Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

The Effect of Using the Question Prompt List on Self-efficacy in Decision Making, Preferences in Participation and Shared Decision Making among People with Breast Cancer.

Protocol summary

Study aim

The Effect of Using the Question Prompt List on Self-efficacy in Decision Making, Preferences in Participation and Shared Decision Making among People with Breast Cancer.

Design

The randomized controlled trial, with parallel groups

Settings and conduct

This study was carried out at the Cancer Institute of Imam Khomeini Hospital. Question Prompt list was provided to eligible patients, and finally, shared decision making, decision self-efficacy, and Preferences for participation were measured. Data, from two groups, was coded and delivered to the statistician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with breast cancer who were referred for adjuvant/ neoadjuvant treatment following tumor resection, knowing their diagnosis of breast cancer, able to read and write Persian; and age 18 years or older Exclusion criteria: a history of psychiatric illness that would prevent them from participating in treatment decision-making, metastatic breast cancer, and reluctance to participate in research

Intervention groups

The intervention group benefited from the QPL and the control group received routine care. The QPL was an organized list of questions that clients could ask their answers at the next appointment with their physician or answer through the WhatsApp messenger, Soroush, And Eita. Patients were followed up during that time and their questions were answered.

Main outcome variables

Shared decision making

General information

Reason for update

This is a single-blind study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044032N1**
Registration date: **2019-07-16, 1398/04/25**
Registration timing: **prospective**

Last update: **2021-02-03, 1399/11/15**
Update count: **3**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

Zahra Yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6642 1685

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z-yazdani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-11-14, 1399/08/24

Trial completion date

2020-11-14, 1399/08/24

Scientific title

The Effect of Using the Question Prompt List on Self-efficacy in Decision Making, Preferences in Participation and Shared Decision Making among People with Breast Cancer.

Public title
The Effect of Using the Question Prompt List on Self-efficacy in Decision Making, Preferences in Participation and Shared Decision Making among People with Breast Cancer.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
able to read and write Persian patients with breast cancer who were referred for adjuvant/ neoadjuvant treatment following tumor resection age 18 years or older knowing their diagnosis of breast cancer

Exclusion criteria:
a history of psychiatric illness that would prevent them from participating in treatment decision-making, metastatic breast cancer, reluctance to participate in research

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation will include three steps: Random sequence generation, allocation concealment and doing a random allocation process. Four random blocks are used to generate random sequences. Random sequence generation by block method will be done using Random Allocation Software. To ensure that random sequence is not predictable for the researcher who will perform the sampling, allocation concealment will be performed using numbered, sealed, opaque envelopes. These two steps are taken by the supervisor and the student who performs the sampling will not be involved in these two phases.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data were coded and delivered to a statistician.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Sixth floor, Central Office of Tehran University of Medical Sciences, Corner of Quds St, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-06-26, 1398/04/05

Ethics committee reference number
IR.TUMS.VCR.REC.1398.359

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
Shared decision making

Timepoint
After intervention

Method of measurement
The 9-item Shared Decision Making Questionnaire

Secondary outcomes

1

Description
Self-efficacy in Decision Making

Timepoint
Before and after intervention

Method of measurement
Decision Self-efficacy Scale

2

Description

Preferences in Participation

Timepoint

Before and after intervention

Method of measurement

Control Preferences Scale

Intervention groups

1

Description

The intervention group received QPLs with questions about chemotherapy, radiotherapy, or a combination of both, depending on what the patient needed. The time taken for QPL to make decisions was different in terms of the referral time of each patient and was measured as an auxiliary variable. The researcher responded to patient questions through a social network and followed them up. Patients met radiologist and shared their opinion with her and the final decision was made.

Category

Other

2

Description

Control group: The control group benefited from routine care and did not receive any intervention to help making decision .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Imam Khomeini Hospital

Full name of responsible person

Marzieh Lashkari

Street address

Cancer Institute, Imam Khomeini Hospital Complex, Keshavarz Blvd, Tehran

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158-13145

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+98 21 6658 1524

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crc@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Reza Negarandeh

Street address

Sixth floor, Central Office of Tehran University of Medical Sciences, Corner of Quds St, Keshavarz Blvd

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Yazdani

Position

Student of community health nursing/Master of Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Nosrat St., Tohid Sq., Tehran, Iran

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Email

zy.nurse@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Reza Negarandeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Zahra Yazdani

Position
Student of community health nursing/Master of Sciences

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
The outcomes and basic characteristics of the participants will be shared after being unidentified.

When the data will become available and for how long
Data will be released when the results are published.

To whom data/document is available
All people will have access to published data.

Under which criteria data/document could be used
Data can be used for people who intend to write systematic review and meta-analysis.

From where data/document is obtainable
To receive the data, you can send an email to the following address: zy.nurse@gmail.com

What processes are involved for a request to access data/document
After reviewing the request, the data will be sent by email.

Comments