

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effects of multimedia education on illness uncertainty in women with breast cancer

Protocol summary

Study aim

Determining the Effect of Multimedia Education on Uncertainty in Women with Breast Cancer.

Design

A randomized clinical trial was a single-blind clinical trial. A total of 60 patients were selected. Simple and objective sampling was done based on entry and exit criteria.

Settings and conduct

Before the uncertainty intervention, two groups of test and control are measured, then the educational DVD is provided to the test group. The uncertainty of both groups is determined 1 and 2 months after the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient's willingness to participate in the study. Confirmation of breast cancer by an oncologist. Awareness of the patient from his illness (the disease has not been hidden from him). Age 30 to 60 years old. At least six months have passed since they became infected and treated for cancer. Literacy to read and write in Persian. Access to the computer and the ability to use it at the beginner, level (Open CD and access information). The lack of cognitive and mental problems. The absence of a history of chronic underlying disease such as multiple sclerosis, AIDS, heart and respiratory failure. The patient is not in the stage 4. Exit criteria: Unwillingness to continue cooperation in the study, Immigration of the patient, Patient death

Intervention groups

Samples will be available in the DVD Intervention Team with educational content and training on how to use it and two weeks to view it. During this time, the researcher will remind the participants with SMS. The telephone number will be provided to them in order to be able to contact the researcher in the event of a problem or a question. In the control group, no intervention will be performed and only the uncertainty of the samples will be measured.

Main outcome variables

Multi-media education is expected to reduce uncertainty in women with breast cancer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180406039206N1**

Registration date: **2018-05-26, 1397/03/05**

Registration timing: **retrospective**

Last update: **2018-05-26, 1397/03/05**

Update count: **0**

Registration date

2018-05-26, 1397/03/05

Registrant information

Name

sara sadat hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4261 2862

Email address

hosseyani.s@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-16, 1396/08/25

Expected recruitment end date

2018-01-15, 1396/10/25

Actual recruitment start date

2017-11-16, 1396/08/25

Actual recruitment end date

2018-02-01, 1396/11/12

Trial completion date
empty

Scientific title
The effects of multimedia education on illness uncertainty in women with breast cancer

Public title
The effects of multimedia education on illness uncertainty in women with breast cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Awareness of the patient Have been at least six months old and have been treated for cancer. Literacy to read and write in Farsi Access to the computer and the ability to use it at the beginner level (Open CD and access information) Lack of history of chronic underlying chronic diseases such as multiple sclerosis, AIDS, heart and respiratory failure Patient is not at the end of stage (stage 4). Age 30 to 60 years Lack of cognitive and mental problems Confirmation of breast cancer by an oncologist
Exclusion criteria:
 Unwillingness to continue cooperation in the study Immigration of the patient death of the patient

Age
From **30 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
One-step cluster sampling will be done, so that from among the oncology clinics of Omid and Ghaem in Mashhad and Neyshabur, each center will first use the registers of patients referring to each center, a list of affected women Breast cancer will be prepared as a sampling frame for 60- 30 years, and then, using a simple random method, the research units will be selected from this list and DVD will be provided with multimedia tutorials along with the training required for patient delivery.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blindness of this study is a single blind blind blinded only after the study participants are kept blind to the study groups.

Placebo
Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشگاه علوم پزشکی گناباد

Street address

خیابان امام خمینی ، دانشگاه علوم پزشکی گناباد

City

گناباد

Province

Razavi Khorasan

Postal code

64199-43175

Approval date

2017-09-26, 1396/07/04

Ethics committee reference number

GMU.REC.1396.66

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce uncertainty and improve health.

Timepoint

Uncertainty measurements before intervention and 1 and 2 months after intervention.

Method of measurement

Uncertainty questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Samples will be included in the DVD intervention group with relevant educational content. Then, they will be given instructions on how to use this DVD and a two-week timetable for viewing the training program. During these two weeks, the researcher will

remind participants to use the multimedia broadcast app. They will also provide a telephone number to contact the researcher in the event of a problem or a question.

Category

N/A

2

Description

Control group: In the control group, no intervention is performed by the researcher, and only the uncertainty of the samples will be measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان 22 بهمن نیشابور

Full name of responsible person

سارا سادات حسینی

Street address

شهرک قدس، بلوار قدس غربی، پلاک 203

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939784959

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Email

hosseinisara345@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

علی محمد پور

Street address

گناباد، حاشیه جاده آسیایی، دانشگاه علوم پزشکی گناباد

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gonabad

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

سارا سادات حسینی

Position

دانشجو

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

شهرک قدس، بلوار قدس غربی، پلاک ۲۰۳

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

سارا سادات حسینی

Position

دانشجو

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The impact of multimedia education on uncertainty in women with cancer

When the data will become available and for how long

2018

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Research studies

From where data/document is obtainable

email_hosseinisara345@yahoo.com

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

1 month

Comments