

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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
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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
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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

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Person responsible for scientific inquiries

Contact

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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