

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 2026

The effect of problem- based learning on quality of life and life style of patients with breast cancer

Protocol summary

Study aim

Determining the Effect of Learning by Learning Method on Problem Solving on Quality of Life in Patients with Breast Cancer

Design

The sampling method was available in this way. By referring to the Oncology Department of Tohid Hospital in Sanandaj, the number of patients admitted to the diagnosis of breast cancer was determined and completed until a sample size (50 patients) was completed, then the sample They were randomly assigned to case and control groups based on random numbers.

Settings and conduct

First, the quality of life and healthy lifestyle questionnaires were assessed in both groups. Then, participants in the case group were trained for five sessions of one to one and a half hours based on a planned program based on problem-solving learning in groups of 4 to 5. During this period, no training was given to the control group. Finally, after completing the intervention, the samples again completed the questionnaires in two groups.

Participants/Inclusion and exclusion criteria

Criteria for inclusion in the study included age range of 20-60 years, patient collaboration, compliance with the informed consent form, participation in the training program by the participants, lack of history of chronic disease, drug use, mental illness and having appropriate physical conditions. Exclusion criteria included the lack of cooperation and dissatisfaction with the company in the study, as well as severe physical conditions and the history of chronic disease, drug use and mental illness.

Intervention groups

The case group participants were trained for five sessions of one to one and a half hours at the time of admission based on a program designed based on problem-solving learning in groups of 4 to 5. During this period, no training was given to the control group. The

educational content of this study in the general aspect of cancer include: fatigue, nausea and vomiting, pain, painful breathing, sleep disturbances, anorexia, diarrhea and constipation, and economic problems, in the specific aspect of the cancer including symptom scales, sexual function, imagination of the future And self-concept in the field of lifestyle, including dimensions of health accountability, physical activity, nutrition, spiritual growth, interpersonal relationships, and stress management. The intervention method was also carried out in 8 steps: First, the basic information about the problem to be taught was explained by the trainer, then the patient was asked to make the hypotheses based on his previous knowledge and experience 2. The instructor provided the information in response to the patient's questions. 3. The educator wanted the patient to address his major problems with regard to the studies and information collected. 4- The educator asked the patient to plan and say what he was saying. 5. The educator wanted the patient to have scientific defects. Which in his ability to understand the issue was raised.6 The educator gave the patient the opportunity to work on the problem on the basis of the method he chose and guided the patient, After review, he expects the patient to discuss the issue by choosing his own and provide solutions and how to implement the remedies. 7 The patient will explain any changes that have been made to the problem, and according to priorities, an issue. In detail, the controversy was discussed. The patient at this stage did what he did during the independent study and provided the new information specifically The specific question, explained why this information is particularly useful.

Main outcome variables

The quality of life of breast cancer in functional dimensions, quality of life, breast cancer in symptomatic dimensions, lifestyle in breast cancer

General information

Reason for update

Acronym**IRCT registration information**IRCT registration number: **IRCT20121015011122N2**Registration date: **2018-03-14, 1396/12/23**Registration timing: **retrospective**Last update: **2018-03-14, 1396/12/23**Update count: **0****Registration date**

2018-03-14, 1396/12/23

Registrant information**Name**

Hossein Feizi

Name of organization / entity**Country**

Iran (Islamic Republic of)

Phone

+98 87 3377 2638

Email address

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Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2016-10-22, 1395/08/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2016-12-20, 1395/09/30

Trial completion date

empty

Scientific title

The effect of problem- based learning on quality of life and life style of patients with breast cancer

Public title

the effect of problem- based learning on quality of life and life style

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The age range of between 20 and 63 years patient cooperation the completion of the informed consent form, participation in the training program by the participants absence of a history of chronic disease, drug use, mental illness theand having appropriate physical conditions

Exclusion criteria:

Incomplete cooperation of samples dissatisfaction with the company in the research severe physical conditions and the history of chronic disease, drug use and mental illness

AgeFrom **22 years** old to **63 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **50**Actual sample size reached: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Samples were randomly divided into case and control groups based on random numbers

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**

Ethics Committee of Kurdistan University of Medical Sciences

Street address

University of Medical Sciences, School of Nursing and Midwifery, Kordestan, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

6618634683

Approval date

2016-10-30, 1395/08/09

Ethics committee reference number

IR.MUK.REC.1395/235

Health conditions studied**1****Description of health condition studied**

breast cancer

ICD-10 code

C44.501

ICD-10 code description

Unspecified malignant neoplasm of skin of breast

Primary outcomes

1

Description

quality of life

Timepoint

Before and after the intervention

Method of measurement

Standard Quality of Life Quality Questionnaire, Breast Cancer Quality of Life Quality Questionnaire and Health Promotion Lifestyle Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: this group was trained for five sessions of one to one and a half hours at the time of admission based on a program designed based on problem-solving learning in groups of 4 to 5. The educational content of this study in the general aspect of cancer include: fatigue, nausea and vomiting, pain, painful breathing, sleep disturbances, anorexia, diarrhea and constipation, and economic problems, in the specific aspect of the cancer including symptom scales, sexual function, imagination of the future And mental self-concept in the context of lifestyle, including dimensions of health accountability, physical activity, nutrition, spiritual growth, interpersonal relationships, and stress management .

Category

N/A

2

Description

Control group: no intervention was performed in the control group during the training period in the experimental group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Hossein Feizi

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University of Medical Sciences, School of Nursing and Midwifery, Kordestan, Sanandaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Hossein Feizi

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University of Medical Sciences, School of Nursing and Midwifery, Kordestan, Sanandaj

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

hossein feizi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 3 months after printing the article

To whom data/document is available

Researchers working in academic and non-academic institutions

Under which criteria data/document could be used

For use as a research tool, as a discussion, use the research method

From where data/document is obtainable

Hossein Feizi, via personal e-mail (h_feyzi65@yahoo.com) and academic email (feizi.h@muk.ac.ir) and Kurdistan, Sanandaj, Medical Sciences University, Nursing and Midwifery Faculty, 08733772638, 09181731736

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

Send an email from the contact, receive and check the sent email, answer after a week

Comments