

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 Subjectin 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

**Street address**

Ali Ibn Abitalib square, Imam Ali Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0000

**Email**

Kianifarfatemeh@gmail.com

**2**

**Recruitment center**

**Name of recruitment center**

Arsen Clinic

**Full name of responsible person**

Fatemeh Kianifar

**Street address**

Zeytoon Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7719756383

**Phone**

+98 34 3424 2452

**Email**

Kianifarfatemeh@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Tayebeh Negahban Bonabi

**Street address**

Faculty of Nursing and Midwifery, Parastar Boulevard

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

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. Tayebeh Negahban

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Parastar Boulevard

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

negahbant@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Tayebeh Negahban

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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rafsanjan

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**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

negahbant@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Fatemeh Kianifar

**Position**

Ms.Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Parastar Blvd

**City**

Rafsanjan

**Province**

Kerman

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7718796755

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

kianifar@gmail.com

**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