

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effects of yoga on the quality of life in breast cancer patients undergoing chemotherapy and radiotherapy

#### Protocol summary

##### Summary

The aim of this study was to investigate the effect of yoga on quality of life in breast cancer patients undergoing chemotherapy and radiotherapy. The four-group clinical trial was conducted in two stages, before and after the intervention. Population study was women with breast cancer referred to Syedalshohada "AS" hospital in Isfahan. In total, 80 female patients with breast cancer pathologic stage II and III were randomly sampled. Exclusion criteria included relapse, and disease duration was less than 2 weeks. Yoga intervention program was for 75 minutes a day in between, versus the control group was 8 weeks without getting any CAM. The instrument for data collecting included questionnaire demographic; quality of life questionnaire Organization for Research and Treatment of Cancer (Europe EORTC QLQ-C30); and a standard questionnaire specifically to assess quality of life in breast cancer (EORTC QLQ-BR23) which was conducted face to face interviews by a specialist oncology with patients, over three months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013071513998N1**

Registration date: **2013-08-07, 1392/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-07, 1392/05/16

##### Registrant information

###### Name

Faridokht Yazdani

###### Name of organization / entity

Islamic Azad University, Najafabad branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 33 1229 1111

###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Islamic Azad University, Najafabad branch

###### Expected recruitment start date

2012-05-21, 1391/03/01

###### Expected recruitment end date

2012-08-22, 1391/06/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effects of yoga on the quality of life in breast cancer patients undergoing chemotherapy and radiotherapy

###### Public title

Roll of yoga to improve the quality of life in breast cancer patients receiving chemotherapy

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criteria: 1 - having age between 25 to 65 years, 2 - a consciousness, 3 - ability to communicate and interact appropriately in completing the questionnaire, 4 - Pathological diagnosis of breast cancer, 5 - willingness of patients to participate in study, 6 - Stage I and II breast cancer pathology, 7 - no metastasis or lymphatic metastasis zone, 8 - or complete a simple mastectomy, breast conservation surgery

(lumpectomy, quadrantectomy), 9 - two to six weeks after completion of chemotherapy and or radiation, 10 - Combination therapy: prescribing two or more chemotherapeutic agents for the treatment of cancer (and other performance enhancing drugs have a synergistic effect). 11 - External beam radiation (teletherapy): The patient has been exposed to radiation producing devices, 12 - not use other methods of complementary medicine at the time of the study, 13 - more than 2,500 white blood cells per cubic millimeter, 14 - Count platelets more than 50,000 per cubic millimeter, 15 - temperature less than 38.3 ° C or 101 ° F, 16 - no signs of infection and bleeding. Exclusion criteria for recurrence, disease duration less than 2 weeks, disorder comorbidity with other mental disorders, a history of cancer, previous surgery on the breast.

**Age**

From **25 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**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**

Isfahan University of Medical Sciences

**Street address**

Research Department, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code****Approval date**

2011-12-31, 1390/10/10

**Ethics committee reference number**

290211

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

breast cancer

**ICD-10 code**

2013 ICD-1

**ICD-10 code description**

•A primary or metastatic malignant neoplasm involving the breast. The vast majority of cases are carcinomas arising from the breast parenchyma or the nipple. Malignant breast neoplasms occur more frequently in females than in males. -- 2003

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

quality of life

**Timepoint**

8 weeks after intervention

**Method of measurement**

questionnaire Organization for Research and Treatment of Cancer Europe EORTC QLQ-C30)); and a standard questionnaire specifically to assess quality of life in breast cancer (EORTC QLQ-BR23);

**Secondary outcomes**

empty

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

Intervention group: Yoga sessions will run for 8 weeks 75 minute every couple of days. Technique was the yoga asana. The importance of education given stretching muscles, tendons and ligaments joint, muscle contraction on timely in whole body, reverse movements, torsion and bending modes, status of balance, breathing and relaxation techniques. Insufficient attention was being for every company that she was able to perform the exercises for health. To ensure of doing yoga by cancer patients undergoing chemotherapy and radiotherapy, gave them home exercise checklist and asked them to do exercise at least twice a day and mark on checklist. At the start of the next session, after receiving the checklist, the instructional content review and were answered to individual questions. 8 weeks after the intervention, the experimental group patients' quality of life was measured again.

**Category**

Lifestyle

**2****Description**

Control group: The control group patients were asked

during the investigation 8 weeks; do not use a variety of complementary and alternative therapies such as yoga. During this period, the researcher only to be followed them by a call from (once every two weeks). After 8 weeks, once again invited the control group, and were given questionnaires to complete it. After the last of gathering data, the educational pamphlet in yoga was given to control group, and clients to use yoga and other programs were referred to Omid Mehr Community depended to Center of Prognosis and Treatment of Breast Disease in Syedolshohada (AS) hospital.

#### Category

Lifestyle

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Isfahan Syedolshohada (AS) Hospital

###### Full name of responsible person

Faridokht Yazdani

###### Street address

Isfahan University of Medical Science

###### City

Isfahan

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Islamic Azad University, Najafabad branch

###### Full name of responsible person

Research Assistant

###### Street address

Research Department, Najafabad branch

###### City

Najafabad

##### Grant name

طرح های پژوهشی

##### Grant code / Reference number

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

Yes

##### Title of funding source

Islamic Azad University, Najafabad branch

##### 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

Islamic Azad University, Najafabad Branch

##### Full name of responsible person

Faridokht Yazdani

##### Position

MSc - faculty

##### Other areas of specialty/work

##### Street address

Nursing and Midwifery School, Najafabad Branch, Islamic Azad University, Isfahan, Iran

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##### Web page address

### Person responsible for scientific inquiries

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Administer

##### Full name of responsible person

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##### Other areas of specialty/work

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### Person responsible for updating data

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Faridokht Yazdani

##### Position

MSc / faculty

**Other areas of specialty/work****Street address**

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**Web page address****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*