

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Effect of Stress Management Program on Psychological Distress of Cancer Patients and Caring Burden and Quality of Life of Their Caregivers

#### Protocol summary

##### Study aim

Investigation effect of stress management program on psychological distress of cancer patients and caring burden and quality of life of their caregivers

##### Design

Parallel randomized superiority controlled trial, using a random blocking allocation that cannot be blinded and sample size will be 60.

##### Settings and conduct

The research will be performed in Bahar Hospital in Shahroud that conducted. Standard questionnaires of quality of life, caring burden and stress, anxiety and depression at the beginning and 7 days after intervention will be completed.

##### Participants/Inclusion and exclusion criteria

Caregiver and patient age at least 15 years old; no psychological disorders in the caregiver; no drug addiction in the caregiver; no hearing or vision impairment in the caregiver. The caregiver should have the most contact with the patient; ability to access the Internet and online mass communication; have the minimum ability to use smartphones and social networks; no participation in other supportive interventions; the caregiver should not be a member of the healthcare system ; the caregiver is a family member of the patient; definitive diagnosis of cancer has been made by a doctor; the stage of the cancer is known; patients undergo chemotherapy.

##### Intervention groups

Intervention group: For the intervention group, 4 weekly sessions of 60 minutes are held in the form of participation in a group video call (webinar) in the form of lectures, group discussions, questions and answers, slide shows and clips. Outline of the session: (1- Stress signs/symptoms and their effect on health 2- Relaxation exercises 3- Social skills training, communication techniques, communication styles (aggressive, passive and assertive) 4 - Coping strategies (emotion and problem based).

#### Main outcome variables

Quality of life; caring burden

#### General information

##### Reason for update

Due to the lack of permission from the medical center to implement the intervention on the anticipated date, sampling and implementation of the intervention in the current study were conducted from January 16, 2024, to two months thereafter.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180728040617N3**  
Registration date: **2021-03-14, 1399/12/24**  
Registration timing: **prospective**

Last update: **2025-01-20, 1403/11/01**

Update count: **1**

##### Registration date

2021-03-14, 1399/12/24

##### Registrant information

###### Name

Seyedmohammad Mirhosseini

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 3811

###### Email address

mirhoseinim@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-16, 1402/10/26

##### Expected recruitment end date

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div>2024-03-19, 1402/12/29</div> <div>Actual recruitment start date</div> <div>empty</div> <div>Actual recruitment end date</div> <div>empty</div> <div>Trial completion date</div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <div>randomly assigned to Group A (intervention) or B (control group) in the order determined by the software, and the sampling process will be performed sequentially until sampling is completed. Individuals are assigned to the target group in order of their entry into the study and randomly through randomized blocks.</div>                                                                                                                                                           |
| <div>Scientific title</div> <div>Effect of Stress Management Program on Psychological Distress of Cancer Patients and Caring Burden and Quality of Life of Their Caregivers</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <div>Blinding (investigator's opinion)</div> <div>Not blinded</div>                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <div>Public title</div> <div>Effect of Stress Management Program on Psychological Distress of Cancer Patients and Caring Burden and Quality of Life of Their Caregivers</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <div>Blinding description</div> <div>Placebo</div> <div>Not used</div> <div>Assignment</div> <div>Parallel</div> <div>Other design features</div>                                                                                                                                                                                                                                                                                                                                               |
| <div>Purpose</div> <div>Supportive</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <div>Secondary Ids</div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <div>Inclusion/Exclusion criteria</div> <div>Inclusion criteria:</div> <div>Caregiver and patient age at least 15 years. No psychological disorders in the caregiver. No drug addiction in the caregiver. No hearing or vision impairment in the caregiver. The caregiver should have the most contact with the patient. Ability to access the Internet and online mass communication software. Have the minimum ability to use smartphones and social networks. Non-participation in other supportive interventions. The caregiver should not be a member of the health care system. The caregiver is a family member of the patient. The definitive diagnosis of cancer has been made by a doctor. The stage of the disease of each patient is known Patients undergo chemotherapy.</div> <div>Exclusion criteria:</div> <div>Do not participate in the post-test. Absence from more than two sessions in support sessions. The reluctance of the caregiver to participate in the sessions. Patient death during the study Transfer the patient to other medical centers Occurrence of stressful events (except for the usual treatment process) for the patient or caregiver</div> | <div>Ethics committees</div> <div>1</div> <div>Ethics committee</div> <div>Name of ethics committee</div> <div>Ethics committee of Shahroud University of Medical Sciences</div> <div>Street address</div> <div>Tehran st.</div> <div>City</div> <div>Shahroud</div> <div>Province</div> <div>Semnan</div> <div>Postal code</div> <div>3614773955</div> <div>Approval date</div> <div>2021-02-07, 1399/11/19</div> <div>Ethics committee reference number</div> <div>IR.SHMU.REC.1399.158</div> |
| <div>Age</div> <div>From 15 years old</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <div>Health conditions studied</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <div>Gender</div> <div>Both</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <div>1</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <div>Phase</div> <div>N/A</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <div>Description of health condition studied</div> <div>Cancer</div>                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <div>Groups that have been masked</div> <div>No information</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <div>ICD-10 code</div> <div>C00-C97</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <div>Sample size</div> <div>Target sample size: 60</div> <div>More than 1 sample in each individual</div> <div>Number of samples in each individual: 2</div> <div>Patient's psychological distress of each caregiver</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <div>ICD-10 code description</div> <div>Malignant neoplasms</div>                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <div>Randomization (investigator's opinion)</div> <div>Randomized</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <div>Primary outcomes</div> <div>1</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <div>Randomization description</div> <div>Caregivers will be divided into intervention and control groups by random block allocation using quadruple blocks created by SPSS software version 22. According to the sample size of 60 in the present study, 15 quadruple blocks will be considered. Each caregiver will be</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <div>Description</div> <div>Caregivers Caring burden</div> <div>Timepoint</div> <div>At the beginning of the study (before the intervention) and 7 days after intervention.</div> <div>Method of measurement</div> <div>Novak &amp; Guest Caring Burden Questionnaire</div>                                                                                                                                                                                                                     |

