

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Survey on the effect of a health literacy promotion program on health literacy and death anxiety in women with breast cancer

Protocol summary

Study aim

Determination of the impact of a health literacy improvement program on health literacy and death anxiety in women with breast cancer

Design

This randomized clinical trial has two group, control and intervention. The sample size is 66 persons with parallel and non-blind design

Settings and conduct

This study was conducted in Isfahan's Seyed al-Shohada Hospital on women with breast cancer referring to this hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Had breast cancer with doctor's approval Being in treated as an outpatient or hospitalized Awareness of the diagnosis The duration of the diagnosis of the disease is up to six months Age over 18 years Have reading and writing skills Tendency to cooperate Didn't have any related health promotion training Didn't have any disease in metastatic stage
Exclusion criteria: Not to cooperate Incompleted questionnaire Death Don't attending for more than 2 sessions in the training program

Intervention groups

The training program consists of 4 sessions, twice a week. The time of each session is 45-60 minutes. After the end of the workshops, a one-day group workshop will be held. The feedback-based approach, the statement sheet and pictures used to patient's training . The intervention's end is on a month after the follow up times. The control group persons have had a training session by giving them an educational pamphlet. The questionnaires will be completed in 3 stages: before the intervention, the end of the intervention and a month after the end of the intervention

Main outcome variables

Health literacy; Death Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180506039541N1**

Registration date: **2018-06-22, 1397/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-22, 1397/04/01**

Update count: **0**

Registration date

2018-06-22, 1397/04/01

Registrant information

Name

Marjan Aboudzadeh Behbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 2463

Email address

m.aboudzadeh@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey on the effect of a health literacy promotion program on health literacy and death anxiety in women with breast cancer	
Public title	Improving health literacy on health literacy and death anxiety in breast cancer
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Had breast cancer with doctor's approval Being in treated as an outpatient or hospitalized Awareness of the diagnosis The duration of the diagnosis of the disease is up to six months Age over 18 years Have reading and writing skills Tendency to cooperate Didn't have any related health promotion training Didn't have any disease in metastatic stage
Exclusion criteria:	Not to cooperate Incompleted questionnaire Death Don't attending for more than 2 sessions in the training program
Age	From 18 years old
Gender	Female
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 66 Actual sample size reached: 60
Randomization (investigator's opinion)	Randomized
Randomization description	We using cards on which letters A and B are written. The researcher selects one of the packets containing letters A or B randomly for each of the patients who are eligible to enter the study.Card A is for the intervention group and B to allocate to the control group.
Blinding (investigator's opinion)	Not blinded
Blinding description	The patients do not know their allocation in the intervention or control group
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	Name of ethics committee Ethics committee of Isfahan University of Medical Sciences Street address Hezarjarib St., Faculty of Nursing and Midwifery., Isfahan University of Medical Sciences City Isfahan Province Isfahan Postal code 8174673461 Approval date 2018-03-11, 1396/12/20 Ethics committee reference number IR.MUI.REC.1396.3.705
Health conditions studied	
<u>1</u>	
Description of health condition studied	Health literacy
ICD-10 code	Z55
ICD-10 code description	Problems related to education and literacy
<u>2</u>	
Description of health condition studied	Death anxiety
ICD-10 code	F40
ICD-10 code description	Phobic anxiety disorders
Primary outcomes	
<u>1</u>	
Description	Health literacy Level
Timepoint	At the beginning of the study, the end of the intervention, a month after the end of the intervention
Method of measurement	Health literacy questionnaire in Iranian women with breast cancer
<u>2</u>	
Description	Death anxiety
Timepoint	At the beginning of the study, the end of the intervention, a month after the end of the intervention
Method of measurement	Templar death anxiety scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The education program consists of 4 sessions, twice a week, which is held in the hospital in the morning shift for each patient. The duration of each session is 60-45 minutes. After that, a group session will be held in the presence of a specialist physician. In addition, the researcher also uses a telenursing program, to improve health literacy.

Category

Rehabilitation

2

Description

Control group: There are no interventions in this group. The questionnaires will be completed in 3 stages: before the intervention, the end of the intervention and a month after the end of the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Al-Shahada Hospital, Isfahan

Full name of responsible person

Masoud Bahrami

Street address

Hezar Jerib St., Department of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan

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bahrami@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

Department of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

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Email

m.aboudzadeh@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Marjan Aboudzadeh Behbahani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Department of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Bahrami

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The results of the study will be published in the form of a paper

Study Protocol

No - There is not 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 final report of the study is being prepared and the final paper will be published

When the data will become available and for how long

6 Months after the end of study

To whom data/document is available

Researchers and faculty members

Under which criteria data/document could be used

Using the results of the study can be used for future research

From where data/document is obtainable

Masoud Bahrami: Bahrami@nm.mui.ac.ir
Marjan Aboudzadeh: mabodzadeh@yahoo.com

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

Submitting a request for a master of RCT, approving a research committee at a university, receiving a proposal for a research project, accept or declining demand

Comments

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Marjan Aboudzadeh Behbahani

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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