Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Family-Centered Empowerment Model on Cancer-stigma in patients with cancer

Protocol summary

Study aim
Determining the impact of family-centered empowerment model on cancer stigma in cancer patients

Design
Study will be conducted as a clinical trial with two groups: a control and an intervention group, using a single-blind method, with random allocation through the use of sealed envelopes on 80 patients.

Settings and conduct
This study will be conducted in the hematology department or the outpatient chemotherapy center of Ayatollah Rouhani Hospital in Babol. 40 patients will be placed in each group. The questionnaire related to cancer stigma will initially be completed by both groups. Then, one month after the implementation of family-center empowerment model through virtual environment in the intervention group, and one month after the pre-test in the control group, the questionnaire will be completed again by the patients.

Participants/Inclusion and exclusion criteria
Registering the diagnosis of cancer related to the digestive, blood circulation and urogenital system, at least 6 months have passed since the diagnosis, the patient is over 18 years old and the caregiver is between 18 and 60 years old, lack of previous care history of a cancer patient by the caregiver, ability to use virtual environment Failure to enter: Suffering from mental problems and learning disorders, unwillingness to attend the meetings, are among health care providers

Intervention groups
In this study, the control and intervention group will receive routine cancer care. In the intervention group, the patient and their family caregiver will undergo family-centered empowerment model in four main steps, which include: Understanding the threat, Enhancing self-efficacy/problem-solving, Promoting self-belief and self-esteem through educational participation, Evaluation.

Main outcome variables
Cancer stigma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250112064366N1**
Registration date: **2025-02-22, 1403/12/04**
Registration timing: **prospective**

Last update: **2025-02-22, 1403/12/04**
Update count: **0**

Registration date
2025-02-22, 1403/12/04

Registrant information

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Elham Emamgholizadeh Baboli

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-03, 1404/01/14

Expected recruitment end date
2025-06-21, 1404/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of Family-Centered Empowerment Model on Cancer-stigma in patients with cancer

Public title
Effect of family education on the attitude towards cancer in patients with cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The diagnosis and type of cancer in the patient's file should be recorded by the physician The patient should be suffering from cancer related to the digestive system, circulatory system, and urinary-reproductive system (considering the widespread prevalence of these cancers in Mazandaran province) At least 6 months should have passed since the onset of the cancer The patient should be able to communicate verbally with the researcher The patient's age should be over 18 years The patient must have at least basic reading and writing skills There should be the possibility of accessing the patient after discharge from the hospital The patient and the family caregiver must be fluent in Persian The family caregiver should be between the ages of 18 and 60 The family caregiver should not have a history of caring for a cancer patient The family caregiver should have the ability to read and write The family caregiver should have the ability to use virtual environment by a smartphone

Exclusion criteria:
The patient and the family caregiver do not want to attend the meetings The patient and the family caregiver are among the health care providers The patient has mental problems and learning disorders (recording mental and learning disorders in the patient's file and history of previous illnesses and taking antipsychotic drugs) The family caregiver has a mental problem (taking antipsychotic drugs)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are selected through convenience sampling and are randomly divided into two groups: control and intervention. To achieve randomization, a method of drawing sealed envelopes is used. In this method, a number of envelopes are designated by the researcher for the intervention group, and the same number of envelopes is allocated for the control group. Then, by merging the envelopes together (drawing the envelopes), one envelope is drawn and its allocation is recorded. After being drawn, that envelope is returned to the collection of other envelopes. Then the letters are merged again, and another letter is produced. This process continues until a random sequence corresponding to the sample size is reached. The concealment of random allocation is also carried out using opaque envelopes that are sealed with a random sequence. In this method, a random sequence is first generated using the mentioned method. Then, based on the sample size of the research, a number of letters are prepared with aluminum envelopes (to ensure the content of the letters is not visible), and each of the generated random sequences is recorded on one letter. The letters are then placed in the envelopes in order. In order to maintain a random sequence, the envelopes are numbered on the outside in the same order. Finally, the flaps of the envelopes are sealed and placed in a box in order. At the time of starting the registration of participants, based on the order of arrival of eligible participants for the study, one of the envelopes is opened in sequence, revealing the assigned group of that participant. The intervention and control groups are matched based on the average ratio of gender and age.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, a single-blind method will be used for the patients. In this way, for the intervention group, in addition to providing routine care, family-centered empowerment model will be conducted for the patient and their family caregiver, while the control group will only receive routine cancer-related care. It is worth mentioning that none of the participants will be aware of which group they belong to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Health Research Institute - Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganj Afrooz St., Babol

City
Babol

Province
Mazandaran

Postal code
4717647745

Approval date
2024-11-18, 1403/08/28
Ethics committee reference number
IR.MUBABOL.HRI.REC.1403.278

Health conditions studied

1

Description of health condition studied
Digestive system cancer
ICD-10 code
C16
ICD-10 code description
Malignant neoplasm of stomach

2

Description of health condition studied
Digestive system cancer
ICD-10 code
C15
ICD-10 code description
Malignant neoplasm of esophagus

3

Description of health condition studied
Digestive system cancer
ICD-10 code
C17
ICD-10 code description
Malignant neoplasm of small intestine

4

Description of health condition studied
Digestive system cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

5

Description of health condition studied
Digestive system cancer
ICD-10 code
C19
ICD-10 code description
Malignant neoplasm of rectosigmoid junction

6

Description of health condition studied
Digestive system cancer
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

7

Description of health condition studied
Digestive system cancer
ICD-10 code
C21
ICD-10 code description
Malignant neoplasm of anus and anal canal

