Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Cognitive-Behavioral Therapy plus Hypnosis (CBTH) intervention on anxiety, depression and quality of life in patients with breast Cancer: A randomized controlled trial

Protocol summary

Summary

The present study is a pretest-posttest clinical trial with a control group. The aim of this study is determination of the efficacy of combined cognitive and hypnosis therapy in depression and quality of life in patients with breast cancer at Imam Khomeini Hospital in Mazandaran, Iran. The statistical population consisted of all patients with breast cancer who were referred to Tooba Clinic and Imam Khomeini Hospital in Sari. 32 patients were randomly assigned into two groups of cognitive behavioral therapy with hypnosis and conventional therapy, and each group included 16 patients .Inclusion criteria include breast cancer diagnosis, writing literacy, physical ability, medical treatment, chemotherapy, hypnosis grade5, and more than 5 SPIEGELs and over 18 years of age, and exclusion criteria including history of attending other psychotherapy sessions, use Psychiatric drugs, acute mental disorder, illiterate, psychiatry (comorbidity).Hypnosis with cognitive-behavioral therapy will be performed in 8 one-hour weekly sessions for the experimental group, and the control group will be waiting and all patients will be complete the consent form. Demographic form, resilience, anxiety and depression questionnaire and quality of life questionnaire will be completed at the beginning of treatment, the end of treatment and 2months after treatment by patients.

General information

Acronym

Cognitive-Behavioral Therapy plus Hypnosis in cancer

IRCT registration information

IRCT registration number: **IRCT201703161457N13**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Mehran Zarghami

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences and Department of Psychiatry, Mazandaran Univ

Country

Iran (Islamic Republic of)

Phone

+98 15 1328 5659

Email address

mzarghami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-01-31, 1396/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Cognitive-Behavioral Therapy plus Hypnosis (CBTH) intervention on anxiety, depression and quality of life in patients with breast Cancer: A randomized controlled trial

Public title
Efficacy of Cognitive-Behavioral Therapy plus Hypnosis (CBTH) intervention in patients with breast Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria include breast cancer diagnosis, writing literacy, physical ability, medical treatment, chemotherapy, hypnosis grade5, and more than 5 SPIEGELs and over 18 years of age, and exclusion criteria including history of attending other psychotherapy sessions, use Psychiatric drugs, acute mental disorder, illiterate, metastatic breast cancer patients, incomplete questionnaires, medical psychiatry (co-morbidity).
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Block randomized Trial

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran university of medical sciences
Street address
sari,juibar roud
City
Sari
Postal code
Approval date
2016-09-22, 1395/07/01
Ethics committee reference number
IR.MAZUMS.REC.95.2225

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
(C50-C50)
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Anxiety
Timepoint
2 months
Method of measurement
questionnair

2

Description
Depression
Timepoint
2 months
Method of measurement
questionnair

Secondary outcomes

1

Description
resilience
Timepoint
2 months
Method of measurement
Questionnaire

2

Description
Quality of life
Timepoint
2 months
Method of measurement
Questionnaire

Intervention groups

1

Description
combination of Hypnoses and cognitive behavioral therapy in 8 one-hour weekly sessions in group
Category
Behavior

2

Description

common treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fatemeh taghizadeh

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research and technology of Mazandaran university of medical sciences

Full name of responsible person

Dr Majid saeedi

Street address

Sari,moallem SQ

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research and technology of Mazandaran 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

Mazandaran University of medical sciences

Full name of responsible person

Fatemeh taghizadeh

Position

MSc

Other areas of specialty/work

Street address

Sari,Addiction institute

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Addiction institute

Full name of responsible person

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Position

psychiatrist

Other areas of specialty/work

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Mehran.zarghami@gmail.com

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Fatemeh taghizadeh

Position

Other areas of specialty/work

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fatemehtaghizadeh93@gmail.com

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