

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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**

Semnan

**Province**

Semnan

**Postal code**

3514799442

**Phone**

+98 23 3345 1336

**Email**

are20935@gmail.com

## 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**

Gorgan

**Province**

Golestan

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4914739975

**Phone**

+98 17 3215 3000

**Email**

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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Semnan University, Damghan 5 km Road, Semnan

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Rosa Salehian

**Position**

Student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Province**

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**Postal code**

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**Phone**

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**Email**

are20935@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**

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