

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effectiveness of Group Behavior Activation Therapy on Attributional Styles, Depression and Quality of life in Patients with Breast Cancer

Protocol summary

Summary

Objectives: this study aims to investigate the effectiveness of the group behavior activation therapy on attributional styles, depression and quality of life in females with breast cancer. Materials and Methods: this research is a quasi-experimental study with a pretest-posttest control group design. In 2015, from all patients referring to Mashhad Omid hospital, 30 individuals with breast cancer were selected through available sampling method and were randomly assigned to two experimental and control groups. Implementation: the experimental group underwent group behavior activation therapy during 8 weeks while the control group followed the ordinary course of the sessions provided by the Omid hospital. Attributional Style Questionnaire (ASQ), Short Form Health Survey (SF-36) and Beck Depression Inventory-II (BDI-II) were used in the pretest and posttest. Inclusion criteria consisted of the following: the final diagnosis of developing breast cancer by the physician; signing a written consent form to participate in the study, and having at least a diploma for education. Exclusion criteria were as follows: mental retardation; suicide attempt at the beginning of the study; personality and psychotic disorders; using alcohol and addictive drugs, and absence of more than two sessions. Interventions: the experimental group underwent group behavior activation therapy during 8 weeks while the control group followed the ordinary course of the Omid hospital programs. Attributional Style Questionnaire (ASQ), Short Form Health Survey (SF-36) and Beck Depression Inventory-II (BDI-II) were applied in the pretest and posttest. The main outcome variables: Attributional Styles, quality of life and depression.

General information

Acronym

GBAT

IRCT registration information

IRCT registration number: **IRCT201602083372N2**

Registration date: **2016-03-16, 1394/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-16, 1394/12/26

Registrant information

Name

Hossein Shareh

Name of organization / entity

Iran University of Medical Sciences, Tehran
Psychiatric Institute; Hakim Sabzevari University

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1655

Email address

h.shareh@stu.iuums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Group Behavior Activation Therapy on Attributional Styles, Depression and Quality of life in

Public title

The Effect of Group Behavior Activation Therapy in Patient with Breast Cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the final diagnosis of developing breast cancer by the physician; signing a written consent form to participate in the study, and having at least a diploma for education. Exclusion criteria: mental retardation; suicide attempt at the beginning of the study; personality and psychotic disorders; using alcohol and addictive drugs, and absence of more than two sessions.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Of all the patients with breast cancer referring to the Mashhad Omid hospital in 2015, 30 individuals were selected through available sampling method and were randomly (Using a table of random numbers) assigned to two experimental and control groups.

Secondary Ids

empty

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

Azad University of Neishabur

Street address

Iran, Neishabur, Pajoheshstreet, Azad University of Neishabur

City

Neishabur

Postal code**Approval date**

2015-10-02, 1394/07/10

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Breast Cancer

ICD-10 code

C50.8

ICD-10 code description

Malignant neoplasm: Overlapping lesion of breast

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

Depression

Timepoint

Before and after intervention

Method of measurement

Beck Depression Inventory-II (BDI-II)

2**Description**

Quality of life

Timepoint

Before and after intervention

Method of measurement

Short Form Health Survey (SF-36)

3**Description**

Attributional Styles

Timepoint

Before and after intervention

Method of measurement

Attributional Style Questionnaire (ASQ)

Secondary outcomes

empty

Intervention groups**1****Description**

The control group spent the routine process of the sessions held by the Omid hospital.

Category

N/A

2**Description**

The experimental group received group activation behavior therapy for eight weeks

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Omid hospital

Full name of responsible person

Dr. Soudabeh Shahid Sales

Street address

Mashhad-Omid hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Center of Hakim Sabzevari University

Full name of responsible person

Hossein Shareh

Street address

Hakim Sabzevari University, Tohid City, Sabzevar,
Khorasan-e- Razavi, Iran

City

Sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Center of Hakim Sabzevari University

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

Hakim Sabzevari University

Full name of responsible person

Hossein Shareh

Position

Assistant Professor/ Ph.D

Other areas of specialty/work

Street address

Hakim Sabzevari University, Tohid City, Sabzevar,
Khorasan-e- Razavi, Iran

City

Mashhad

Postal code

Phone

+98 51 4441 0104

Fax

Email

hsharreh@yahoo.com.au, hoshareh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

Hossein Shareh

Position

Assistant Professor/ Ph.D

Other areas of specialty/work

Street address

Hakim Sabzevari University, Tohid City, Sabzevar,
Khorasan-e- Razavi, Iran

City

Mashhad

Postal code

Phone

+98 51 4441 0104

Fax

Email

hsharreh@yahoo.com.au, hoshareh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

Hossein Shareh

Position

Assistant Professor/ Ph.D

Other areas of specialty/work

Street address

Hakim Sabzevari University, Tohid City, Sabzevar,
Khorasan-e- Razavi, Iran

City

Mashhad

Postal code

Phone

+98 51 3841 7740

Fax

Email

hsharreh@yahoo.com.au

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