Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effect of using mobile application on the management of chemotherapy side effects and quality of life in patients with breast cancer

Protocol summary

Study aim
Determining the effect of using a mobile application on the management of chemotherapy side effects and quality of life in breast cancer patients

Design
A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 72 patients using Randomize.Com for randomization.

Settings and conduct
This research is presented in Omid Hospital of Mashhad as the study center of the research.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Female patients, at least 18 and at most 60 years old, with the ability to read and write, patients with a smartphone capable of using the application, patients undergoing chemotherapy, willing to participate in the study. Exclusion criteria: patients with chronic mental problems and psychiatric diagnoses including major depressive disorder and anxiety disorders, presence or history of uncontrolled medical diseases except breast cancer, patients participating in another study, patients receiving radiotherapy and biotherapy at the same time they receive

Intervention groups
Receiving chemotherapy in the usual way, simultaneously using the application for a period of 4 weeks At the beginning of the study, the complications of the participating patients, as well as their quality of life are evaluated through a questionnaire in both the intervention and control groups, then they are re-evaluated again after 4 weeks. Finally, by analyzing and comparing the findings obtained in patients of both groups, we will examine the impact of using the application on the management of complications and quality of life in breast cancer patients undergoing chemotherapy.

Main outcome variables
Complications management Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230402057801N1**
Registration date: **2023-05-12, 1402/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-12, 1402/02/22**
Update count: **0**

Registration date
2023-05-12, 1402/02/22

Registrant information

Name
Marziyeh Raee Mehneh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3551 0790

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of using mobile application on the management of chemotherapy side effects and quality of life in patients with breast cancer

Public title
Evaluating The Effect of Using An Mobile-Application on The Management of Chemotherapy Complication and Quality of Life in Breast Cancer Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Literate patients Patients diagnosed with breast cancer Patients undergoing chemotherapy Patients with smartphones that can use this application Ability and willingness to participate in the study
Exclusion criteria:
Patients with chronic mental problems and psychiatric diseases, including major depressive disorder and anxiety disorders Presence or history of uncontrolled medical conditions other than cancer Patients participating in another study related to symptom management Patients who undergo radiotherapy and biotherapy at the same time as chemotherapy

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to evaluate the impact of the designed application, patients who have been diagnosed with breast cancer and are receiving chemotherapy in Omid Hospital of Mashhad, who also meet the criteria for entering our study, were randomly divided into two control and intervention groups using the block method. are placed (randomization will be done using the envelope method, the said sequence will be generated using the randomize.com site)

Blinding (investigator's opinion)
Single blinded

Blinding description
In connection with the blinding of the participants, the participants of each group will remain unaware of the existence of the other study group as well as the existence of the application. In connection with the data analyst, after collecting the data, we will give data related to each group to the data analysts without specifying which group they belong to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ferdowsi University
City
Mashhahd
Province
Razavi Khorasan
Postal code
9351991358

Approval date
2023-03-04, 1401/12/13

Ethics committee reference number
IR.MUMS.FHMPM.REC.1401.198

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
Evaluation of complications and quality of life of the participants

Timepoint
At the beginning of the study (before the start of the intervention) and 4 weeks after

Method of measurement
using two standard questionnaires QLQ-BR23 and

Secondary outcomes

1

Description
Evaluation of the satisfaction of the participants in the

intervention group in connection with the use of the application

Timepoint

At the beginning of the study and 4 weeks after using the application

Method of measurement

Using a standard satisfaction questionnaire

Intervention groups

1

Description

Intervention group: Receiving chemotherapy in the usual way, along with using the application for 4 weeks at the beginning of the study, the complications of the participating patients, as well as their quality of life, were evaluated through a questionnaire in both the intervention and control groups, and it was re-evaluated again after the intervention period of 4 weeks. Finally, by analyzing and comparing the findings obtained in patients of both groups, we will examine the impact of using the application on the management of complications and quality of life in breast cancer patients undergoing chemotherapy.

Category

Lifestyle

2

Description

Control group: Receiving chemotherapy in the usual way, at the same times as before and as it was received in the past, without any intervention from our side and according to the hospital's protocol and past routine at the beginning of the study, the complications of the participating patients, as well as their quality of life, were evaluated through a questionnaire in both the intervention and control groups, and it was re-evaluated again after the intervention period of 4 weeks. Finally, by analyzing and comparing the findings obtained in patients of both groups, we will examine the impact of using the application on the management of complications and quality of life in breast cancer patients undergoing chemotherapy.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

سودابه شهید ثالث

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Masoume Sarbaz DinAbadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Informatics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Marziyeh Raei Mehne

Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Health information technology

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Person responsible for updating data

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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
No - There is not 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