

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 914 313 4470

Email address

m.bayrami@tabrizu.ac.ir

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		92159
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 <i>No information</i>		
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		
<u>1</u>		
Ethics committee		
Name of ethics committee Ethics committee of Tabriz University of Medical Sciences		
Street address 4th 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		
Health conditions studied		
<u>1</u>		
Description of health condition studied breast cancer		
ICD-10 code C50.9		
ICD-10 code description Malignant neoplasm of breast		
Primary outcomes		
<u>1</u>		
Description Quality of life		
Timepoint Before treatment and 1 week after treatment		
Method of measurement Quality of life Scale		
<u>2</u>		
Description General health		
Timepoint before treatment and 1 week after treatment		
Method of measurement GHQ Scale		
Secondary outcomes empty		
Intervention groups		
<u>1</u>		
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		
<u>2</u>		
Description Control group do not receipt any treatment program.		
Category N/A		
Recruitment centers		
<u>1</u>		
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

Street address

Child Psychology Office, Fifth Floor, Milad building,
Corner of MiliBank, 17 Shahrivar Street

City

Tabriz

Postal code**Phone**

+98 41 1557 5849

Fax**Email**

shirinzeinali@yahoo.com

Web page address**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

City

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****Name of organization / entity**

Tabriz University

Full name of responsible person

Shirin Zeinali

Position

PhD student in Tabriz University

Other areas of specialty/work**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University

Full name of responsible person

Shirin Zeinali

Position

PhD student in Tabriz university

Other areas of specialty/work**Street address**

Child Psychology Office, Fifth Floor, Milad building,
Corner of MiliBank, 17 Shahrivar Street

City

Tabriz

Postal code**Phone**

+98 41 1557 5849

Fax**Email**

shirinzeinali@yahoo.com

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