

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison the effect of providing health information, based on client needs and nurse diagnosis, on anxiety of family members of cancer patients

Protocol summary

Study aim

Comparison of the effect of providing health information, based on client's needs and based on nurse's diagnosis, on the anxiety of family members of cancer patients

Design

Pre and post-test intervention research and phase 3. with parallel groups, on 40 first-degree family members of cancer patients, randomization at first by targeted method and then by minimization based on classes of anxiety and education

Settings and conduct

This study will be conducted in Ali Ibn Abitalib Hospital and Arsen Clinic in Rafsanjan. Family members of cancer patients will be provided with health information based on their needs. For the second group, health information will be identified during the nurse's interactions and based on the nurse's diagnosis. The anxiety score of the samples in the two groups before and after the intervention will be determined through the Spielberger situational anxiety questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First-degree family members of all patients with cancer in Rafsanjan in the age range of 18-75 years and diagnosed with cancer in the last 6 months, who have at least a high school diploma, sufficient cognitive ability to answer questions and obtain a moderate to high anxiety score from the Spielberger Situational Anxiety Scale. Exclusion criteria: Having a history of mental illness or addiction and unfortunate events in the last 6 months and the occurrence of circumstances that force one to leave the question and answer with the nurse.

Intervention groups

Intervention group 1: Providing cancer-related health information based on the needs of family members of cancer patients. Intervention group 2: health information related to cancer will be identified during the nurse's

interactions and the required information will be provided in different areas based on the nurse's diagnosis.

Main outcome variables

Anxiety state

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230611058452N1**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **retrospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Fatemeh Kianifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0000

Email address

kianifarfatemeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

2022-11-22, 1401/09/01

Actual recruitment end date

2023-01-31, 1401/11/11

Trial completion date

2023-01-31, 1401/11/11

Scientific title

Comparison the effect of providing health information, based on client needs and nurse diagnosis, on anxiety of family members of cancer patients

Public title

Investigating the effect of providing health information on family members anxiety of cancer patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range of 18-75 years Patients who have been diagnosed with cancer in the last 6 months Having at least a diploma in literacy Having sufficient cognitive ability for questioning and answering Being a first degree family member (father, mother, child, sibling and spouse) Provide written informed consent to participate in the study Getting a moderate to high anxiety score from the Spielberger situational anxiety scale

Exclusion criteria:

Having a known mental illness or addiction Experiencing any adverse events in the past 6 months Occurrence of circumstances that force you to leave questions and answers with the nurse

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Minimization method: Allocation of the first Subject in each class in one of the study groups will be by random drawing through a sealed envelope. The second sample with the same characteristic will be assigned to the next group in the same class.

Blinding (investigator's opinion)

Single blinded

Blinding description

The anxiety score of the samples in the two groups before and after the intervention will be determined through the Spielberger situational anxiety questionnaire by a researcher associate who does not know how to allocate the samples in the groups, by face-to-face interview method.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2022-07-30, 1401/05/08

Ethics committee reference number

IR.RUMS.REC.1401.092

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

The effect of providing cancer related health information on the anxiety of family members of cancer patients

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

The level of anxiety States

Timepoint

Before and after the intervention

Method of measurement

Spielberger state anxiety scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: For this group, information related to various health aspects of cancer patients will be provided by the nurse based on the needs and requests expressed by their family members.

Category

Other

2

Description

Intervention group2: For the second group, cancer-related health information was identified during the nurse's interactions and based on the nurse's diagnosis, the information needed in different areas such as the nature of cancer, diagnostic methods, treatment methods, disease process, disease consequences, treatment complications and disease recurrence symptoms, acceptance of the disease by the patient and family, recognition of symptoms that require immediate intervention, recognition of the psychological changes of patients in response to cancer, emotional support, proper relationship with the patient, nutrition, rehabilitation at home and the level of patients' activities and return to Normal life activities will be provided.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib Hospital

Full name of responsible person

Fatemeh Kianifar

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Ali Ibn Abitalib square, Imam Ali Blvd

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2

Recruitment center

Name of recruitment center

Arsen Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Tayebbeh Negahban Bonabi

Street address

Faculty of Nursing and Midwifery, Parastar Boulevard

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negahbant@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Tayebbeh Negahban

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available