8

Description of health condition studied
Digestive system cancer
ICD-10 code
C22
ICD-10 code description
Malignant neoplasm of liver and intrahepatic bile ducts

9

Description of health condition studied
Digestive system cancer
ICD-10 code
C23
ICD-10 code description
Malignant neoplasm of gallbladder

10

Description of health condition studied
Digestive system cancer
ICD-10 code
C24
ICD-10 code description
Malignant neoplasm of other and unspecified parts of biliary tract

11

Description of health condition studied
Digestive system cancer
ICD-10 code
C25
ICD-10 code description
Malignant neoplasm of pancreas

12

Description of health condition studied
Digestive system cancer
ICD-10 code
C26
ICD-10 code description
Malignant neoplasm of other and ill-defined digestive organs

13

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

14

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C51
ICD-10 code description
Malignant neoplasm of vulva

15

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C52
ICD-10 code description
Malignant neoplasm of vagina

16

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C53
ICD-10 code description
Malignant neoplasm of cervix uteri

17

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C54
ICD-10 code description
Malignant neoplasm of corpus uteri

18

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C55
ICD-10 code description
Malignant neoplasm of uterus, part unspecified

19

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C56
ICD-10 code description
Malignant neoplasm of ovary

20

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C57
ICD-10 code description
Malignant neoplasm of other and unspecified female genital organs

21

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C58
ICD-10 code description
Malignant neoplasm of placenta

22

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C60
ICD-10 code description
Malignant neoplasm of penis

23

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C61
ICD-10 code description
Malignant neoplasm of prostate

24

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C62
ICD-10 code description
Malignant neoplasm of testis

25

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C63
ICD-10 code description
Malignant neoplasm of other and unspecified male genital organs

26

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C64
ICD-10 code description
Malignant neoplasm of kidney, except renal pelvis

27

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C65
ICD-10 code description
Malignant neoplasm of renal pelvis

28

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C66
ICD-10 code description
Malignant neoplasm of ureter

29

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C67
ICD-10 code description
Malignant neoplasm of bladder

30

Description of health condition studied
Urinary-reproductive system cancer
ICD-10 code
C68
ICD-10 code description
Malignant neoplasm of other and unspecified urinary organs

31

Description of health condition studied
Circulatory system cancer
ICD-10 code
C81
ICD-10 code description
Hodgkin lymphoma

32

Description of health condition studied
Circulatory system cancer
ICD-10 code
C82
ICD-10 code description
Follicular lymphoma

33

Description of health condition studied
Circulatory system cancer
ICD-10 code
C83
ICD-10 code description
Non-follicular lymphoma

34

Description of health condition studied
Circulatory system cancer
ICD-10 code
C84
ICD-10 code description
Mature T/NK-cell lymphomas

35

Description of health condition studied
Circulatory system cancer
ICD-10 code
C85
ICD-10 code description
Other specified and unspecified types of non-Hodgkin lymphoma

36

Description of health condition studied
Circulatory system cancer
ICD-10 code
C86
ICD-10 code description
Other specified types of T/NK-cell lymphoma

37

Description of health condition studied
Circulatory system cancer
ICD-10 code
C88
ICD-10 code description
Malignant immunoproliferative diseases and certain other B-cell lymphomas

38

Description of health condition studied
Circulatory system cancer
ICD-10 code
C90
ICD-10 code description
Multiple myeloma and malignant plasma cell neoplasms

39

Description of health condition studied
Circulatory system cancer
ICD-10 code
C91
ICD-10 code description
Lymphoid leukemia

40

Description of health condition studied
Circulatory system cancer
ICD-10 code
C92
ICD-10 code description
Myeloid leukemia

41

Description of health condition studied
Circulatory system cancer
ICD-10 code
C93
ICD-10 code description
Monocytic leukemia

42

Description of health condition studied
Circulatory system cancer
ICD-10 code
C94
ICD-10 code description
Other leukemias of specified cell type

43

Description of health condition studied
Circulatory system cancer
ICD-10 code
C95
ICD-10 code description
Leukemia of unspecified cell type

44

Description of health condition studied
Circulatory system cancer
ICD-10 code
C96
ICD-10 code description
Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue

Primary outcomes

1

Description
Cancer stigma score in the (A questionnaire for measuring attitudes toward cancer (cancer stigma)
Timepoint
Measuring cancer stigma at the beginning of the study (before the start of the intervention) in both the intervention and control groups and 30 days after the start of the study in the control group and 75 days after the start of training in the intervention group
Method of measurement
Questionnaire for measuring attitudes toward cancer (cancer stigma)

Secondary outcomes

empty

Intervention groups

1

Description
In this group, the patient and his family caregiver, who is one of his first-class people, in addition to receiving routine cancer care and treatment, family-oriented training based on empowerment in 4 steps including 1. Understanding the threat, 2. Improving self-efficacy/problem solving, 3. Improving self-confidence and self-esteem through educational participation and 4. They will receive evaluation.
Category
Other

2

Description
Control group: This group only receives routine cancer care and treatment, and training based on family empowerment will not be implemented for this group of patients
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani hospital
Full name of responsible person
Hasanali Jafarpoor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Babol 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Not applicable
Title and more details about the data/document
After the end of the study and data analysis, the results and data including study protocol, statistical analysis map, clinical study report after removing confidential information will be available to all people who want to access and use this study
When the data will become available and for how long

Beginning of the access period from 2026

To whom data/document is available

All people

Under which criteria data/document could be used

Access is free

From where data/document is obtainable

Applicants can receive documents through the email address elhamegzb75@gmail.com.

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

Applicants should proceed with a full explanation of the purpose of accessing data and documents through a signed and official letter. Approximate time to send documents is 2 weeks.

Comments