

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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)

Phone

+98 66 3312 0160

Email address

heidari.h@lums.ac.ir

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

City

Khorramabad

Province

Lorestan

Postal code

6814993165

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 QOLLI-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

Street address

5 kilometers of Khorram Abad Borujard road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 3312 0174

Fax

+98 66 3312 0173

Email

Heidari.H@Lums.ac.ir

Web page address

<http://research.lums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Heshmatullah Heydari

Street address

5 km of Khorram Abad-Boroujerd road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 3312 0172

Fax

+98 66 3312 0173

Email

research@lums.ac.ir

Web page address

<http://research.lums.ac.ir/>

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Heshmatullah Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

5 km of Khorram Abad-Boroujerd road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

0174 3312 66 98 +

Fax

+98 66 3312 0173

Email

Hidari74@gmail.com

Web page address

<http://research.lums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Heshmatullah Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

5 km of Khorram Abad-Boroujerd road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 1233 0174

Fax

+98 66 1233 0173

Email

hidari74@gmail.com

Web page address

<http://research.lums.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Heshmatullah Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

5 km of Khorram Abad - Borujard road

City

Khorramabad

Province

Lorestan

Postal code

6815644667

Phone

0174 3312 66 98 +

Fax

+98 66 3312 0173

Email

Hidari74@gmail.com

Web page address

<http://research.lums.ac.ir/>

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