Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of community-based palliative support interventions on the palliative outcomes of patients with advanced cancer and the quality of life of their family caregivers

Protocol summary

Study aim
Determining the impact of community-based palliative support interventions on the quality of life of patients with advanced cancer and their family caregivers

Design
The clinical trial has a control group, with parallel groups, without blinding, randomized using the table of random numbers. The sample size is estimated to be approximately 54 people for each intervention and control group, which considering the drop of 10 A percentage will be considered for each group of 60 people

Settings and conduct
The attending physician puts the cancer patient on palliative treatment with the presence of the student and caregiver at the comprehensive health service center in the first week after introducing the patient and the family, they will get to know the team members including the doctor, psychologist, nurse and nutritionist. 2 weeks later, the nurse will visit the patient's home through the health center and provide training and interventions based on their care needs. At the end of two months, 4 to 6 weeks after the completion of the interventions, the questionnaire will be provided to the test group

Participants/Inclusion and exclusion criteria
Entry requirements: willingness to participate in the study; Age group between 20 and 75 years old; Estimated minimum survival of six months for the patient Exclusion criteria: participation in similar training courses; the patient can't attend the training sessions; disorientation about time and place.

Intervention groups
Intervention group: after getting familiar with the patient and their family, the nurse team conducts a home visit and provides the necessary training according to their needs. Control group: routine care from the health center without further intervention.

Main outcome variables
Quality of life, palliative care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180721040540N5**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **retrospective**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date
2023-06-07, 1402/03/17

Registrant information

Name
Heshmatolah Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of community-based palliative support interventions on the palliative outcomes of patients with advanced cancer and the quality of life of their family caregivers

Public title
The effectiveness of community-based supportive palliative interventions
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Having advanced cancer Having health records in comprehensive health centers Age range between 20 and 75 years Estimating the minimum survival of six months for the patient (due to cancer) The inclusion criteria of the patient's main family caregiver included a willingness to participate in the study A person who cares for patients on a daily basis but is not paid for the care they provide
Exclusion criteria:
Participation in similar training courses Lack of consciousness of time and place The patient can't attend the training sessions Known diseases
Age
From **20 years** old to **75 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
According to the provided list of qualified people from health centers, using a table of random numbers, moving from top to bottom even codes for the control group and odd codes for the intervention group as an example in are considered and this work continues until reaching the sample size for two groups.
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 Lorestan University of Medical Sciences
Street address
Lorestan University of Medical Sciences, Kamalvand Road, Khorramabad, Borujerd, km 5
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Approval date
2023-01-23, 1401/11/03
Ethics committee reference number
IR.LUMS.REC.1401.258

Health conditions studied

1

Description of health condition studied
Quality of Life
ICD-10 code
ICD-10 code description

2

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

3

Description of health condition studied
cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of Life
Timepoint
2 months, a week before, a month after
Method of measurement
The score obtained from the QOLLTI-F questionnaire

2

Description
Palliative care

Timepoint

2 months, a week before, a month after

Method of measurement

The score obtained from the POS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:the method of interventions in the intervention group will be as follows; When the doctor puts the cancer patient on palliative treatment, a meeting will be held with the presence of the family members in the presence of the student and caregiver working in the comprehensive health service center, and the consent and cooperation of the family to cooperate and receive palliative services from The channel of comprehensive health service centers will be acquired. The questionnaires will be provided to the research samples (patients and family caregivers) and they will be given the opportunity to complete them in a self-reported form. Then the student will explain the patient care plan and how to access services during the illness to the patient and family and encourage the patient and family to continue caring for the patient at home if the patient's condition is stable. In this meeting, the student will explain to the patient and family based on the type of cancer, the prognosis of the disease, the needs of the patient, the care that should be provided for him, as well as the structure of comprehensive health service centers, the capacities and how to access these services. The student will provide necessary training on how to provide care and also adapt the care environment to the patient and family at home. During the first week after the introduction, if the patient's condition is favorable, the patient and his main caregiver are invited to the comprehensive health center where the patient's family is a member, and the patient and the family meet with the team members, including doctors, psychologists, nurses, and nutritionists. They will get to know each other. In this meeting, the patient's case will be examined by the doctor and necessary information will be collected from the patient and the family. Also, the necessary information will be collected by other experts and necessary training will be given to the patient and family. Two weeks after the introduction, the nurse will visit the patient's home again through comprehensive health service bases and provide the necessary interventions and training to the patient and the patient's family based on the patient's condition and care needs. Home visit once every two weeks (of course, depending on the patient's condition) will be done through the comprehensive health service database channel, for two months from the time the patient entered the study. From the beginning of the palliative treatment, the patient and the family will be able to communicate with the nurse through the WhatsApp social messenger as well as the phone and get answers to their questions from the health staff. In the numerous meetings held with the presence of the patient and his family, things such as the diagnosis of patients' care needs, the nature of cancer, chemotherapy, radiotherapy and the importance of self-care will be discussed. Also, it will be discussed about digestive complications, problems related to skin, hair, fatigue, shortness of breath, pain, diarrhea, and vomiting, and proposed solutions to reduce and control these complications, as well as ways to improve the patient's adaptation in the field of social, family, and psychological issues. . A training booklet on how to care for the patient will be provided to the intervention group. In fact, the research starts from the specialized centers in the clinic accompanied by a specialist and continues to the people's homes, then it continues through the comprehensive health centers of the patient's place of residence. In addition to the educational and care services provided to the patient, the potential of other people present in the centers such as doctors, psychologists and nutritionists will also be used. At the end of two months and also 4-6 weeks after the completion of the interventions (to evaluate the sustainability of the interventions), the questionnaires will be provided to the test group, and again the QOLLTI-F family quality of life questionnaires of cancer patients and palliative care outcomes in adults with Cancer POS will be completed.

Category

Lifestyle

2

Description

Control group: During the research period, the control group received their usual care from health service providers and no intervention will be done for them by the research team.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University of Medical Sciences

Full name of responsible person

Heshmatullah Heydari

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Sponsors / Funding sources

1

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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
Khoram-Abad 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
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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
No - There is not 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
The final thesis report and questionnaires are shared
When the data will become available and for how long
After registering the thesis and publishing the articles related to the project
To whom data/document is available
The research team, the university's research officials, the supervisors' plan, the editors of specialized journals of researchers in the field of medical sciences
Under which criteria data/document could be used
Conducting research to improve the quality of life of cancer patients and their families
From where data/document is obtainable
Responsible researcher
What processes are involved for a request to access data/document
Coordinating with the researcher via e-mail, referring to the library of the Nursing Faculty of Lorestan University of Medical Sciences
Comments
Special cases are not considered