

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of multimethod education on self efficacy of patients with breast cancer and their family care givers strain

Protocol summary

Summary

The aim of this study is to investigate the effect of combined teaching method on self efficacy of breast cancer patients and their family caregivers strain. This study is a randomized controlled trial. Participants will be selected from patients referring to Ghazi Hospital of Tabriz University of medical sciences. The main inclusion criteria is breast cancer diagnosis and the main exclusion criteria is participating in similar teaching programs. After giving conscious consent, patients will be allocated to either control or intervention groups. Intervention group will receive at least 2 face to face sessions including learning about the disease, pain control methods, nutritional points, managing side effects related to chemotherapy according to patient or caregivers need. Brochures about teaching materials will be given to patients too. Teaching will be conducted by role playing whenever needed. For 4 weeks patients will be followed by telephone in order to answer to patients and families possible questions and guide them if needed. Control group will receive routine care and after finishing the study written material will be given to them. Finally the self efficacy of patients and their family care givers strain will be determined and compared before and after the study in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206196810N2**

Registration date: **2012-07-03, 1391/04/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-03, 1391/04/13

Registrant information

Name

Alireza Mohajjel Aghdam

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

mohajjela@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multimethod education on self efficacy of patients with breast cancer and their family care givers strain

Public title

The effect of education on self efficacy of patients with breast cancer and their family care givers strain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Breast cancer diagnosis; Undergoing chemotherapy; Existence of a family member; Ability to attend teaching Sessions; Tendency to attend in study;

Knowing at least reading and writing; First sessions of treatment; Equal treatment for all participants. Exclusion criteria: Attending in the same educational or research programs; Having somebody with the same disease in family and friends; Inability to attending educational Sessions; Interaction of participants; Being nurse or doctor; History of mental disorder or bad events about the caregiver.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht st.

City

Tabriz

Postal code

Approval date

2012-06-25, 1391/04/05

Ethics committee reference number

9142

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Family caregiver strain

ICD-10 code

F99

ICD-10 code description

Unspecified mental disorder

Primary outcomes

1

Description

Self efficacy of breast cancer patients

Timepoint

before the intervention and four weeks after the intervention

Method of measurement

Based on a scale to measure self-efficacy of cancer patients

2

Description

Family caregivers Strain of breast cancer patients

Timepoint

before the intervention and four weeks after the intervention

Method of measurement

Based on a scale to measure caregivers strain index

Secondary outcomes

empty

Intervention groups

1

Description

Patients and family in intervention group will receive 2 sessions of teaching with combining of several teaching methods like verbal teaching, giving written materials and role playing; then, to follow up the patients and their family, phone calls will be made to answer possible questions and giving directions. Content of teaching includes the concept of disease, chemotherapy side effects and their management.

Category

Other

2

Description

Control group receives routine care and after the study brochures of information will be given to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology Oncology research centre (Ghazi hospital)

Full name of responsible person

Zahra Kochaki nejad Eram Sadati

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Sakineh Mohamad Alizadeh

Street address

Faculty of Nursing & Midwifery of Tabriz , Shariety South St.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Tabriz University of Medical Sciences

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 of medical sciences

Full name of responsible person

Zahra Kochaki nejad Eram Sadati

Position

Nursing Master of Science Student

Other areas of specialty/work

Street address

Faculty of Nursing & Midwifery of Tabriz, Shariety South St.

City

Tabriz

Postal code

Phone

+98 41 1479 7713

Fax

Email

sarasadat70@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Alireza Mohajjel Aghdam

Position

Faculty member, Master of nursing, medical surgical nursing

Other areas of specialty/work

Street address

Medical-Surgical nursing group, Faculty of Nursing & Midwifery of Tabriz, Shariety South St.

City

Tabriz

Postal code

Phone

+98 41 1479 6770

Fax

Email

mohajjela@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University Of Medical sciences

Full name of responsible person

Zahra Kochaki najad Eram Sadati

Position

Nursing Master of Science Student

Other areas of specialty/work

Street address

Faculty of Nursing & Midwifery of Tabriz , Shariety South St.

City

Tabriz

Postal code

Phone

+98 41 1479 6770

Fax

Email

sarasadat70@yahoo.com

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