## 2

### Description

Caregivers Quality of Life

### Timepoint

At the beginning of the study (before the intervention) and 7 days after intervention.

### Method of measurement

Quality of Life Questionnaire SF-36

## Secondary outcomes

### 1

#### Description

Patients' psychological distress

#### Timepoint

At the beginning of the study (before the intervention) and 7 days after intervention.

#### Method of measurement

Lovibond Depression, Anxiety and Stress Scale (DASS-21)

## Intervention groups

### 1

#### Description

Intervention group: For the intervention group, 4 weekly sessions of 60 minutes are held in the form of participation in a group video call (webinar) in the form of lectures, group discussions, questions and answers, slide shows and clips. Outline of the session: (1- Stress and its effect on health, stress signs/symptoms 2- Relaxation exercises and their benefits 3- Social skills training, verbal/non-verbal communication techniques, different communication styles (aggressive, passive and assertive) 4 - Teaching coping strategies with stress (emotion-oriented and problem-oriented). Data collection tools included demographic information form, SF-36 quality of life questionnaire, Novak & Guest caring burden and Lovibond stress, anxiety and depression scale (DASS-21) which were administered by all caregivers and their patients before the intervention before the first session. (Intervention and Control Group), will be completed online. After 7 days from the end of the intervention sessions, the mentioned questionnaires will be completed to assess the effect of the intervention.

#### Category

Other

### 2

#### Description

Control group: They will receive routine support from the treatment centre. Supporting contents will be provided to the control group after the intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bahar Hospital

##### Full name of responsible person

Seyedmohammad Mirhosseini

##### Street address

22th Bahman St.

##### City

Shahrour

##### Province

Semnan

##### Postal code

3614773947

##### Phone

+98 23 3239 5054

##### Email

smohammadmh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahrour University of Medical Sciences

##### Full name of responsible person

Mohammad Hassan Emamian

##### Street address

Tehran st.

##### City

Shahrour

##### Province

Semnan

##### Postal code

3614773947

##### Phone

+98 23 3239 5054

##### Email

emamian@shmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahrour 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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Seyedmohammad Mirhosseini

**Position**

Bachelor in Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

7th Sq, Shahroud University of Medical Sciences,  
Shahroud, Iran.

**City**

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**Province**

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**Postal code**

3614773955

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Hossein Ebrahimi

**Position**

Associate professor Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Seyedmohammad Mirhosseini

**Position**

Bachelor in Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Postal code**

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**Phone**

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**Fax****Email**

mirhoseinim@shmu.ac.ir

## 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**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

Some of the patient and caregivers' demographic information can be shared after unidentifying individuals. All of the caregivers quality of life, caring burden and patients psychological distress assessment information can be shared with caregivers after unidentified individuals.

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

After publishing the article

**To whom data/document is available**

Project partners

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

People who do similar research

**From where data/document is obtainable**

It will be done by email with the person in charge of the project.

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

Data is made available to individuals via email.

**Comments**