

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparing the effectiveness of group Positive-Behavior Therapy and group Cognitive-Behavioral Therapy on the Cognitive regulation of emotion in Women with Breast Cancer

#### Protocol summary

##### Study aim

Comparison of the effect of group positive behavior therapy and group cognitive behavioral therapy on cognitive regulation Excitement, women with breast cancer

##### Design

Among the people who have received a diagnosis, according to the entry and exit criteria, we prepare a list and randomly select 45 of them, and randomly divide them into three groups. Then, randomly, one of the groups will be used as a control group, the other group as experimental group 1 (positive behavioral therapy), and the third group as experimental group 2 (cognitive behavioral therapy).

##### Settings and conduct

45 women with breast cancer referred to Milad Shahr Hospital in Tehran were selected and answered the cognitive emotion regulation questionnaire, then they were randomly assigned to three groups using the rand function of Excel software. Each group was placed in one of the plans, and the control group did not receive information about the process and how it was implemented until the end of the research. Educational sessions in the field of cognitive regulation of emotion at the positive life center under the cover of the welfare organization on a weekly basis for 8 sessions of 90 minutes (Fridays: cognitive behavioral therapy group from 9 to 10:30 and positive therapy group from 11 to 12 :30) was taught.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with breast cancer who have completed at least one month of their chemotherapy period must declare full consent to participate in the research. Exclusion criteria: history of psychiatric and psychological interventions during the past year, use of psychiatric drugs

##### Intervention groups

group cognitive behavioral therapy, positive behavioral therapy, control group

##### Main outcome variables

Regulation of excitement, self-blame and others, acceptance and rumination, concentration and positive re-evaluation, perspective-taking, catastrophizing.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220212054000N2**

Registration date: **2022-12-16, 1401/09/25**

Registration timing: **retrospective**

Last update: **2022-12-16, 1401/09/25**

Update count: **0**

##### Registration date

2022-12-16, 1401/09/25

##### Registrant information

##### Name

Mona DanaeiKousha

##### Name of organization / entity

Islamic Azad University of Birjand

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6453 8495

##### Email address

mona.dk@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-22, 1400/02/02

**Expected recruitment end date**

2021-05-05, 1400/02/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effectiveness of group Positive-Behavior Therapy and group Cognitive-Behavioral Therapy on the Cognitive regulation of emotion in Women with Breast Cancer

**Public title**

Investigating the effect of group positive behavior therapy and group cognitive behavioral therapy on the cognitive regulation of emotion

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having completed at least one month of Chemotherapy

Having at least a diploma Being married

**Exclusion criteria:**

History of psychiatric and psychological interventions during the past year Taking psychiatric drugs Being single Having a physical illness such as Diabetes

**Age**

From **25 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After performing the pre-test stage in a joint session, people were randomly assigned a number using a list of numbers, and based on the lottery, the first person was placed in group 1, the second person was placed in group 2, and the third person was placed in group 3. Each group was randomly assigned to the first group (cognitive behavioral therapy), the second group (positive behavioral therapy), and the third group did not receive any intervention as a control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Individuals were blinded to be placed in groups, and after three groups were determined, each group was blindly placed in one of the plans (neither the participants nor the researcher knew about the placement of individuals in the groups until the day of the training sessions). The

analyst did not know about the people and groups under analysis.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Damghan University of Medical Sciences

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Cheshme Ali Blvd

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**Province**

Semnan

**Postal code**

3671637915

**Approval date**

2021-04-05, 1400/01/16

**Ethics committee reference number**

IR.IAU.DAMGHAN.REC.1400.004

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

Breast Cancer

**ICD-10 code**

C50

**ICD-10 code description**

Malignant neoplasm of breast

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

Cognitive regulation of emotion

**Timepoint**

Beginning of the study (before the intervention) and end of the study (after the intervention) 60 days later

**Method of measurement**

Cognitive regulation questionnaire of Garnevsy, Kraij and Spinhaven

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: cognitive behavioral therapy (education of cognitive and behavioral techniques during 8 sessions and each session for 90 minutes based on the Leahy protocol). Brief description of the group members' introduction and familiarization sessions with each other and the therapist, group members' familiarization with the rules and regulations of the group, answers to possible questions or doubts of the group members, explanation of the purpose and necessity of the sessions by the therapist, patient education in the field of the nature of the disease, familiarization of the patients with the models An existing opinion in the field of psychological aspects of pain-radiation therapy and its relationship with depressed mood and depression, behavioral activation training, familiarizing members with the conceptual model of classical cognitive-behavioral therapy, investigating the role of emotions in the experience of pain, the effect of negative thoughts and emotions on the aggravation of depression and Reducing activities, recognizing negative thoughts, introducing members to the techniques of managing negative emotions, learning and managing to deal with negative thoughts and emotions, problem solving skills, identifying thinking errors, the role of cognitions in the experience of negative feelings, training cognitive errors, training how to detect errors cognitive, training in cognitive reconstruction techniques, coping with stress, training in relaxation and pleasant mental imagery, lifestyle, examining the achievements of the course from the participants' point of view and the importance of relapse prevention

#### Category

Behavior

### 2

#### Description

Group: Positive attitude therapy (behavioral techniques during 8 sessions and each session for 90 minutes based on Seligman's protocol) The summary of intervention training sessions on positive attitude therapy and the therapist's role and client's responsibilities were studied. The meaning is in the continuation of depression and emptiness of life. It is discussed in terms of three paths of happiness (pleasure, experience and meaning). The theory is about establishing and developing positive emotions. A special plan is designed to implement the abilities. Good memories against bad memories: In the context of the role of good and bad memories in maintaining health. It is discussed in terms of appreciation. The importance of positive emotions is discussed. We discuss the current activities to increase positive emotions.

#### Category

Behavior

### 3

#### Description

Control group: no intervention (during the course, they only participated in the pre-test and post-test stages and did not receive any intervention.)

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Milad Hospital

##### Full name of responsible person

Mona DanaeiKousha

##### Street address

Hemmat Highway

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Tehran

##### Province

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1449614531

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr. Ali Abadi

##### Street address

Ayatollah Ghaffari Blvd

##### City

Birjand

##### Province

South Khorasan

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9717811111

##### Phone

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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

Islamic Azad University

#### 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**  
Islamic Azad University  
**Full name of responsible person**  
Mona DanaeiKousha  
**Position**  
Lecturer at the non-profit Ivanki University and PhD student in psychology  
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Master  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The data can be presented in the form of an Excel file without the details of the participants

### When the data will become available and for how long

After the articles are published

### To whom data/document is available

University researchers

### Under which criteria data/document could be used

Mention the reason for use and registration of authors in their research title

### From where data/document is obtainable

Email of the first author

### What processes are involved for a request to access data/document

The approval of all authors and the publication of names in the research has been done

### Comments

