

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effects supportive care delivery on mood states, general health and competence of caregivers of cancer patients undergoing chemotherapy

#### Protocol summary

##### Study aim

Determining the impact of supportive care on general health, competence and mood states of caregivers of cancer patients undergoing chemotherapy

##### Design

Clinical trial, double blinding, sample size 60. Simple random table with Random Number Generator software will be placed into two control or intervention groups.

##### Settings and conduct

The study will be conducted in the chemistry department of Peymaniye Jahrom Hospital. The study will include 3 stages before the intervention (4 questionnaires will be filled), intervention (8 individual and group sessions) and after the intervention (4 mentioned questionnaires will be filled immediately and 1 month later). is double blind The researcher collecting data in the last stage and the statistical consultant were blinded.

##### Participants/Inclusion and exclusion criteria

Age: older than 18 years old; be the main caregiver; not being health personnel; not taking care of another chronic patient; having the physical ability and mental to participate in the study.

##### Intervention groups

Control group: usual care of the chemotherapy department (nurse and doctor visits and chemotherapy)  
Intervention group: supportive care will be provided for 8 weeks.

##### Main outcome variables

Improving the physical condition of patients, meeting the needs of caregivers, developing the role of nurses

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230128057252N1**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

##### Registration date

2023-07-08, 1402/04/17

##### Registrant information

###### Name

foroogh miri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5444 8187

###### Email address

foroogh.2001f@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-06, 1402/04/15

##### Expected recruitment end date

2024-01-21, 1402/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effects supportive care delivery on mood states, general health and competence of caregivers of cancer patients undergoing chemotherapy

##### Public title

The effects nurse supportive care delivery on mood states, general health and competence of caregivers of patients undergoing chemotherapy

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age: older than 18 years old  
The main caregiver of a patient undergoing chemotherapy  
No health personnel  
Not taking care of another chronic patient at the same time  
Having the ability Physical and mental to participate in the study

##### **Exclusion criteria:**

Significant emotional distress  
Reluctance to continue cooperation,  
Discontinuation of cooperation in patient care  
Death of the patient

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

#### **Sample size**

Target sample size: **60**  
More than 1 sample in each individual  
Number of samples in each individual: **30**  
The sample was the main caregivers of cancer patients who met the inclusion criteria

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

First, a call will be made in the chemotherapy department. After that, 60 people will be selected from among the volunteers who meet the Word criteria using the Random Number Generator software, and then random allocation will be done into two groups with the help of the previous software from among the 60 selected people.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The filling of the questionnaires will be done by the research assistant and the data analyst will be done by the statistical expert blindly  
Nurses provider routine care and person who will collect data in the study selection will also be blinded.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

#### **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Jahrom University of Medical Sciences

##### **Street address**

Jahrom University of Medical Sciences. Mtahari St.

##### **City**

Jahrom

##### **Province**

Fars

##### **Postal code**

7414846199

#### **Approval date**

2023-01-29, 1401/11/09

#### **Ethics committee reference number**

IR.JUMS.REC.1401.120

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

CAREGIVERS OF CANCER PATIENTS

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### **1**

#### **Description**

Mood state

#### **Timepoint**

Before starting the study - immediately after the intervention - 1 month after the intervention

#### **Method of measurement**

PROFILE OF MOOD STATES (POMS)

### **2**

#### **Description**

General health

#### **Timepoint**

Before starting the study - immediately after the intervention - 1 month after the intervention

#### **Method of measurement**

General health questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Caregiver competency

#### **Timepoint**

Before starting the study - immediately after the intervention - 1 month after the intervention

## Method of measurement

Caregiver competence Scale

## Intervention groups

### 1

#### Description

For the intervention group: supportive care will be provided for 8 weeks. Intervention steps: 1- Checking the initial evaluation results with questionnaires in the intervention group. 2- Holding training and counseling sessions in small groups (5-7 people) based on the common needs of caregivers, at least 8 sessions for each group (1 session per week). The location of the meetings was inside the chemotherapy department or one of the conference rooms of the hospital. Educational content includes: disease symptom management, stress management, fatigue management, pain control, nutrition maintenance, home care, psychological distress management. 3-Individual training based on the special needs of people if the caregiver declares. 4-Providing a booklet prepared according to the unique needs of caregivers among cancer patients according to scientific sources. Weekly telephone follow-up regarding the provided training and new needs and performing the recommended care. At least 2 times per week 6- Forming a virtual group with the aim of greater interaction and providing educational videos and CDs based on the unique needs of caregivers.

#### Category

Behavior

### 2

#### Description

Control group: For the control group: the usual treatments of the chemotherapy department (chemotherapy - doctor's visit if necessary and nurse's visit) were performed.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Pymanie hospital

##### Full name of responsible person

Najme Safajo

##### Street address

Pymanie hospital, Jahad Squ.

##### City

Jahrom

##### Province

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##### Postal code

7414846199

##### Phone

+98 71 5414 2221

## Email

hpeymanie@gmail.com

## Web page address

https://peymanie.jums.ac.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Jahrom University of Medical Sciences

##### Full name of responsible person

Kavoss Solhjo

##### Street address

Jahrom University of Medical Sciences, Motahari street

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##### Province

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##### Postal code

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##### Phone

+98 71 5434 0405

##### Email

k.solhjo@jums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

##### Full name of responsible person

Mohsen Hojat

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

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mohsenhojat.mh@gmail.com

## Person responsible for scientific inquiries

### Contact

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

### Contact

**Name of organization / entity**  
Jahrom University of Medical Sciences  
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**Other areas of specialty/work**

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**Province**  
Fars  
**Postal code**  
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**Phone**  
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**Email**  
mohsenhojat.mh@gmail.com

## 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

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

### Title and more details about the data/document

All data can be shared after de-identifying samples

### When the data will become available and for how long

Access 6 months after results are printed

### To whom data/document is available

Only for researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Meta-analysis is allowed

### From where data/document is obtainable

mohsen hojat mohsenhojat.mh@gmail.com 0098 9307915244

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

6 months after the publication of the article, contact the COrespond author's email (Dr. Hojjat) and receive it as soon as possible

### Comments