

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of Problem-Solving Therapy on Psychological Wellbeing in Breast Cancer Patients

Protocol summary

Summary

The purpose of this study is to investigate the effectiveness of problem-solving therapy for psychological well-being in women affected by breast cancer. The study is a clinical trial, which is done on 38 women affected by breast cancer. Inclusion criteria: patients who are older than 18 years old, aware of their disease, have finished middle school at least; and at least 6 month has passed from definite diagnosis of their disease, and the result of their psychological well-being test is 2SD less than the mean. Exclusion criteria: having a history of mental problems, being affected by cognitive disorders such as delirium, dementia, taking antipsychotic medications, being affected by impaired cognitive performance and suffering from psychological disorders, suffering from other serious physical problems or other types of cancer simultaneously, being addicted to drugs. The data is collected using Ryff Psychological Well being Questionnaire. The participants who achieve the minimum score are divided into intervention and control groups: each group includes 19 participants. The author offers the intervention group weekly ninety-minute sessions of problem-solving therapy for 8 weeks. After completing counseling course and one month later, both groups will complete Ryff Psychological Well being Questionnaire again. The main outcome in this study is psychological well being.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011431940N1**
Registration date: **2017-03-28, 1396/01/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-28, 1396/01/08

Registrant information

Name

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Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Problem-Solving Therapy on Psychological Wellbeing in Breast Cancer Patients

Public title

Effect of Problem-Solving on Psychological Well-being

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are older than 18 years

old and are aware of their disease; have finished middle school at least, and at least 6 month from definite diagnosis; the result of their psychological wellbeing test is 2SD less than the mean. Exclusion criteria: having a history of mental problems; being affected by cognitive disorders such as delirium or dementia; taking antipsychotic medications; being affected by impaired cognitive performance who are suffering from psychological disorders; suffering from simultaneous serious physical problems or other types of cancer; being addicted to drugs (drug abuser).

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jondi shapoor University

City

Ahvaz

Postal code**Approval date**

2017-01-01, 1395/10/12

Ethics committee reference number

IR.AJUMS.REC. 1395 .589

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**

Psychological Wellbeing

Timepoint

Before intervention, immediately after intervention, one month after intervention

Method of measurement

Ryff Psychological Wellbeing Questionnaire

Secondary outcomes**1****Description**

Personal growth

Timepoint

Before intervention, immediately after intervention, one month after intervention

Method of measurement

Personal Growth Scale

2**Description**

Positive relations with others

Timepoint

Before intervention, immediately after intervention, one month after intervention

Method of measurement

Positive Relations with Others Scale

3**Description**

Self-autonomy

Timepoint

Before intervention, immediately after intervention, one month after intervention

Method of measurement

Self-autonomy Scale

4**Description**

Life satisfaction

Timepoint

Before intervention, immediately after intervention, one month after intervention

Method of measurement

Life Satisfaction Scale

5**Description**

Spirituality
Timepoint
Before intervention, immediately after intervention, one month after intervention
Method of measurement
Spirituality Scale

6

Description
Happiness and Optimism
Timepoint
Before intervention, immediately after intervention, one month after intervention
Method of measurement
Happiness and Optimism Scale

Intervention groups

1

Description
The intervention group is offered eight structured ninety-minute sessions of problem-solving therapy.
Category
Behavior

2

Description
The control group is offered only routine care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Shafa Hospital
Full name of responsible person
Elham Taeidi
Street address
Golestan Boulevard
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science
Full name of responsible person
Dr Behzad Sharief Makhmal
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Ground Floor, Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science
City

Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science
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
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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