

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of blended in-person and on-line supportive care on quality of life of new cases of breast cancer

Protocol summary

Study aim

Investigating the effect of providing support and palliative care services in the form of face-to-face and online combination on the quality of life of newly diagnosed breast cancer patients

Design

A clinical trial with a control group, with parallel groups, one-blind, randomized on 210 patients

Settings and conduct

The study is in the field of support and care services and will be implemented on patients who have been diagnosed with breast cancer. This study will be carried out in Omid Hospital, Isfahan. This study is double blind and the participants and the analyst are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria are women with breast cancer, oncology specialist referral, no serious psychiatric illness, no substance abuse or dependence. Exclusion criteria: serious psychiatric illness, substance abuse.

Intervention groups

This study includes three groups. Two intervention groups and one control group. In the first intervention group, people are first referred by an oncology specialist, and then the patients are given information about the disease and receive support and care services. In the first group, people receive face-to-face services, and care and support services include psychiatrists, psychologists, nutritional consultants, and spiritual psychologists. In the second intervention group, they receive online services, which are available in the Web-app designed by our researchers. The third group is the control group that does not receive any services.

Main outcome variables

Cancer Quality of Life ; patient Quality of Life ; Anxiety and depression ; Supportive Care Needs ;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230119057155N2**

Registration date: **2023-08-27, 1402/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-27, 1402/06/05**

Update count: **0**

Registration date

2023-08-27, 1402/06/05

Registrant information

Name

seyedeh hanieh salimi arshad moghaddam pishkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4432 9865

Email address

haniyehsalimi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of blended in-person and on-line supportive care on quality of life of new cases of breast cancer

Public title

Investigating the effect of blended in-person and on-line supportive care on quality of life of new cases of breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women newly diagnosed with breast cancer
Oncology specialist referral
No serious psychiatric illness
No substance abuse or addiction

Exclusion criteria:

metastasis
Participating in other treatment programs at the same time.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, the study population will be randomly assigned to three groups, two intervention groups and one control group using the double consent zelen preference method. In order to randomly assign patients to each group, the block balance method will be used in such a way that we use a block of four letters to make random allocation sequences and choose the number of letters in each block as four and choose the total number of blocks that In the end, we will have a list where the mark in front of each number determines which group the person will be assigned to. The mentioned process was done with the help of the Sealedenvelop site.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the study will be blinded. The analyst who must review and analyze the data will be blinded to the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Isfahan University of Medical Sciences - Al-Zahra Research Centers

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-75731

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.ARI.MUI.REC.1401.305

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**

Hospital anxiety and depression

Timepoint

Before the intervention - after the intervention - 12 weeks after the intervention - 24 weeks after the intervention

Method of measurement

Hospital anxiety and depression scale(HADS)

2**Description**

Quality of life of patients

Timepoint

Before the intervention - after the intervention - 12 weeks after the intervention - 24 weeks after the intervention

Method of measurement

EORTC QLQ-C30

3**Description**

Quality of life in breast cancer patients

Timepoint

Before the intervention - after the intervention - 12 weeks after the intervention - 24 weeks after the intervention

Method of measurement

(EORTC QLQ-BR23)

4

Description

Supportive care needs

Timepoint

Before the intervention - after the intervention - 12 weeks after the intervention - 24 weeks after the intervention

Method of measurement

(SCNS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People who have recently been diagnosed with breast cancer. They are informed that there are a number of support and care services in person. In-person services include two visits to a psychiatrist, psychologist, nutritionist, and spiritual psychologist. Also, cancer-related trainings are provided to them in various fields.

Category

Other

2

Description

Intervention group: People who have recently been diagnosed with breast cancer. They are informed that there are a number of support and care services available online. These services include an educational site and will be provided to them in the form of a Web-app. They will be provided with cancer-related education in various fields.

Category

Other

3

Description

Control group: People who have recently been diagnosed with breast cancer. These people are not given any information about these services and support care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-shohada hospital

Full name of responsible person

Narges Rahmania

Street address

Motahahri street

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Province

Isfahan

Postal code

8184917354

Phone

+98 31 3235 0210

Email

nrg-rahmanian@yahoo.com

Web page address

<https://omid.mui.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Neda Yavari

Street address

Hezar jarib street

City

Isfahan

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Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

edo@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan university of medical science

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

Esfahan University of Medical Sciences

Full name of responsible person

Hanieh Salimi Arshad Moghaddam

Position

Student

Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Narges Rahmanin
Position
research assistance
Latest degree
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Person responsible for updating data

Contact

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Sharing the information of participants in such a way that they are not identifiable

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Specialists and researchers

Under which criteria data/document could be used

By obtaining permission from the researcher and informing her/him

From where data/document is obtainable

By sending an email to Haniyeh Salimi (salimimobina120@gmail.com)

What processes are involved for a request to access data/document

By sending an email to Haniyeh Salimi (salimimobina120@gmail.com)

Comments