Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of implementing the family-centered empowerment model on resilience and hope in breast cancer patients referred to diagnostic and treatment centers

Protocol summary

Study aim

Determining the effect of implementing the family-centered empowerment model of resilience and hope in breast cancer patients

Design

The study will include an intervention group and a control group, each consisting of 44 participants. A total of 88 participants will be recruited from diagnostic and treatment centers in Ilam based on the inclusion criteria. Participants will be randomly assigned to either the intervention or control group using a block randomization procedure with a block size of 2.

Settings and conduct

The study will be conducted at diagnostic and treatment centers in Ilam. The study will involve an 8-session educational program for both the patient and their caregiver. During this time, the control group will not receive any intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Confirmed diagnosis of cancer by a medical specialist. Age between 18 and 65 years. At least 6 months have passed since the diagnosis of breast cancer. Fully alert and oriented. Ability to read and write. No underlying medical conditions. No major stressful life events, such as the death of a loved one, within the past 6 months. Completion of the informed consent form. Exclusion criteria for patients •Patient's unwillingness to continue •Crisis during the study •Incomplete questionnaires •Missing more than one session of the educational program

Intervention groups

The family-centered empowerment model will be implemented in four main stages over eight sessions for the intervention group: 1) Threat perception, 2) Enhancement of self-efficacy/problem-solving, 3) Enhancement of self-belief and self-esteem through educational participation, and 4) Evaluation. The control group, after obtaining informed consent, will receive standard care

Main outcome variables

resilience - hope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250105064279N1**
Registration date: **2025-04-02, 1404/01/13**
Registration timing: **prospective**

Last update: **2025-04-02, 1404/01/13**
Update count: **0**

Registration date

2025-04-02, 1404/01/13

Registrant information

Name

Masoumeh Zeraati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3225 1543

Email address

masoomehzeraati97mz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date

2025-08-22, 1404/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of implementing the family-centered empowerment model on resilience and hope in breast cancer patients referred to diagnostic and treatment centers

Public title

Investigating the effect of implementing the family-centered empowerment model on resilience and hope in breast cancer patients referred to diagnostic and treatment centers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of cancer by a specialist doctor Based on clinical findings, cytological studies, and medical diagnosis, the breast cancer is staged at 1-3. Age between 18 and 65 years At least 6 months have passed since the breast cancer diagnosis- Fully conscious and alert Able to read and write at a basic level No visual or auditory impairments that significantly affect communication No history of underlying medical conditions (such as heart attack, stroke, heart failure, acute psychiatric illness, or known psychiatric disorder) No significant stressful life events, such as the death of a loved one, within the past 6 months(based on patient reports) Completion of an informed consent form to participate in the study Living with at least one family member Not employed as a healthcare provider

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, 88 breast cancer patients were selected from diagnostic and treatment centers in Ilam, based on the study's inclusion criteria. Subsequently, they were randomly assigned to two groups (intervention and control) using a block randomization method with a block size of 2

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 Ilam University of Medical Sciences

Street address

Banganjab, Ilam University of Medical Sciences, Research and Technology Building

City

ilam

Province

Ilam

Postal code

6939177143

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.MEDILAM.REC.1403.247

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description

resilience

Timepoint

before the intervention - after the intervention and one month after the intervention

Method of measurement

Connor-Davidson Resilience Scale

2

Description

hope

Timepoint

before the intervention - after the intervention and one month after the intervention

Method of measurement

Miller Hope Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: : The stages of the family-centered empowerment model are in 4 main steps, respectively, including 1- understanding the threat, 2- promoting self-efficacy/problem solving, 3- promoting self-confidence and self-esteem through educational participation, 4- evaluation will be done during 8 sessions for the intervention group. became .
Category
Other

2

Description
Control group: Patients in the control group will not be subjected to any intervention in the form of research
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital, Ilam
Full name of responsible person
Masoumeh Zeraati
Street address
Banganjab, the end of the research boulevard
City
ilam
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Postal code
٦٩٣١٩٣٤٨٣٣
Phone
+98 84 3224 8555
Email
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Web page address
http://razi.medilam.ac.ir/en-us/

2

Recruitment center
Name of recruitment center
Oncology offices in the city of Ilam
Full name of responsible person
Masoumeh Zeraati
Street address
Ilm University of Medical Sciences Research Boulevard Bangunjab District
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
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Masoumeh Zeraati
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Non-communicable diseases research center
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
Ilam University of Medical Sciences
Full name of responsible person
Masoumeh Zeraati
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All potentially identifiable data can be shared after individuals have been anonymized
When the data will become available and for how long
Access to the data will begin six months after the results are published
To whom data/document is available
For all researchers
Under which criteria data/document could be used
For use in other research
From where data/document is obtainable
A.raiesifar@gmail.com You can refer to this email address :masoomehzeraati97mz@gmail.com
What processes are involved for a request to access data/document
After the completion of the study and the publication of the results, by sending an email to the responsible author, the documentation can be accessed within a maximum of 6 weeks
Comments