

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4254

##### Email address

yektash@sums.ac.ir

##### 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

**Full name of responsible person**

Dr hossein jamali

**Street address**

Namazi square

**City**

Shiraz

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

Fatemeh School of Nursing and Midwifery

**Full name of responsible person**

Elaheh Ghanbari

**Position**

Master of Nursing Student

**Other areas of specialty/work****Street address**

College of Nursing and Midwifery, Namazi square

**City**

Shiraz

**Postal code**

71936-13119

**Phone**

+98 71 3647 4254

**Fax**

+98 71 3647 4252

**Email**

stud2280422123@sums.ac.ir

**Web page address**

nurs-midwif.sums.ac.ir

**Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shahrzad Yektatalab

**Position**

Assistant professore

**Other areas of specialty/work****Street address**

Zand street, Shiraz University of Medical Sciences

**City**

Shiraz

**Postal code**

7193613119

**Phone**

+98 71 3647 4254

**Fax**

+98 71 3647 4252

**Email**

yekdash@sums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shahrzad Yektatalab

**Position**

Assistant professore

**Other areas of specialty/work****Street address**

Zand street, Shiraz University of Medical Sciences

**City**

Shiraz

**Postal code**

7193613119

**Phone**

+98 71 3647 4254

**Fax**

+98 71 3647 4252

**Email**

yekdash@sums.ac.ir

**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*