Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of family-centered empowerment on the quality of life and self-efficacy in cancer patients undergoing chemotherapy in Shariati Fasa Hospital

Protocol summary

Study aim

Studying the effect of family-centered empowerment on the quality of life and self-efficacy of cancer patients undergoing chemotherapy at Shariati Hospital, Fasa, in 2025.

Design

In this study, the sample size was determined with a confidence level of 95%, a test power of 80%, and based on the results of the study by Masoudi et al. (35), considering the possibility of sample attrition and with the aim of improving the statistical power of the tests, 40 people were determined for each group, for a total of 80 people. Volunteers who met the entry requirements for the study were divided into two intervention and control groups based on the random selection software. The randomization method of individuals into two groups was performed using the Balanced Block Randomization method in the form of Random Allocation software in a one-to-one ratio.

Settings and conduct

The study was conducted at Shariati Hospital in Fasa County.

Participants/Inclusion and exclusion criteria

I. c.: At least two months after cancer diagnosis, age 30 to 60 years, having a caregiver or active family member.
E. c.: Unwillingness to continue participating

Intervention groups

For the test group, the family-centered empowerment program is implemented based on the steps of the empowerment model. The steps of the family-centered empowerment model are in order and in 4 main steps: 1- Understanding the threat, 2- Improving self-efficacy/problem solving, 3- Improving self-confidence and self-esteem through educational participation, and 4- Evaluation.

Main outcome variables

quality of life, self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250611066184N1**
Registration date: **2025-08-05, 1404/05/14**
Registration timing: **prospective**

Last update: **2025-08-05, 1404/05/14**
Update count: **0**

Registration date

2025-08-05, 1404/05/14

Registrant information

Name

Azam Zare Banadkoki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-21, 1404/07/29

Expected recruitment end date

2026-02-08, 1404/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of family-centered empowerment on the quality of life and self-efficacy in cancer patients undergoing chemotherapy in Shariati Fasa Hospital

Public title
Investigating the effect of family-centered empowerment on the quality of life and self-efficacy in cancer patients undergoing chemotherapy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
At least two months have passed since the diagnosis of cancer , having a caregiver or active family member not suffering from serious and debilitating complications of cancer undergoing chemotherapy able to speak and communicate able to read and write not suffering from another chronic disease adults aged 30 to 60 years willing to participate in the study , interested and able to learn the material

Exclusion criteria:
Absence of more than one session in training sessions unwillingness to continue cooperation in the present study.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals who are willing and meet the entry requirements for the study are divided into two groups: intervention and control based on the random selection software. The randomization method of individuals into two groups is carried out using the Balanced Block Randomization method in the Random Allocation software in a one-to-one ratio.

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 Fasa University of Medical Sciences

Street address
Abn Sina Squre

City
Fasa

Province
Fars

Postal code
۷۴۶۱۶-۸۶۶۸۸

Approval date
2024-10-26, 1403/08/05

Ethics committee reference number
IR.FUMS.REC.1403.088

Health conditions studied

1

Description of health condition studied
in cancer patients undergoing chemotherapy

ICD-10 code
Z51.11

ICD-10 code description
Encounter for antineoplastic chemotherapy

Primary outcomes

1

Description
quality of life

Timepoint
before, after and 2 month after

Method of measurement
To assess quality of life, a specific questionnaire for measuring quality of life in cancer patients, developed by Arneson in 1987, is used. This questionnaire was standardized by Montazeri and colleagues in Iran.

Secondary outcomes

1

Description
self efficacy

Timepoint
before, after and two month after

Method of measurement
The Self-Care Self-Efficacy Questionnaire was first designed by Lu in 1996 for cancer patients and was translated into a Persian version and used by Azizi.

