Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Couple therapy adaptation on the life quality and mental health of patients with breast cancer and their spouses and comparing the results to those of control group : Effectiveness study

Protocol summary

Summary

Objectives: Objectives: This study aims at investigating the effects of couple therapy adaptation on patients with breast cancer and their spouses and studying the efficacy of this adaptive treatment on the life quality and mental health of those spouses and comparing the results to those of control group. Design: This study is a semi-experimental research based on pre-test and post-test with a control group. Research population consists of all patients with breast cancer, having come to Shahid Ghazi Hospital for Chemotherapy. From the above-mentioned population, 40 subjects have been selected through available non-random sampling Execution: Subjects are divided into two experimental and control groups in a random manner. Then, subjects in the experimental group are being trained for “breast cancer adaptation” in 6 sessions. Subjects in control group will not receive any training. Criteria for Entrance to and Exit from the Study: Diagnosis of breast cancer in the subjects and their high education are of criteria for entering into the study. Lack of knowledge regarding the disease and lack of inclination of patients’ spouses for attending at intervention sessions are of criteria for exiting from the study. Interventions: Subjects in both experimental and control groups will be initially tested using measuring tools for mental health and life quality. Then, subjects in the experimental group are being trained for “breast cancer adaptation” and will be post-tested for the extent of change in life quality (elementary consequent variable) and mental health (secondary consequent variable) and compared to those in control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013113015590N1**
Registration date: **2014-01-27, 1392/11/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-27, 1392/11/07

Registrant information

Name
Mansoor Beyrami
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Hematology and Oncology Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

Expected recruitment start date

2013-12-23, 1392/10/02

Expected recruitment end date

2014-02-21, 1392/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Couple therapy adaptation on the life quality and mental health of patients with breast cancer and their spouses and comparing the results to those of control group : Effectiveness study

Public title
Couple therapy adaptation on patients with breast cancer and their spouses=Effectiveness study
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria: Diagnosis of breast cancer, Self awareness from cancer, high education in patients, education in patients in their partner,Chemotherapy
Exclusion criteria: Have other disease (for example: other kind of cancer), Lack of knowledge regarding the disease, lack of inclination of patients' spouses for attending at intervention sessions
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
4tth office,First Floor, Ghazi Hospital, Tabriz University, Golghasht Street
City
Tabriz
Postal code
2356
Approval date
2013-11-22, 1392/09/01
Ethics committee reference number
92159

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50.9
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Quality of life
Timepoint
Before treatment and 1 week after treatment
Method of measurement
Quality of life Scale

2

Description
General health
Timepoint
before treatment and 1 week after treatment
Method of measurement
GHQ Scale

Secondary outcomes

empty

Intervention groups

1

Description
Experiment group will intervened with adaptation program in 6 sessions. The component of intervention is: Knowing about cancer and breast cancer, Stress control, Relaxation, Positive relationship with partner, Identifying partner sense and emotions.
Category
Behavior

2

Description
Control group do not receipt any treatment program.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hematology and Oncology Research Center, Tabriz University of Medical Sciences, Tabriz, Iran
Full name of responsible person
Pari Ghaem
Street address
2th office, First Floor, Ghazi Hospital, Tabriz University, Golghasht Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hematology and Oncology Research , Tabriz University of Medical Scienc
Full name of responsible person
Jamal Eyvazi
Street address
3rth office,First Floor, Ghazi Hospital, Tabriz University of Medical Sciences, Golghasht Street
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Tabriz
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, Hematology and Oncology Research , Tabriz University of Medical Scienc
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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Web page address

Person responsible for updating data

Contact

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