Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessment the influence of uncertainty toleration-based intervention among couples on mental adjustment with illness in women with breast cancer

Protocol summary

Study aim
Determining the influence of uncertainty toleration-based intervention among couples on mental adjustment with illness in women with breast cancer who have referred to Urmia Medical Education and Research Center in 2020-2021

Design
Clinical trial with control and intervention group, with parallel groups, non-blinded, randomized, on 100 patients. An envelope containing even and odd numbers was used for randomization. Even numbers are for the control group and odd numbers are for the intervention group

Settings and conduct
Study place: Imam Khomeini Hospital, Urmia. There is no blinding in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range of 30 -60 years; breast cancer in stage 1,2, and 3 according to pathology report; breast cancer awareness; after more than 48 hours of chemotherapy; being married and lived more than 12 months with her partner; not attending other educational sessions; having mental health. Non inclusion criteria: having other cancers or life-threatening illnesses.

Intervention groups
Intervention group: Uncertainty tolerance intervention will be done on couples in intervention group, which will include groups of 6 to 10 individuals and will be held weekly in 6 sessions, lasting 60 to 90 minutes each. The designed interventions include: helping to create the ability to tolerate ambiguous situations, improving positive beliefs about worries, cognitive avoidance and negative orientation towards the problems. To evaluate the participants, a diary will be provided for each person to record her daily behavior Control group: The control group will not receive the any intervention. But due to ethical norms, after the intervention, one or two sessions will do for them.

Main outcome variables
Mental Adaptation to cancer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150125020778N21**
Registration date: **2020-12-13, 1399/09/23**
Registration timing: **retrospective**

Last update: **2020-12-13, 1399/09/23**
Update count: **0**

Registration date
2020-12-13, 1399/09/23

Registrant information

Name
Fatemeh Moghaddam Tabrizi

Name of organization / entity
Uromia University of Medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-30, 1398/02/10

Expected recruitment end date
2020-02-21, 1398/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the influence of uncertainty toleration-based intervention among couples on mental adjustment with illness in women with breast cancer

Public title

The effect of intervention on couples on mental adjustment with illness

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

age range of 30 -60 years old breast cancer in stage 1,2, and 3 according to pathology sheet awareness of breast cancer in herself after more than 48 hours of chemotherapy being married and living more than 12 months with her partner not attending other educational sessions the patient and her partner should be mentally healthy i.e., not having hospitalization history in psychiatry and no history of antidepressant medicine use

Exclusion criteria:

Having other cancers Having any life-threatening illness

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

By taking into account the inclusion criteria and getting the consent, 100 couples enter the study by availability sampling method. Using the envelope containing odd and even numbers, 50 people will be selected randomly for the control group and 50 for the intervention group.Even numbers are for the control group and odd numbers are for the intervention group

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 Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, next to the emergency center, Resalat blvd

City

Urmia

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West Azarbaijan

Postal code

5714783734

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

IR.UMSU.REC.1398.032

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

Mental Adaptation with cancer

Timepoint

Before intervention and 6 weeks after the first session

Method of measurement

Mental adjustment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Uncertainty tolerance intervention will be done on couples in intervention group, which will include groups of 6 to 10 with titles introduce, communicate and encourage clients to express their views on their experiences in applying methods of adjustment before, providing effective solutions and use and interpret and discuss each item of the intervention program that will be held weekly in 6 sessions, each of them lasting 60 to 90 minutes. Researcher will use tools

such as flash card, PowerPoint, pamphlets, lectures and group discussion to more effective intervention program during the intervention. The designed interventions include: helping to create the ability to tolerate ambiguous situations, improving positive beliefs about worries, cognitive avoidance and negative orientation towards the problems. To evaluate the participants, a diary will be provided for each person to record her daily behavior

Category

Lifestyle

2

Description

Control group:The control group will not receive the any intervention. But due to ethical norms that they were in the control group, after the intervention, one or two sessions will do for them

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Fatemeh Mogaddam Tabrizi

Street address

Imam Khomeini hospital; Ershad street; Ayatollah Mdarres boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Urmia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Mogaddam Tabrizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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
Not applicable

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

Clinical Study Report
Not applicable

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