

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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 grade 5, 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 2 months 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**  
Fateme 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**  
Fateme taghizadeh  
**Position**  
MSc  
**Other areas of specialty/work**  
**Street address**

Sari,Addiction institute  
**City**  
Sari  
**Postal code**  
**Phone**  
+98 11 3311 3278  
**Fax**  
**Email**  
fatemehtaghizadeh93@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Addiction institute  
**Full name of responsible person**  
Dr.mehran zarghami  
**Position**  
psychiatrist  
**Other areas of specialty/work**  
**Street address**  
Sari,Addiction institute  
**City**  
Sari  
**Postal code**  
**Phone**  
+98 11 3328 5659  
**Fax**  
**Email**  
Mehran.zarghami@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
**Full name of responsible person**  
Fateme taghizadeh  
**Position**  
**Other areas of specialty/work**  
**Street address**  
**City**  
**Postal code**  
**Phone**  
00  
**Fax**  
**Email**  
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*