Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of decision aid package on selecting therapeutic option and decision outcomes among patients with early stage breast cancer

Protocol summary

Summary

Objective: determination the effect of decision aid package on selecting therapeutic option and decision outcomes in patients with early stage breast cancer. Study: RCT, parallel, not blinded, convenient sampling. Inclusion criteria: 1) Have clinical stage 1 or 2 breast cancer that be approved by the physician 2) Not have previous history of cancer. 3) Not have serious non-malignant diseases such as cardiovascular, respiratory, renal, which may prevent the definitive surgery . 4) They should be literate. Exclusion criteria: 1) If patient requires to intensive care. 2) If patient dies or migrate. 3) If patient participate in other studies. The number of patients participating in this study were 30 patients with early stage breast cancer admitted to Cancer Institute of Imam Khomeini Hospital. The patients have been randomly divided into two groups, intervention (n=15) and control (n=15) groups. The control group were received only routine care and the intervention group were received decision aid' package in addition to the usual care and were conducted for choose of one of therapeutic options mastectomy or lumpectomy with radiotherapy. Patients' follow-up by telephone was done every two weeks for eight weeks after surgery. Outcomes: therapeutic option chosen by patients, decision conflict, and decision regret, in intervention conditions in comparison with controls.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210165987N6**
Registration date: **2013-06-13, 1392/03/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-13, 1392/03/23

Registrant information

Name
Shahrzad Ghiyasvandian
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6692 7171
Email address
shghiyas@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

International Campus, Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of decision aid package on selecting therapeutic option and decision outcomes among patients with early stage breast cancer

Public title

The effect of decision aid in patients with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all case studies will sign an informed consent, and also they should have the following conditions: 1) Have clinical stage 1 or 2 breast cancer that be approved by the physician 2) Not have previous history of cancer. 3) Not have serious non-malignant diseases such as cardiovascular, respiratory, renal, which may prevent definitive surgery . 4) They should be literate. 5) They should have language of Persian dialects. 6) Not have mental disorder and addictions which preventing decision-making process and giving informed consent for participating in this study. Exclusion criteria: In this study, if a patient has one of following characteristics, it will be excluded from the study: 1) If patient requires to intensive care. 2) If patient dies or migrate (so that access to the patient is not possible). 3) If patient participate in other studies

Age
From **21 years** old to **78 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethics Committee

Street address
Tehran, Keshavarz blvd, Ghods st.

City
Tehran

Postal code
1419733171

Approval date
2012-09-30, 1391/07/09

Ethics committee reference number
130/1431/91/د

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
Select therapeutic option

Timepoint
One to four days after intervention

Method of measurement
O'Connor questionnaire

2

Description
Decision conflict

Timepoint
1-4 days after intervention

Method of measurement
O'Connor traditional decisional conflict scale

Secondary outcomes

1

Description
Decision Regret

Timepoint
Eight weeks after intervention

Method of measurement
O'Connor Decision Regret Scale

Intervention groups

1

Description
Intervention 2: Intervention group at the first visit after confirm the diagnosis by physician, to get decision aid package were referred to the research nurse. Decision aid Package includes a information booklet and audiotape and personal worksheet. Information booklet contains information about the disease, treatment options, advantages and disadvantages of each treatment and the effect of treatment on patient survival and quality of life and were informed the patients for choose of one of therapeutic options (mastectomy or lumpectomy with radiation). The audiotape was twenty-minute long and supplements the booklet. And personal worksheet was in order to record the final decision and any questions, comments or ambiguity of the patients

after study package. The patients were asked to return to their doctor up to four days later, after consultation with the people their trusted and study package, to discuss their questions and announce their final decision on the therapeutic option. Telephone follow-up during this period until the return of the patients to prevent the withdrawal of the samples was performed by a research nurse. On the second visit, treatment option and decision conflict questionnaire was completed. Eight weeks after beginning treatment decision regret questionnaire was completed. Patients telephone follow-up was done every two weeks during this eight weeks.

Category

Other

2

Description

Intervention 2: The control group were received routine care. Decision aid package was not given to this group. One to four days after the first visit (before beginning treatment) treatment option and decision conflict questionnaire was completed and eight weeks after treatment, decision regret questionnaire was completed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Imam Khomeini Hospital

Full name of responsible person

Seyyede Narjess Mousavizade

Street address

Tehran, Tohid Sq, Nosrat Street.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Faculty of Nursing and Midwifery, Tehran University of Medical Science

Full name of responsible person

Doctor Ziba Taghizade

Street address

Tehran, Tohid sq, Faculty of nursing and midwifery, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Faculty of Nursing and Midwifery, Tehran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

International Campus, Tehran University of Medical Sciences

Full name of responsible person

Seyyede Narjess Mousavizade

Position

Master of Nursing

Other areas of specialty/work

Street address

Tehran, Tohid sq, Nosrat street, Faculty of nursing and midwifery, Tehran University of Medical Science

City

Tehran

Postal code

Phone

+98 21 6637 7579

Fax

Email

mousavi201089@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Shahrzad Ghiyasvandiyan

Position

Assistant Professor

Other areas of specialty/work

Street address

Tehran, Tohid sq, Faculty of nursing and midwifery,Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6642 0739

Fax

Email

shghiyas@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
International Campus of Tehran University of Medical Sciences

Full name of responsible person
Syyede Narjess Mousavizade

Position
Master of Nursing

Other areas of specialty/work

Street address
Tehran, Tohid sq, Nosrat street, Faculty of nursing and midwifery, University of Tehran

City
Tehran

Postal code

Phone
+98 21 6637 7579

Fax

Email
mousavi201089@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty