

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Email address

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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Tehran
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Tehran
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158-13145
Phone
+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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Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3619
Email
rmo@tums.ac.ir
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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Tehran
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Tehran
Postal code
1419733171
Phone
+98 21 6642 1685
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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Postal code

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Phone

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Email

zy.nurse@gmail.com

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