

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### The impact of telephone-based support on sexual function of women with breast cancer and their husband

#### Protocol summary

##### Study aim

The aim of the study is to investigate the impact of telephone-based support on sexual function of women with breast cancer and their husband.

##### Design

This study will be conducted on 70 patients with breast cancer at Ayatollah khansary Hospital in Arak. The aim of the study is to investigate the impact of telephone-based support on sexual function of women with breast cancer and their husband. Patients will be recruited in the study by convenience sampling and will be assigned randomly to an intervention group who will receive telephone call twice-a-week for third month and control group who will receive routine care. Female Sexual Function Index and International Index of Erectile Function will be completed before the intervention, two months after the intervention and two months after the end of the intervention. Data will be analyzed using SPSS software.

##### Settings and conduct

Ayatollah-Khansari Hospital

##### Participants/Inclusion and exclusion criteria

Aged between 18-45 years, Access to a mobile phone or telephone, Physically and mentally ability to participate in the study, Patients who have mastectomy and undergo chemotherapy and/or radiotherapy, Awareness of their diagnosis, Married

##### Intervention groups

Intervention group: Patients will be contacted twice a week, at certain times of day In the control group: Will be received routine care.

##### Main outcome variables

sexual function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170404033216N2**

Registration date: **2018-12-19, 1397/09/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-19, 1397/09/28**

Update count: **0**

##### Registration date

2018-12-19, 1397/09/28

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3505

###### Email address

m.ebrahimabadi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-04-09, 1398/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of telephone-based support on sexual function of women with breast cancer and their husband

##### Public title

The impact of telephone-based support on sexual function of women with breast cancer and their husband

##### Purpose

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Aged between 18-45 years Access to a mobile phone or telephone Physically and mentally ability to participate in the study Patients who have mastectomy and undergo chemotherapy and/or radiotherapy Awareness of their diagnosis Married

**Exclusion criteria:**  
Lack of interest in participating in every stage of the study Death

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block Randomization, a computer-generated randomization will be used to create an allocation sequence with a block size of four to assign patients to the two study arms. It begins this process by giving each patient an identification number.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In the study neither the participant nor the outcome evaluator are aware of control or intervention groups assignment.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Arak University of Medical Sciences

##### Street address

Great Prophet University Complex, Basij Sq, Sardasht region

##### City

Arak

##### Province

Markazi

#### Postal code

38481-7-6941

#### Approval date

2018-09-22, 1397/06/31

#### Ethics committee reference number

IR.ARAKMU.REC.1397.143

## 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

sexual function

#### Timepoint

The first step, before the intervention, The second step, two months after the intervention, The third stage, two months after the end of the intervention;

#### Method of measurement

Female Sexual Function Index, International Index of Erectile Function

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients will be contacted twice a week, at certain times of the day.

#### Category

Behavior

### 2

#### Description

Control group: Will be receive routine care.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah-Khansari Hospital

##### Full name of responsible person

Dr Arjomandzadegan, Vice Chancellor for research

**Street address**

Great Prophet University Complex, Basij Sq, Sardasht region

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

pajoohesh@arakmu.ac.ir

**Position**

educator

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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m.ebrahimabadi@arakmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Arjomandzadegan, Vice Chancellor for research

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Research@arakmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Maryam Ebrahimabadi

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Nazi Nejat

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

**Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Nazi Nejat

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Do not have enough information

**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