Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of supportive program on spouses caregiver burden and stress in women suffer breast cancer undergoing chemotherapy

Protocol summary

Study aim

1. Determination of the burden of care of spouses of women with breast cancer undergoing chemotherapy before, immediately and six weeks after the intervention program in the intervention and control groups 2. Determination of stress of spouse of women with breast cancer undergoing chemotherapy before, immediately and six weeks after intervention in control and intervention groups 3. Determination of stress of spouse of women with breast cancer undergoing chemotherapy before, immediately and six weeks after intervention program in intervention and control group 4. Determination of quality of life of women with breast cancer before intervention, immediately and six weeks after intervention program in intervention and control group

Design

The experimental and control groups were factorial and non-blinded.

Settings and conduct

Babolsar Shahid Rajaee Hospital Randomization to intervention and control groups The 6 sessions were conducted by the intervention group of 90, 20 and 30 minutes Assessment at three times before, immediately and 6 weeks after intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being Iranian, Literacy, 25 to 60 years old, Monogamy, First Patient receiving chemotherapy, Stage 1 to 3, Patients undergoing chemotherapy , Willingness to participate in the study , Lack of education in medical and paramedical fields, no concurrent counseling or 6 months in advance, no severe psychiatric disorder based on individual history, no depression and severe anxiety , no use of psychiatric drugs Currently , non-addiction, lack of psychiatric and psychological disorders in caregivers. And the patient Exclusion criteria: The exclusion criteria in this study is not considered

Intervention groups

The intervention group included the wives of women with breast cancer

Main outcome variables

The effect of supportive program on spouses and women with breast cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150608022609N7**
Registration date: **2020-04-01, 1399/01/13**
Registration timing: **prospective**

Last update: **2020-04-01, 1399/01/13**
Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Zohre Shahhosseini

Name of organization / entity

Mazandaran Univercity of Medical Science, Nasibe School Of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.shahhosseini@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive program on spouses caregiver burden and stress in women suffer breast cancer undergoing chemotherapy

Public title

The effect of supportive program on caregiving burden and stress of husbands of women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Ability to read and write Ages between 25 to 60 years old Monogamy The first course of patient chemotherapy Stages 1 to 3 of the disease Patients undergoing chemotherapy (at least one chemotherapy session) Willingness to participate in the study Lack of psychiatric and psychological disorders in caregiver and patient No education in medical and paramedical fields Not using concurrent counseling or 6 months ago Absence of severe psychiatric disorder based on the individual history No depression and severe anxiety (according to the DASS-21 questionnaire) No current use of psychiatric drugs (such as antipsychotics, antidepressants and anxiolytics) No addiction

Exclusion criteria:

The output criterion is not considered in this study

Age

From **25 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In the absence of anxiety and depression, further explanations of how the study was conducted to evaluate participation in the informed and written consent study will be obtained from men. Then random allocation for participants is described. Moreover, ethical questions will be answered by participants who did not consent to participate in the study or who were eligible for the study but who were included in the control group. Are given. Afterwards, 80 eligible study caregivers who entered our study will be randomly divided into intervention and control groups. Therefore, 20 blocks and 4 blocks in each group were selected by software using permuted block randomization method. The number of intervention and control groups is equal in each block. In the following, 80 envelopes will be prepared to comply with the concealment principle and the specified groups will be divided into groups I and C in each envelope.The first envelope belongs to the first participant, whose content, based on previous blocking, will determine the task of participants of the entering the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

There are two consequences in this study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

خیابان معلم، میدان معلم، معاونت تحقیقات و فناوری دانشگاه علوم پزشکی مازندران

City

sari

Province

Mazandaran

Postal code

4816715793

Approval date

2020-03-30, 1399/01/11

Ethics committee reference number

IR.MAZUMS..REC.1399.6862

Health conditions studied

1

Description of health condition studied

Caring burden and stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Caregiver burden measurement

Timepoint

Immediately after the intervention and 6 weeks later

Method of measurement

With the DASS questionnaire, mild to moderate grades

are acceptable for men

2

Description
Stress measurement
Timepoint
Immediately after the intervention and 6 weeks later
Method of measurement
Measure with CBT questionnaire. Scores below 72 (Mild to Medium) are acceptable

Secondary outcomes

1

Description
Quality of Life in Breast Cancer Patients
Timepoint
Immediately after the intervention and 6 weeks later
Method of measurement
Quality of life questionnaire for cancer patients, higher scores indicate better quality of life

Intervention groups

1

Description
Intervention group: Wives of women with breast cancer
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Babolsar Shahid Rajaee Hospital
Full name of responsible person
Seyed Zeynab HoseinNezhad
Street address
Shariati Street, Fisheries Management Aspects
City
babolsar
Province
Mazandaran
Postal code
47179-96557
Phone
+98 11 2528 9257
Fax
+98 11 2528 9257
Email
rajaee@muebabol.ac.ir
Web page address
https://rajaee.muebabol.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Akbar Hedayatizadeh Omran
Street address
Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Avenue
City
sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3325 7230
Email
akbar-hedayati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
seyedeh zeynabhoseinnazhad
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Fish Field, beheshti 13
City
فریدونکنار
Province
Markazi
Postal code

4751813343

Phone
+98 11 3566 0005

Email
zeynabhoseinnezhad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Zohreh Shahhosseini

Position
PhD in Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Shirazi Avenue

City
sari

Province
Mazandaran

Postal code
4816715793

Phone
+98 11 3337 4750

Email
Z.Shahhosseini@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
seydeh zeynabhoseinnezhad

Position
University student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Nasibeh Nursin and Midwifery Faculty, Vesal Shirazi Avenue

City
sari

Province
Mazandaran

Postal code
4816715793

Phone
+98 11 3337 4750

Email
zeynabhoseinnezhad@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available