

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

effect of humor therapy on fatigue in breast cancer patients undergoing external radiation therapy

Protocol summary

Summary

The aim of this study is determination the effects of humor therapy on fatigue in breast cancer patients undergoing external radiation therapy. This is a clinical trial study in which 56 breast cancer patients receiving radiation 5 weeks during the treatment will participate. Patients randomly will be assigned into humor therapy and control groups. allocation randomization by bloked randomization will be done. Patients in the experimental group will attend in humor therapy sessions twice a week for a month (a total of 8 sessions). sessions will be held with the three methods; comedy clip, jokes and the fun games. Fatigue questionnaires will be completed each week. The control group will be received routine care.If this study is significant, laughter therapy is a useful step in reducing fatigue and improving the quality of life of cancer patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052313441N1**

Registration date: **2014-01-09, 1392/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-09, 1392/10/19

Registrant information

Name

Fateme Borzoee

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 571446070

Email address

borzoee75026@yahoo.com

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-03-30, 1393/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of humor therapy on fatigue in breast cancer patients undergoing external radiation therapy

Public title

effect of humor therapy on fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included female gender; radiation dose during treatment; 60-50 Gy (6000-5000 rad), cancer stage 0-III; aged 70-18 years; breast surgery history; completion of chemotherapy over at least two weeks; treatment administered during radiation therapy for at least 5 weeks and within a week of radiation therapy; hemoglobin greater than 8. Exclusion criteria included patients with a mental disorder or disease characterized by fatigue(multiple sclerosis; fibromyalgia; AIDS; rheumatoid arthritis).

Age

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

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **56****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**

Sabzevar University of Medical Sciences

Street address

next to the police station to SHahroud road, Sabzevar

City

Sabzevar

Postal code**Approval date**

2013-11-20, 1392/08/29

Ethics committee reference number

medsab.Rec.92.5

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

breast cancer patients with fatigue

ICD-10 code

R53

ICD-10 code description

Malaise and fatigue

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

fatigue

Timepoint

every week for 5 weeks

Method of measurement

FSI questionnaire

Secondary outcomes

empty

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

The control group will receive usual care.

Category

N/A

2**Description**

humor therapy is a type of Complementary and alternative treatments. Three methods of treatment in the intervention group are comedy clips, fun games with awards and jokes, each session will be lasted 60 minutes twice a week for 4 weeks. Sessions led by researcher and runs.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Radiation and Oncology Center of Reza (AS)

Full name of responsible person

Dr Fateme varshooyi

Street address**City**

Mashad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Moosa Tadayonfar

Street address

School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

City

Sabzevar

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar University of Medical Sciences

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

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Borzoe

Position

Senior nursing student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty member of Sabzevar University

Full name of responsible person

Mostafa Rad

Position

PhD Student of Nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

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