Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Supportive-Educational Intervention on Caregiving Burden and Quality of Life of Family Caregivers of Gastric Cancer Patients Under Home-Based Palliative Care

Protocol summary

Study aim

Determining the effect of supportive-educational intervention on caregiving burden and quality of life of family caregivers of gastric cancer patients under home-based palliative care referred to selected centers in Isfahan in 2023

Design

The clinical trial with a control group, with parallel groups, without blinding, randomized by random block method in the form of blocks of four, the sample size for each group was calculated to be 32 people.

Settings and conduct

The samples will be selected by the easy sampling method and based on the list introduced by the selected centers of Isfahan. Then they are placed in two groups of test and control in a random block. The intervention for the test group will be based on the theoretical framework of CARES, which includes an educational-supportive program and will be carried out during 4 sessions over four weeks, individually and at the patient's home by the researcher and with the presence of a supervisor, as well as the supervision of the palliative care team for the caregiver. will be. Caregivers in the control group only receive routine care provided by the hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed willingness, age over 18; ability to read and write; living in Isfahan; being the main caregiver of the patient. Exclusion criteria: suffering from mental and physical disorders; entrusting the responsibility of care to another person; incomplete completion of questionnaires; being a member of the health team.

Intervention groups

Test group: will receive educational-supportive intervention during 4 sessions for four weeks individually and at the patient's home by the researcher and with the presence of a supervisor and also under the supervision of the palliative care team. Control group: receive routine care provided by the hospital.

Main outcome variables

Care burden; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170731035424N4**
Registration date: **2023-08-15, 1402/05/24**
Registration timing: **prospective**

Last update: **2023-08-15, 1402/05/24**
Update count: **0**

Registration date

2023-08-15, 1402/05/24

Registrant information

Name
Sedigheh Farzi
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Supportive-Educational Intervention on Caregiving Burden and Quality of Life of Family Caregivers of Gastric Cancer Patients Under Home-Based Palliative Care

Public title
Effect of Supportive-Educational Intervention on Caregiving Burden and Quality of Life of Family Caregivers of Gastric Cancer Patients Under Home-Based Palliative Care
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness and written informed consent to participate in the study Being over 18 years old Able to read and write Having a place of residence in the geographical area of Isfahan city The family caregiver should be considered as the main caregiver of the patient who is responsible for all the responsibilities of the patient Caregiver should only take care of a chronic illness in the family Not participating in other research projects in this field
Exclusion criteria:
Suffering from any mental and physical disorders in such a way as to cause dysfunction Giving the responsibility of caring for the client to another person during the study Incomplete completion of questionnaires Being a member of the health team
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be placed in two groups of 32 people, test and control, after being selected by random block method in the form of blocks of four (2 test persons and 2 control persons) and 16 blocks which are selected by chance. Also, randomization will be done using Random Allocation software version 1.
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
Research Ethics Committees of Nursing, Rehabilitation and Management schools - Isfahan University of
Street address
Building No. 4, Vice-Chancellor for Research & Technology, Isfahan University of Medical Sciences, Hezar Jerib St.
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Isfahan
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Postal code
81746-73461
Approval date
2023-08-05, 1402/05/14
Ethics committee reference number
IR.MUI.NUREMA.REC.1402.066

Health conditions studied

1

Description of health condition studied
Gastric cancer
ICD-10 code
C16.9
ICD-10 code description
Malignant neoplasm of stomach, unspecified

2

Description of health condition studied
Home-based palliative care
ICD-10 code
Z51.5
ICD-10 code description
Encounter for palliative care

Primary outcomes

1

Description
Caregiving burden
Timepoint
Measurement of previous caregiving burden at the beginning of the study (before the start of the intervention), immediately and two months after the intervention

Method of measurement

Zarit caregiving Burden questionnaire

2

Description

Quality of life

Timepoint

Measurement of previous quality of life at the beginning of the study (before the start of the intervention), immediately and two months after the intervention

