

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### The effect of mindfulness-based stress reduction education through mobile software on resilience of women with breast cancer

#### Protocol summary

##### Study aim

The effect of mindfulness-based stress reduction training through mobile application on resilience of women with breast cancer

##### Design

This study is a quasi-experimental study (educational intervention) pretest-posttest with a control group.

##### Settings and conduct

Decreased resilience following breast cancer is one of the psychological problems experienced by patients. One of the most helpful ways to deal with these undesirable emotional responses is mindfulness-based stress reduction training. women with breast cancer referred to selected medical centers in Rasht, Iran, (Razi Hospital, Besat Clinic) if they have Inclusion criteria will be selected in a convenience manner based on gradual referrals. In order to allocating individuals in the two intervention and control groups, one day clients (even days) will be assigned to the experimental group and the next day clients (odd days) will be assigned to the control group. Data collection tools in this study are demographic information questionnaire and Connor-Davidson standard resilience questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Willingness into the study, being literate, and having a smartphone. Previous and current history of diagnosis of psychiatric disorders based on patient / family opinion, consumption or dependence on alcohol, cigarettes and drugs based on patient / family opinion are the criteria for not entering the study.

##### Intervention groups

Both intervention and control groups (42 people in each group) of women with breast cancer complete research questionnaires before the intervention and then mindfulness-based stress reduction training software is installed on the intervention group mobile phones and they are trained for 8 weeks. The control group does not receive any intervention from the researcher.

##### Main outcome variables

Resilience score of women with breast cancer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170203032374N2**

Registration date: **2021-08-28, 1400/06/06**

Registration timing: **prospective**

Last update: **2021-08-28, 1400/06/06**

Update count: **0**

##### Registration date

2021-08-28, 1400/06/06

##### Registrant information

##### Name

Fatemeh Jafarzadeh-Kenarsari

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3278 1272

##### Email address

jafarzadeh@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-04-21, 1401/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of mindfulness-based stress reduction education through mobile software on resilience of women with breast cancer

**Public title**

The effect of mindfulness through mobile software in breast cancer

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Satisfaction to participate in the study No history of diagnosis of psychiatric disorders based on patient / family comments Non-consumption or dependence on alcohol, cigarettes and drugs based on patient / family opinion Be literate Not attending mindfulness and stress management training classes Having a smart phone with Android or iOS system

**Exclusion criteria:**

Reluctance to continue participating in the study Lack of regular and complete study of the educational program installed on the mobile phone during the study period

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

**Street address**

The old building of the Faculty of Health, in front of 17

Shahrivar Hospital, Shahid Siadati St.Namjoo St.

Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4144666949

**Approval date**

2021-06-30, 1400/04/09

**Ethics committee reference number**

IR.GUMS.REC.1400.147

**Health conditions studied****1****Description of health condition studied**

Breast Cancer

**ICD-10 code**

C50.011

**ICD-10 code description**

Malignant neoplasm of nipple and areola, right female breast

**Primary outcomes****1****Description**

Resilience score in Connor-Davidson Resilience Questionnaire

**Timepoint**

Measurement of resilience score at the beginning of the study (before the start of the intervention) and immediately after the intervention and 8 weeks after the end of the educational intervention (Mindfulness-based stress reduction with the help of mobile-based software).

**Method of measurement**

Connor and Davidson Resilience Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The resilience questionnaire consists of 25 items and five areas: perception of individual competence, trust in individual instincts and negative emotional tolerance of questions, positive acceptance of change and safe relationships, control and negative effects. Before the intervention, both groups will complete the research questionnaires and then the educational software will be installed on the mobile phones of the experimental group and the participants in the intervention group will be trained through this software. Mindfulness-based stress reduction educational content in 8 parts will be compiled by a clinical

psychologist and designed by an experienced programming expert in the form of special mobile educational software. After the intervention and 8 weeks after the intervention, the resilience questionnaire will be completed again by both groups and information will be collected. The control group did not receive any intervention from the researcher.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Razi Hospital and Besat Clinic

**Full name of responsible person**

Yalda Dnyaei-Mobarrez

**Street address**

Shahid Beheshti School of Nursing and Midwifery  
Rasht, Daneshjoo St., Shahid Beheshti Highway, Rasht,  
Guilan, Iran

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4146939841

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nursing@gums.ac.ir

**Web page address**

<https://www.gums.ac.ir/nmr/Default.aspx?tabid=855>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Naghipour

**Street address**

Vice Chancellor for Research of Guilan University of  
Medical Sciences, In Front of 17-Shahrivar Hospital,  
Shahid-Siadati Av., Namjoo St., Rasht, Guilan, Iran

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research@gums.ac.ir

**Web page address**

<https://www.gums.ac.ir/research/default.aspx?tabid=>

1013

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

Yes

**Title of funding source**

Rasht 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**

Rasht University of Medical Sciences

**Full name of responsible person**

Fatemeh Jafarzadeh-Kenarsari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Rasht, Guilan, Iran

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4164816449

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Assistant professor

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## Person responsible for updating data

### Contact

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Rasht University of Medical Sciences  
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Fatemeh Jafarzadeh-Kenarsari  
**Position**  
Assistant Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Reproductive Health  
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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

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available