Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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)

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+98 23 3239 3811

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-16, 1402/10/26

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

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.

Exclusion criteria:

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

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patient's psychological distress of each caregiver

Randomization (investigator's opinion)

Randomized

Randomization description

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 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.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Tehran st.

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.SHMU.REC.1399.158

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description

Caregivers Caring burden

Timepoint

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

Method of measurement

Novak & Guest Caring Burden Questionnaire

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
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22th Bahman St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hassan Emamian
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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
Shahroud 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
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Person responsible for updating data

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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