# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Oct 2026

## The Effect Of Psycho-Educational Interventions Through Mobile Technologies On Self-Esteem And Anxiety In Women With Breast Cancer

## Protocol summary


**Summary**

Objectives: the aim of this study is to assess the effect of psycho-educational intervention through mobile technologies on self-esteem and anxiety in women with non-metastatic breast cancer. Design:in this randomized control trial, at least 60 women aged 20-60 years old with non-metastatic breast cancer will be chosen by simple random allocation method then they will be randomly divided into control and intervention groups by block randomization by a research assistant. To avoid bias, double blinding method will be used for statistical analyst and the researcher. Setting: breast cancer clinics of Shiraz, Iran. Intervention: this 4 weeks program has 2 parts, first psycho-educational interventions will be done through mobile application for the experimental group and then discussion in online chat rooms of social networks will be performed at the end of each weeks. Main outcome: level of self-esteem and anxiety will be assessed before and immediately one week after the intervention using Spielberger state trait anxiety inventory and Rosenberg self-esteem questionnaire.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015072123279N2**
Registration date: **2016-07-08, 1395/04/18**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2016-07-08, 1395/04/18

**Registrant information**

**Name**

Shahrzad Yektatalab

**Name of organization / entity**

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research ,Shiraz University of Medical Sciences

**Expected recruitment start date**

2016-07-22, 1395/05/01

**Expected recruitment end date**

2016-10-22, 1395/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect Of Psycho-Educational Interventions Through Mobile Technologies On Self-Esteem And Anxiety In Women With Breast Cancer

**Public title**

The Effect Of Psycho-educational Interventions On Self-esteem And Anxiety In Women With Breast Cancer

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: age 20-60 years old ; willingness to participate in the research ; suffering from non-metastatic cancer ; being able to read and write ; having access and being able to use a smart phone and internet and social network. Exclusion criteria: irregular

participation in the treatment sessions ; suffering from any serious diseases other than breast cancer ; a history of chronic mental disease or use of psychiatric drugs ; a history of participation in the psycho-education courses similar to the application's content.

**Age**
From **20 years** old to **59 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**

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

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Shiraz University Of Medical Sciences

**Street address**
Zand street, Shiraz University Of Medical Sciences

**City**
Shiraz

**Postal code**
71348-14336

**Approval date**
2016-04-24, 1395/02/05

**Ethics committee reference number**
IR.SUMS.REC.1395.20

## Health conditions studied

### 1

**Description of health condition studied**
Organic anxiety disorder

**ICD-10 code**
F06.4

**ICD-10 code description**
Organic anxiety disorder

### 2

**Description of health condition studied**
Self-esteem

**ICD-10 code**
-

**ICD-10 code description**
-

## Primary outcomes

### 1

**Description**
Anxiety

**Timepoint**
before the intervention, 1 week after the intervention

**Method of measurement**
Spielberger State Trait Anxiety Inventory

### 2

**Description**
Self-esteem

**Timepoint**
before the intervention, 1 week after the intervention

**Method of measurement**
Rosenberg Self-Esteem Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
No intervention considered for the control group.

**Category**
N/A

### 2

**Description**
Psycho_educational interventions will be done for the experimental group through smartphone application, members can interact with each other and the researcher via social network for 1 month. Their activity will be assessed during the intervention.

**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Motahari polyclinic

**Full name of responsible person**
Dr hossein jamali

**Street address**
Namazi square
**City**
Shiraz

**2**

**Recruitment center**
**Name of recruitment center**
Emam Reza polyclinic
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Dr hossein jamali
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Namazi square
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice Chancellor for Research of Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Basir Hashemi
**Street address**
Zand street, Shiraz University of Medical Sciences;Vice President of Research
**City**
Shiraz
**Grant name**
**Grant code / Reference number**
10534
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice Chancellor for Research of Shiraz University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

## Sharing plan

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

**Study Protocol**
*empty*

**Statistical Analysis Plan**
*empty*

**Informed Consent Form**
*empty*

**Clinical Study Report**
*empty*

**Analytic Code**
*empty*

**Data Dictionary**
*empty*