Intervention groups

1

Description

Intervention group: Before the intervention, the demographic characteristics checklist, quality of life questionnaire, and self-efficacy questionnaire are completed by the intervention group. And a pre-test is taken from the sample units. For the test group, the family-centered empowerment program is based on the steps of the empowerment model and according to the designed educational program. The first step (perception of threat) sessions will be held in groups of 10 people, consisting of 5 patients and 5 family members (one member of the main family caregiver), in the form of discussion and exchange of opinions and questions and answers by the researcher in one of the hospital meeting rooms using educational aids such as whiteboards, projectors, and PowerPoint. After selecting the first 5 patients, the first step empowerment sessions will be held with a family member of the patient, and the subsequent sessions for the subsequent steps will be held individually (one patient and one family member). The interval between sessions will be between 5 and 7 days, depending on the patient and the family caregiver. The patient will participate in these sessions with the family caregiver. The researcher will have the role of educational, supportive, and guiding participation. The intervention stages are as follows:. The steps of the family-centered empowerment model will be carried out in four main steps: 1- Understanding the threat, 2- Promoting self-efficacy/problem solving, 3- Promoting self-confidence and self-esteem through educational participation, and 4- Evaluation: 1. Step 1, Understanding the threat: The first step in the family-centered empowerment model is to increase perceived severity and sensitivity. The purpose of perceived severity (awareness and knowledge of the individual about the disease) is for the individual to understand the seriousness of the disease by recognizing the risks or complications of the disease and to feel threatened by it. In order to sensitize and increase the level of information of patients and their families, group sessions will be held on the nature of the disease, symptoms, complications, prognosis of the disease, diet, treatment regimen, physical activities, and laboratory tests during two sessions (each session 40 to 60 minutes) with educational aids. At the end of the training sessions, questions and answers will be held to ensure understanding of the material. Both the patient and the family caregiver will participate in the discussions and their problems will be identified, discussed and prioritized. 2. The second step, self-efficacy: Problem solving or problem solving will be implemented in a group method. For this purpose, problem solving sessions (two 40-60 minute sessions) will be held for a group of patients and their families. In these sessions, patients and families will practically face problems and the problem-solving process. In these two sessions, the skills necessary for better disease control will be explained and practiced. Then, patients and families will be asked to practice this skill. For example, one of the problems faced by patients undergoing chemotherapy is nausea and vomiting, and the type of drug that controls this condition and the dosage amount will be demonstrated in class. Also, with regard to the condition of hair loss, how to use a wig will be taught and practiced. 3. Step Three, Self-Belief and Increased Self-Confidence: In this step, the patient will be asked to teach the family the material discussed in the previous sessions during a session and to do so with the researcher's help and guidance if needed. The goal of this step is to increase the patients' self-confidence due to observing their ability to provide information to family members and support the family. 4. Step Four, Evaluation: Evaluation consists of 2 steps. 1- Process evaluation 2- Final evaluation 5. Process evaluation will be carried out during the empowerment sessions in such a way that the educational materials of the previous sessions will be evaluated in the form of questions and answers in the next session. The final evaluation will be carried out immediately and two months after the intervention, quality of life and self-efficacy questionnaires will be completed by both intervention groups. And a post-test will be taken again. During this period, the researcher will follow up with the patient and the family caregiver via telephone call. Follow-up and telephone call will be made every 5 days for 5 to 10 minutes to answer their questions.

Category

Lifestyle

2

Description

Control group: Initially, the demographic characteristics checklist, quality of life questionnaire, and efficacy questionnaire are completed by the control group and a pre-test is administered to them. The control group receives training in the form of lectures and face-to-face according to the routine of the inpatient ward. Considering that the training received by patients is during hospitalization and at the time of discharge from the hospital, the quality of life questionnaire and self-efficacy questionnaire are completed again at the time of discharge, and a post-test is also administered. In the following two months, the quality of life and self-efficacy questionnaires are completed and the post-test is administered again.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Fasa Hospital

Full name of responsible person

Azam Zare

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Sponsors / Funding sources

1

Sponsor
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Grant name
Office of Research, Fasa University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa 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
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Fasa University of Medical Sciences
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Azam Zare
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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

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

All potential data is shareable after individuals are de-identified.

When the data will become available and for how long

Access begins 4 months after results are published.

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

To write meta-analysis studies

From where data/document is obtainable

Dr. Azam Zare - Fasa University of Medical Sciences

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

Submit a written request

Comments