

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects of guided imagery on the quality of life of Women with Breast Cancer

Protocol summary

Study aim

The effects of guided imagery on the quality of life of Women with Breast Cancer

Design

Clinical trial with two groups of control and intervention on 58 patients. Excel software rand function was used for randomization.

Settings and conduct

Women with breast cancer referred to Ramezanzadeh Radiation Therapy Center in Yazd who have undergone radiotherapy and chemotherapy during the last 4 months. Demographic and QLQ_C30 questionnaires will be sent electronically for patients. In the intervention group, in addition to receiving routine care, they will be referred to a one-and-a-half-hour imaging session that will be performed by a single researcher in his office. After 3 weeks and after a one-month follow-up period, the questionnaires will be sent to both groups electronically again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: one to three breast cancer stages in the initial diagnosis: At the beginning of radiation therapy or chemotherapy sessions, or at most 4 months have passed since the end of the sessions: Ability to read and write and be able to hear: Ability to participate in counseling sessions: Willingness to cooperate in the study: Types of surgery including lumpectomy, mastectomy (radical, total, etc.): Ability to use a smartphone to receive questionnaires and listen to audio recorded for home practice. Exclusion criteria: Having other cancers; illnesses or disabilities that prevent participation in counseling sessions and exercises: Having a mental illness under treatment: Having great stresses such as the death of loved ones and divorce in the last 6 months: Substance abuse: Simultaneous participation in another study; Pregnancy.

Intervention groups

Intervention group: The consultation based on guided imaging. Control group: routine care

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049797N2**

Registration date: **2021-12-07, 1400/09/16**

Registration timing: **prospective**

Last update: **2021-12-07, 1400/09/16**

Update count: **0**

Registration date

2021-12-07, 1400/09/16

Registrant information

Name

fatemeh zahra memar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5227 4486

Email address

memar_fateme@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-15, 1400/09/24

Expected recruitment end date

2021-12-20, 1400/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of guided imagery on the quality of life of Women with Breast Cancer

Public title

The effects of guided imagery on the quality of life of Women with Breast Cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

At the initial diagnosis of stage one to three breast cancers At the beginning of radiation therapy or chemotherapy sessions, or at most 4 months have passed since the end of the sessions Ability to read and write and be able to hear Ability to attend counseling sessions Willingness to collaborate in the study Types of surgery including lumpectomy, mastectomy (radical, total, etc.) Ability to use a smartphone to receive questionnaires and listen to recorded audio for homework

Exclusion criteria:

With other cancers An illness or disability that prevents you from attending counseling and exercise sessions Having a mental illness being treated Having great stress like the death of a loved one and divorce in the last 6 months Drug abuse Simultaneous participation in another study Pregnancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **58****Randomization (investigator's opinion)**

Randomized

Randomization description

The specified sample size is 58 women. Each woman will be assigned a number between 1 and 58, which is created by the online site <http://www.randomization.com>. Due to the fact that this study has two groups, the first generation randomization model is used that has two groups; A and B. The samples are entered in each group by order and are got numbers.

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**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Morad Maleki Street

City

Isfahan

Province

Isfahan

Postal code

8471846596

Approval date

2020-12-26, 1399/10/06

Ethics committee reference number

IR.SSU.RSI.REC.1399.033

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

Breast Cancer

ICD-10 code

D70.1

ICD-10 code description

Agranulocytosis secondary to cancer chemotherapy

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

quality of life of Women with Breast Cancer

Timepoint

Questionnaire QLQ_C30 and demographics in the baseline and after 3 weeks and after a one-month follow-up period, the questionnaires will be given electronically to people in both groups.

Method of measurement

Through quality of life questionnaires of the European Cancer Research and Treatment Organization

Secondary outcomes

empty

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

Intervention group: In addition to receiving routine care, samples are guided to a one-and-a-half-hour imaging

session performed by a single researcher in her office. Mental imaging steps and contents expressed are recorded by the patient's mobile phone and the participant is asked to listen to this recorded sound every day from 9 to 10 pm for three weeks and do mental imaging and related tasks specified by the researcher.

Category

Behavior

2

Description

Control group: The control group will receive routine care and will be on a waiting list for receiving intervention, 6 weeks after a one-month follow-up session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ramezanzadeh Radiotherapy Center, Yazd

Full name of responsible person

Mohammad Hasan Gholami

Street address

Shahid Motahari St. - Shahid Ramazanzadeh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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Yazd, Bahonar Square, the central building of Yazd
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

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

Yazd University of Medical Sciences

Full name of responsible person

Maryam Mohammadi

Position

Master of Midwifery Education

Latest degree

Master

Other areas of specialty/work

Midwifery

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Yazd, Safaieh, Bouali St., School of Nursing and
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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Position

Master of Midwifery Education

Latest degree

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Other areas of specialty/work

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