

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

Protocol summary

Study aim

Determination The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

Design

Clinical trials with control group, randomized, with parallel groups, without blinding

Settings and conduct

In two health Education clinics of Ghaem and Omid Hospital in Mashhad, 60 Caregivers and patients (in pairs) are randomly divided into two groups of control and intervention. Before intervention, demographic information and Caregiver Strain questionnaires and Unmet needs are completed by Caregivers and demographic information questionnaires and self-care behaviors are completed by patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria patients: willingness to participate in the study and informed consent, The definitive diagnosis of cancer of the esophagus and stomach and colorectal, Age greater than 18 and less than 65 years, The ability to read and write in Persian, Lack of speech and hearing problems, Candidate of Therapy 3 chemotherapy courses, Having access to the phone, Not a member health team, Lack of support by advocacy group, The main caregiver of being patient, The absence of specific psychological problems in carers and the use of medication to treat it; Unwillingness to continue cooperation

Intervention groups

In the intervention and control group, a 20-minute face-to-face training session is scheduled for caregivers of cancer patients. During this meeting, will be explained on how to care for the patient and At the end of the meeting, will be given several educational pamphlets include the materials taught to caregivers. In addition to

face-to-face training and educational pamphlets, the intervention group will receive four telephone consultations within 2 months (three courses of chemotherapy).

Main outcome variables

Caregiver Strain, Unmet Needs, Self-care Behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181114041660N1**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **prospective**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

fatemeh ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3523 8858

Email address

ghorbanif941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

Public title
The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Inclusion criteria patients: willingness to participate in the study and informed consent The definitive diagnosis of cancer of the esophagus and stomach and colorectal Age greater than 18 and less than 65 years The ability to read and write in Persian Lack of speech and hearing problems Candidate of Therapy 3 chemotherapy courses Having access to the phone Not a member health team Lack of support by advocacy group Inclusion criteria caregivers: willingness to participate in the study and informed consent The main caregiver of being patient The ability to read and write in Persian Having access to the phone Lack of speech and hearing problems The absence of specific psychological problems and the use of medication to treat it Not a member health team Lack of support by advocacy group
Exclusion criteria:
 Unwillingness to continue cooperation Failure to answer telephone calls and disconnect (if He/She does not answer 3 phone calls) The occurrence of stressful events for carers and patients during an intervention such as divorce, death of close relatives, sick death and job loss Failure to fully complete all three questionnaire of the self-care patients by the patients and the Burden and Unmet needs by the caregivers The patient's inappropriate general condition during the intervention so that his continued cooperation is not feasible Caregiver support by support groups

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block.Put the Four blocks in a sealed envelope and Then

they will be arranged in a straightforward Lottery way.

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Ebne sina St, Mashhad Nursing and Midwifery Faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-10-16, 1397/07/24

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.056

Health conditions studied

1

Description of health condition studied

Esophagus Cancer

ICD-10 code

C15

ICD-10 code description

Malignant neoplasm of esophagus

2

Description of health condition studied

Stomach Cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

3

Description of health condition studied

Colon Cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

4

Description of health condition studied

Colon Cancer

ICD-10 code

C19

ICD-10 code description

Malignant neoplasm of rectosigmoid junction

5

Description of health condition studied

Rectum Cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

6

Description of health condition studied

Rectum Cancer

ICD-10 code

C21

ICD-10 code description

Malignant neoplasm of anus and anal canal

Primary outcomes

1

Description

Caregiver Strain

Timepoint

Before the intervention and at the end of the intervention (the end of the second month)

Method of measurement

Zarit caregiver Burden Inventory

2

Description

unmet needs

Timepoint

Before the intervention and at the end of the intervention (the end of the second month)

Method of measurement

Supportive Care Needs Survey Partners and Caregivers

3

Description

self-care behaviors

Timepoint

Before the intervention and at the end of the intervention (the end of the second month)

Method of measurement

Nail Self-care Dairy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, a 20-minute face-to-face training session will be provided to caregivers of cancer patients. During this meeting, will be briefly explained on how to care for the patient, nutrition, activity and rest, the prevention of infection and the management of the symptoms of the disease and the side effects of chemotherapy and at the end of the meeting several educational pamphlets includes subjects taught will be given to carers. In addition to face-to-face training and educational pamphlets, the intervention group will receive four telephone consultations within 2 months (in the first course of chemotherapy after entering the study 2 calls and in the second and third chemotherapy course each one will receive a call). In the first telephone interview, a review of educational materials about patient problems and self-care with the patient is conducted and the second session will be discussed with the caregiver about symptoms management, Uncertainty reduction, optimistic attitudes and effective adjustment skills.

Category

Other

2

Description

Control group: In the control group, a 20-minute face-to-face training session will be provided to caregivers of cancer patients. During this meeting, will be briefly explained on how to care for the patient, nutrition, activity and rest, the prevention of infection and the management of the symptoms of the disease and the side effects of chemotherapy and at the end of the meeting several educational pamphlets includes subjects taught will be given to carers. Carers will receive routine education through nurses and referral to hospital health Education clinics.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Ghorbani Fatemeh

Street address

Dr. Ali Shariati Square, Beginning at Ahmadabad Street

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Razavi Khorasan
Postal code
9176699199
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ghorbanif941@mums.ac.ir

2

Recruitment center

Name of recruitment center
Omid hospital
Full name of responsible person
Ghorbani Fatemeh
Street address
koohsangi Ave, Alndasht Square
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tafaghodi Mohsen
Street address
University St, Facing University Street 18, Deputy of
University Technology and Research
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Phone
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Email
tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Ghorbani Fatemeh
Position
Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Mashhad, Ebme sina St, Nursing and Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zare Masoud
Position
tutor
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ghorbani Fatemeh

Position

Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used for other human research and health centers

From where data/document is obtainable

Library of the School of Nursing and Midwifery of Mashhad ghorbanif941@mums.ac.ir

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

Visit the Library of Nursing and Midwifery Faculty of Mashhad

Comments