 sessions of Stroke and Kneading back massage each lasting 20 minute

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

center of oncology and radiation therapy of Golestan hospital

Full name of responsible person

Bahman Dashtbozorgi, Ahwaz University of Medical Sciences

Street address

Central library of

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz university of medicine

Full name of responsible person

Pro vice chancellor for research

Street address

Ahwaz University of Medical Sciences, Golestan

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Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz university of medicine

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Bahman Dashtbozorgi

Position

Member of Faculty of Nursing and Midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty