Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The Effect of Palliative Care Based on Spirituality on Pain, Quality of Life and Nausea and Vomiting in Women with Colon Cancer in Amir Shiraz Hospital

Protocol summary

Study aim

The Effect of Palliative Care Based on Spirituality on Pain, Quality of Life and Nausea and Vomiting in Women with Colon Cancer

Design

A randomized clinical trial,with 72 samples,was administered to control and test groups,randomized block,one blinded

Settings and conduct

At Amir Hospital oncology in Shiraz,with training sessions and presentation of pamphlets,Only research samples are unaware of the allocation of study groups

Participants/Inclusion and exclusion criteria

Women aged 25 to 75 with colon cancer who are at stage 1, 2 and 3؛ who are aware of their illness and have minimal religious beliefs. women who are reluctant to engage in research or have severe physical or psychological problems not allowed

Intervention groups

First , after a course of chemotherapy ,questionnaires will distributed.Then at the time of the referral of patients for the next chemotherapy course ,Training program begins for the exam group. And for the control group Only a series of training modules(educational pamphlets) in connection with spirituality-based palliative care are considered.The interval between chemotherapy courses is usually two weeks And every patient needs ten to twelve weeks of chemotherapy.The training program(The curriculum) consists of 6 sessions ,that each session takes an average of 2 hours. Currently, this curriculum includes the following:first session: recitation of verses from Qur'an.second session: praying and discussing the psychological effects of praying.third session: Peer group discussions focused on relationship with God, Yourself ,others and nature.Fourth session: The Spiritual Authority 's Speech.fifth session: Play religious clips.sixth session: group praying.After completing the training course and in the last session ,The questionnaires will be distributed immediately and after a month

Main outcome variables

Pain score؛Quality of Life Score؛Nausea and Vomiting Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042252N1**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-03, 1397/12/12**
Update count: **1**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

parisa sabetsarvestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3784 4396

Email address

123ps74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-19, 1397/10/29

Expected recruitment end date

2019-02-02, 1397/11/13

Actual recruitment start date

2019-01-27, 1397/11/07

Actual recruitment end date

2019-02-16, 1397/11/27

Trial completion date

empty

Scientific title

The Effect of Palliative Care Based on Spirituality on Pain, Quality of Life and Nausea and Vomiting in Women with Colon Cancer in Amir Shiraz Hospital

Public title

The Effect of Palliative Care Based on Spirituality on Pain, Quality of Life and Nausea and Vomiting in Women with Colon Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are at stage 1 and 2 and 3 of their illness Patients who are aware of their diagnosis Patients who have at least one chemotherapy course Patients at the minimum functional level Age between 25 and 75 years Complete mental health Willingness to cooperate Not suffering from other diseases except colon cancer Having minimal spiritual beliefs Lack of vision and hearing problems Lack of experience using palliative care base on spirituality

Exclusion criteria:

Lack of cooperation Occurs a particular physical condition

Age

From **25 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In the sampling method, all available patients Enter the study.These patiens are assigned to the test and control group by Block randomization. A: گروه کنترل B: گروه آزمون B(7) A(5) B(3) A(1) B(8) A(6) A(4) B(2) Then we randomize by Using 9 blocks of 8 people.

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants are informed by informed consent and informed about the purpose of the study. However, they are not familiar with the control group or the test. Spirituality-based palliative care training sessions are held for the intervention group. In order to observe the intellectual property of the participants, the control group will be provided with a pediatric spirituality-based palliative care training package. All members are aware of the purpose of the study, and how they are done, but they are not informed about the two groups of control and test. So, the study is mono-blind, and researcher, clinical caregiver and data analyst are aware of the allocation of control and test groups. For Examples of mental health counselors, nutritionists, pain specialists, clerks, and final data analyst are known from the control and test team members, but participants do not know which groups will be included.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

Street address

Ebnesina square

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2018-11-11, 1397/08/20

Ethics committee reference number

IR.FUMS.REC.1397.095

Health conditions studied

1

Description of health condition studied

colon cancer

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

Primary outcomes

1

Description

Pain score in Short Pain Questionnaire(BPI)

Timepoint

Measuring the pain before and after intervention and one month after the intervention

Method of measurement
Short Pain Questionnaire (Brief Pain Inventory)

2

Description
Quality of Life Score in World Health Organization Quality of Life Questionnaire
Timepoint
Measuring the quality of Life before and after intervention and one month after the intervention
Method of measurement
World Health Organization Quality of Life Questionnaire((WHOQOL-BREF)

3

Description
Nausea and vomiting score in the questionnaire for measurement of nausea and vomiting, Korn et al
Timepoint
Measuring the nausea and vomiting before and after intervention and one month after the intervention
Method of measurement
Questionnaire for measurement of nausea and vomiting by Korn et al (PUQE)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First , after a course of chemotherapy ,questionnaires will distributed between 36 member of the intervention group .Then at the time of the referral of patients for the next chemotherapy course ,Training program begins for the exam group.The interval between chemotherapy courses is usually two weeks . And every patient needs ten to twelve weeks of chemotherapy , depending on the severity of the patient's disease and physician's discretion.The training program(The curriculum) consists of 7 sessions ,that each session takes an average of 1 hours. this curriculum includes the following: Session One: playing verses from the Holy Quran. Second Session: playing prayer and group chants. Session 3: Spiritual and peer-based Support,Talking to Patients about communication with God, your self, Others and Nature.Session Four: Playing Religious video Clips.Session 5: Spiritual Advice.Session Six: Nutrition Advice.Seventh Session: Mental Advice. After completing the training course and in the last session ,The questionnaires will be distributed immediately and after a month.
Category
Rehabilitation

2

Description
Control group: First, after completing a chemotherapy course, questionnaires are distributed among the control group members.Then, at the time of the referral of patients for the next chemotherapy course, these patients will receive only a series of educational pamphlets related to palliative care based on spirituality.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Oncology Hospital
Full name of responsible person
Parisa Sabet Sarvestani
Street address
Farhang shahr, Rajaei Blvd, Infront of Kowsar Water Park
City
Shiraz
Province
Fars
Postal code
7187915998
Phone
+98 71 3632 3532
Email
Amirhp@sums.ac.ir
Web page address
Https://amirhosp.sums.ac.ir/page-amirhp/fa/36/form/pId6915

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
DR. Mojtaba Farjam
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7461686688
Phone
+98 71 5335 0994
Email
Research@fums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Parisa Sabetsarvestani

Position
Student

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
No.599, emam khomeini street, 22 alley

City
Sarvestan

Province
Fars

Postal code
7345187749

Phone
+98 71 3784 4396

Fax

Email
123ps74@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Parisa Sabetsarvestani

Position
Student

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
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Email
123ps74@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
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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
No - There is not 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 data of the study is after statistical analysis and the results are comparable. Access to questionnaires and informed consent form is not permitted.

When the data will become available and for how long
2 months after the final release of the results

To whom data/document is available
Researchers working in academic and scientific institutions and hospital staff

Under which criteria data/document could be used
All clinics that are responsible for caring for patients with colon cancer can use this research to care for patients. It

can also be used for other research on palliative care. The right to use the names of patients, the forms of consent to participate in the research.

From where data/document is obtainable

Parisa sabet sarvestani-09171898537-123ps74@gmail.com Dr shahnaz karimi-09173310457-sh.karimi16@yahoo.com Fasa University of Medical Sciences- research@fums.ac.ir

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

Search the title of research on valid sites calling the responsible person Email to Fasa University of Medical Sciences

Comments