Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Elham Taeidi
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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

Street address

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

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Elham Taeidi

Position

MS in Counseling in midwifery

Other areas of specialty/work

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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