

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

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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 analyser 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

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Pymanie hospital, Jahad Squ.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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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

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