Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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+98 571446070
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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; compeletion 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 questionnarie

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 Scinces

Full name of responsible person
Fateme Borzoee

Position
Senior nursing student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
Faculty member of Sabzevar University

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Mostafa Rad

Position
PhD Student of Nursing

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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