Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the Effectiveness of Motivational interviewing on self-efficacy, treatment adherence, post-surgical adjustment with mastectomy and serum level of CEA tumor marker in Breast Cancer Patients

Protocol summary

Study aim

Study of the Effectiveness of Motivational interviewing on self-efficacy, treatment adherence, post-surgical adjustment with mastectomy and serum level of CEA tumor marker in Breast Cancer Patients

Design

randomized (Packed envelope method), without placebo control, single arm trial. The sample size of this study is 60 individuals: divided into 2 groups of 30 people.

Settings and conduct

The self-efficacy scale for self-management of breast cancer (SESSM-B) (Lee et al., 2012). Department of Oncology, Kowsar Hospital in Semnan.

Participants/Inclusion and exclusion criteria

Women older than 18 years with the diagnosis of breast cancer at the Kowsar Hospital in Semnan province. Inclusion criteria: Women older than 18 years; diagnosis of breast cancer, Grade 2 or 3 has been received by an oncologist and performed mastectomy and period of chemotherapy; she has not previously been involved in psychological interventions or not receiving psychotherapy by another psychologist or psychiatrist. Exclusion criteria: Dissatisfied to participate in the study.

Intervention groups

Control group: Only for comparison with intervention group, no treatment is performed. Intervention group: In intervention group, motivational interviewing according to the protocol individually and by the researcher for patients will be performed during 5 sessions (1 session per week). Also blood samples from both groups will be taken before and after psychological intervention to assess the CEA serum level.

Main outcome variables

CEA tumor marker.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N29**
Registration date: **2018-02-04, 1396/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**
Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-18, 1396/07/26

Expected recruitment end date

2018-04-14, 1397/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the Effectiveness of Motivational interviewing on self-efficacy, treatment adherence, post-surgical adjustment with mastectomy and serum level of CEA tumor marker in Breast Cancer Patients

Public title
Study of the Effectiveness of Motivational interviewing on self-efficacy, post-surgical adjustment with mastectomy in Breast Cancer Patients.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women older than 18 years Diagnosis of breast cancer, Grade 2 or 3 has been received by an oncologist and performed mastectomy and period of chemotherapy She has not previously been involved in psychological interventions or not receiving psychotherapy by another psychologist or psychiatrist
Exclusion criteria:
Dissatisfied to participate in the study

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: randomized blocks. Random unit: Individual. Randomization Tool: Table of random numbers.

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 Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442

Approval date
2017-10-18, 1396/07/26

Ethics committee reference number
IR.SEMUMS.REC.1396.113

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
CEA tumor marker.

Timepoint
Before and after the intervention

Method of measurement
Blood Test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In intervention group, motivational interviewing according to the protocol individually and by the researcher for patients will be performed during 5 sessions (1 session per week).

Category
Treatment - Other

2

Description
Control group: Only for comparison with intervention group, no treatment is performed.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital

Full name of responsible person
Eshagh Rahimian

Street address
Kowsar Hospital, Street Amin, Semnan

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Maziar Ahmadi

Street address
Islamic Azad University of Gorgan Branch, Student Street, Shahid Kalantari Blvd, Gorgan.

City
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Province
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ahmadi.golsefidi@iran.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Eshagh Rahimian

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

Name of organization / entity
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Student

Latest degree
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Other areas of specialty/work
Psychology
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Gorgan
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Postal code
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+98 17 3215 3000
Email
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available