Method of measurement

The world health organization quality of life brief version questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention for the test group will be based on the CARES theoretical framework to address the needs of family caregivers in palliative care settings. This intervention, which includes an educational-supportive program during 4 sessions for four weeks (one session each week) individually and at the patient's home by the researcher and with the presence of a supervisor and also under the supervision of the palliative care team (including: the researcher, supervisor, doctor, psychologist, clergy, nurse, nutritionist) will be done for the caregiver. The first session of the intervention will begin with the introduction of the caregiver and the goals of the research and its process. In this way, the caregivers of the test group were invited by the researcher through a phone call in groups of 8-9 people to the study room of Seyed-al-Shohada Hospital, and each group will get to know the research team and how to participate in the research process during a 90-minute session. In addition, explanations about the concepts of palliative care at home and the caring role will be presented to them, and each of the caregivers will discuss the problems and challenges in the field of patient care. Also, during this meeting, the needs of the caregivers in the field of patient care will be identified, and at the end of the session, the questions and doubts of the caregivers will be answered, and they will be welcomed. The second session of the intervention will be conducted in order to identify the individual needs of the caregiver and develop a training-support program. In this way, after making the necessary arrangements, the researcher, by attending the patient's home together with the supervisor and taking into account the conditions of the home and the caregiver's literacy level, during a 60-minute session, talked with him about his relationship with the patient, the situation Life, occupation, physical-mental health, capacity and willingness to provide care and the impact of care in his/her daily life will be addressed and thus will identify the individual needs of the caregiver. Also, in this active participation, the researcher will answer the questions and doubts of the caregivers. After this meeting, the researcher, in a joint meeting with the presence of the palliative care team and the supervision of the supervisor in the study room of Seyed-al-Shohada Hospital, summarized the needs of the caregivers based on their active participation and benefiting from the results of the qualitative study by Taleghani et al. family caregivers of patients with stomach cancer will pay and finally they will develop an educational-support program. It should be noted that in the second session, there will be an active and two-way telephone follow-up between the researcher and the caregiver with the aim of re-examining the needs of the caregiver, which may not have been addressed during the researcher's presence at the patient's home, in order to respond to these needs if necessary. also be included in the educational-supportive program. In the third session, the training-support program for each caregiver will be implemented individually and his needs will be re-evaluated. In this way, during this meeting, after making the necessary arrangements, the researcher will present the content of the educational-support program for care by being present at the patient's home accompanied by the supervisor. Training on the practical aspects of care (including managing the patient's physical symptoms, acquiring practical skills for daily care of the patient and managing the patient's nutritional plan) as well as focusing on preparing the caregiver for possible confrontation with bereavement and reactions related to it. The main components of this program will be Also, during this 60-minute session, the researcher will review the caregiver's needs, which may not have been addressed in the previous sessions. Since the program will have the ability to be updated, if there are new needs for the caregiver and the educational-support program does not respond to it, the researcher will discuss the matter by phone with the supervisor and consult with him at the same moment. The carer will contact a member of the palliative care team by phone depending on his needs. It should be noted that during this meeting, the active communication between the researcher and the caregiver will be maintained through phone calls in order to resolve possible ambiguities and problems in the implementation of the program. In the fourth session, after making the necessary arrangements, the researcher will again be present at the patient's home accompanied by the supervisor, and while answering questions and doubts regarding the educational-supportive program, he will discuss with the caregiver about the responsiveness of the content provided in order to resolve He will address their needs and problems in patient care and get a general summary of the sessions. At the end of the meeting, the researcher will provide the research questionnaires again to the caregiver to complete. It should be noted that at the same time as this meeting, the research questionnaires will be distributed again by the researcher to the control group to be completed.

Category

Lifestyle

2

Description
Control group: Caregivers in the control group will not receive an intervention like the one intended for the test group during the research period, and they will only receive the routine care provided by the hospital.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyed-al-Shohada Hospital

Full name of responsible person
Dr. Abdullah Askari

Street address
Seyed-al-Shohada Hospital, Nah Farshadi Quarter., Khayyam St.

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Isfehan

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Ali Hatami

Position
Master of Science in Medical Surgical Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Ph.D.

Other areas of specialty/work
Nursery

Street address
Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St.

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

By maintaining the confidentiality of the individual characteristics of the participants, the results of the study will be shared based on the objectives of the study.

When the data will become available and for how long

The access period will start 1 month after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions are allowed to send requests to receive non-identifiable personal data or other documents. The use of documents and data will be allowed only to reduce the burden of care and improve the quality of life of caregivers of cancer patients, as well as to improve nursing knowledge.

From where data/document is obtainable

In order to receive the documents, it is necessary to refer to the main executive of the project and the relevant student. Based on this, applicants can send their requests to the responsible executive (Sedighehfarzi@nm.mui.ac.ir) or the student (alihatami@nm.mui.ac.ir) via email.

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

The application is sent via email and the response or sending of documents to the applicant (after the necessary checks to prevent violation of the confidentiality of the participants' information) will be after 2 weeks at most.

Comments