

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessing the effectiveness of utilizing two-dimensional QR codes on patient cards for breast cancer patients undergoing chemotherapy in enhancing knowledge and satisfaction with self-care education compared to the traditional paper-based method

Protocol summary

Study aim

1. A comparison of self-care knowledge levels before and after accessing educational content. 2. Determining patient satisfaction levels in both the intervention and control groups with self-care educational materials. 3. Assessing patient satisfaction levels with the use of two-dimensional QR codes in the intervention group. 4. Evaluating patient satisfaction levels with paper pamphlets in the control group.

Design

Clinical trial with Control group, with parallel groups, double-blind, randomized, on 100 patients. The randomization function of Excel software will be used for randomization.

Settings and conduct

All cancer patients referred to Omid Hospital who are undergoing chemotherapy are divided into two control and intervention groups. The control group will receive the necessary training through paper and the experimental group will have access to the training electronically through two-dimensional barcode scanning. Finally, the obtained knowledge scores are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Breast cancer patients attending hospital self-care unit undergoing chemotherapy. 2. Having a smartphone as a barcode scanner

Intervention groups

For patients in the subjects group, the two-dimensional barcode will be inserted on the patient's chemotherapy appointment card.

Main outcome variables

Measuring the level of knowledge of patients before and after access to training, Measuring the satisfaction level of patients in the control group using the paper method Measuring the level of satisfaction of patients in the intervention group using the electronic method (use of

two-dimensional barcodes)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220818055741N1**

Registration date: **2023-09-08, 1402/06/17**

Registration timing: **retrospective**

Last update: **2023-09-08, 1402/06/17**

Update count: **0**

Registration date

2023-09-08, 1402/06/17

Registrant information

Name

sareh keshvardoost

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3842 6082

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s.keshvardoost69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of utilizing two-dimensional QR codes on patient cards for breast cancer patients undergoing chemotherapy in enhancing knowledge and satisfaction with self-care education compared to the traditional paper-based method

Public title

Assessing the effectiveness of two-dimensional QR codes on breast cancer patients' knowledge and satisfaction levels.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Breast cancer patients attending outpatient clinic for health education undergoing chemotherapy Having a smartphone as a barcode scanner Being literate in reading and writing

Exclusion criteria:**Age**

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization
Randomization Unit: Individual Randomization tool: using SPSS statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, data collectors, and data analyst remain blinded to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mashhad University of Medical Sciences

Street address

Omid Hospital, El Nadasht Crossroad, Sangi St

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Province

Razavi Khorasan

Postal code

9188793786

Approval date

2023-02-13, 1401/11/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.603

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

Breast cancer patients

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

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

Measurement of patients' knowledge levels is calculated through the scores obtained from the questionnaire.
Measurement of patient satisfaction is assessed through the questions in the questionnaire.

Timepoint

Two weeks to one month.

Method of measurement

Through the researcher-developed questionnaire.

Secondary outcomes

empty

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

Intervention group: This group of patients, after the initial introduction to the concept of self-care and the objectives of the program, and after completing the ethical consent form, receive the prepared content for chemotherapy sessions in the form of pamphlets on the hospital's website. They access these pamphlets by scanning the QR codes on their mobile phones. These pamphlets consist of a total of 10 readiness pamphlets for chemotherapy, including education related to the introduction of breast cancer, treatment methods,

common side effects of chemotherapy, physical self-care techniques, and nutritional and psychological education.

Category

Prevention

2

Description

Control group: This group of patients, After the initial introduction to the concept of self-care and the objectives of the program, and after completing the ethical consent form, this group of patients receives the prepared content for chemotherapy sessions in the form of conventional paper pamphlets available at the hospital. These paper pamphlets consist of a total of 10 readiness pamphlets for chemotherapy, including education related to the introduction of breast cancer, treatment methods, common side effects of chemotherapy, physical self-care techniques, and nutritional and psychological education.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Hanie Shariatmadari

Street address

Omid Hospital, El Nadasht Crossroads, Koh Sangi St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour-Mobarhan

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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

sareh keshvardoost

Position

researcher

Latest degree

Master

Other areas of specialty/work

Medical Informatics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Hanie Shariatmadari

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Demographic information, all patient education forms and briefing session information, all statistical information, and informed consent forms are ready to be sent.

When the data will become available and for how long

The data will be ready to send after three months.

To whom data/document is available

Researchers, medical center staff, and administrators

Under which criteria data/document could be used

Help the patient

From where data/document is obtainable

Send email to shariatmadarih3@mum.ac.ir

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

Send an email to shariatmadarih3@mum.ac.ir to mention the research title and introduce the applicant's required files.

Comments

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