Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 trail, 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 than18 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 than18 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 analysor 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
Fars
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
City
Jahrom
Province
Fars
Postal code
7414846199
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
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Second floor, Nursinh faculty, Jahrom University of Medical Sciences, Motahari street

City
Jahrom
Province
Fars
Postal code
7414846199
Phone
0098 71543405
Email
mohsenhojat.mh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
mohsen hojat
Position
Asisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Second floor, Nursinh faculty, Jahrom University of Medical Sciences, Motahari street
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
0098 71543405
Email
mohsenhojat.mh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Mohsen Hojat
Position
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Second floor, Nursinh faculty, Jahrom University of Medical Sciences, Motahari street
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
0098 71543405
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