Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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
Street address
Cheshme Ali Blvd
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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 Garnevsky, 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Latest degree

Master

Other areas of specialty/work

Psychology

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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