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

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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
Isfehan
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 Rahmanian
Street address
Motahahri street
City
Isfahan
Province
Isfehan
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
Province
Isfehan
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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Postal code
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Phone
0098 32371103
Email
salimimobina120@gmail.com

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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Other areas of specialty/work
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Person responsible for updating data

Contact
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Esfahan University of Medical Sciences
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salimimobina120@gmail.com

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