Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of spiritual palliative care guidelines in patients with cancer

Protocol summary

Study aim
Investigating the effectiveness of spiritual palliative care guidelines in patients with cancer

Design
A parallel two-group clinical trial involving 44 patients

Settings and conduct
This study will be conducted on cancer patients at Beheshti Hospital in Hamedan in 2025. Blinding is not possible in this study and the study will be conducted as an open-label study. The researcher will visit the operating room department of Beheshti Hospital in two shifts, morning and evening. After grouping the patients into two groups randomly and following specific instructions, the desired variables will be measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 60 years, Having colon, breast, or prostate cancer, having been diagnosed with cancer for at least 6 months, no known mental illness, no physical illness other than cancer, no sensory impairments such as vision or hearing problems affecting learning. Exclusion criteria: Using addictive substances, having diseases other than cancer

Intervention groups
In this study, the intervention group includes 22 patients who will be given spiritual palliative care instructions during 8 one-hour sessions (Introduction and exploration of meaning and values - Connection with the higher self and the source of faith - Meditation through prayer and book therapy - Finding meaning in suffering and illness - Connection with others and a sense of belonging - Trust, hope, and patience in the face of limitations - Identity and its promotion and self-help practice - Conclusion and integration). Patients in the control group will receive only routine care and spiritual palliative care guidelines will not be applied to them.

Main outcome variables
Patients' quality of life, cancer patients' perception of the quality of palliative care, consequences of providing palliative care to patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230129057271N5**
Registration date: **2025-12-12, 1404/09/21**
Registration timing: **prospective**

Last update: **2025-12-12, 1404/09/21**
Update count: **0**

Registration date
2025-12-12, 1404/09/21

Registrant information

Name
Sina Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3320 8792

Email address
sinaghasemi19980@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01

Expected recruitment end date
2026-04-21, 1405/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effectiveness of spiritual palliative care guidelines in patients with cancer

Public title
Applying spiritual palliative care guidelines in patients with cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 60 years old Having sufficient literacy skills to complete the survey Cancer diagnosis for at least 6 months Lack of known mental illness Willingness to voluntarily participate in the study Failure to participate in other related educational programs Lack of sensory impairments, such as vision or hearing problems, that affect learning Having colon, breast, or prostate cancer
Exclusion criteria:
Use of addictive substances Having diseases other than cancer Occurrence of a specific incident before the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of patients in two groups will be done in random blocks so that; The block size is equal to 4. The randomization tool in this research will be the use of four envelopes containing two sheets A and two sheets B, each time by removing one of the sheets, the patient will be placed in the intervention or control group. The removed sheets will not be returned to the envelope until the 4 sheets are finished. After determining the assignment of the first 4 patients, the sheets are returned to the envelope and the next 4 patients will continue in this way until the sample size is completed.
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 Baqiyatallah Hospital
Street address
Baqiyatallah University of Medical Sciences, South Sheikh Bahai, Mulla Sadra Street, Vanak Square, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۶۴۷۱
Approval date
2025-10-06, 1404/07/14
Ethics committee reference number
IR.BMSU.BAQ.REC.1404.097

Health conditions studied

1

Description of health condition studied
Colon cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

2

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

3

Description of health condition studied
Prostate cancer
ICD-10 code
C61
ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Quality of life of patients
Timepoint
At the beginning of the study (before intervention) and after the last session of implementing spiritual palliative care guidelines
Method of measurement
Using the Missoula – VITAS quality of life index (MVQOLI)

2

Description
Patients' perceptions of the quality of palliative care
Timepoint
After the last session of implementing spiritual palliative care guidelines
Method of measurement
Using the patients' perspectives of the quality of palliative care questionnaire

3

Description
Incidence of palliative care outcomes
Timepoint
After the last session of implementing spiritual palliative care guidelines
Method of measurement
Using the Palliative Care Outcome Scale (POS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: During this study, the intervention group included patients who would receive spiritual palliative care from a nurse. Spiritual palliative care instructions will be provided to them over 8 sessions (Titles: Introduction and exploration of meaning and values - Connection with the higher self and the source of faith - Meditation through prayer and book therapy - Finding meaning in suffering and illness - Connection with others and a sense of belonging - Trust, hope, and patience in the face of limitations - Identity and its promotion and self-help practice - Conclusion and integration), and patients will be taught the relevant materials. These materials will be presented to patients in accordance with the titles mentioned and solely based on spiritual therapy and with the aim of spirituality in patients. In each session, the researcher will be present at the patient's bedside and in the inpatient ward for one hour and will teach or share relevant matters with the patient, and at the end of the session, the assignments related to the session will be handed over to the patient. During this study, each session will be held in a separate week. This guideline was developed by the researchers involved in the study, and its face and content validity was reviewed by university faculty members.
Category
Other

2

Description
Control group: In this study, the control group includes patients who will only receive routine nursing care and will not receive spiritual palliative care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshti hospital
Full name of responsible person
Seyed Morteza Hosseini
Street address
Beginning of Eram Boulevard, Ghaem Square, Hamedan
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr. Abbas Ali Imani Fooladi
Street address
Baqiyatallah University of Medical Sciences, South Sheikh Bahai, Mulla Sadra Street, Vanak Square, Tehran
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Tehran
Postal code
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Phone
+98 901 669 0780
Email
researchcenter@bmsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Morteza Hosseini

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Contact

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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