Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of spiritual care on resilience and self-efficacy of patients with cancer referred to oncology ward of shahid beheshti related hospitals

Protocol summary

Study aim

The effect of spiritual care on resilience and self-efficacy of elderly with cancer referred to oncology ward of shahid beheshti related hospitals

Design

Our study was a single-blind clinical trial in which the available samples were randomly divided into two control (25) and intervention (25) groups based on the inclusion and exclusion criteria. that the intervention group received spiritual care, derived from the spiritual-religious strategies of Richard and Bergin, and the control group did not receive any training.

Settings and conduct

The samples were selected in the oncology department of Shahada Tajrish and Imam Hossein (AS) hospitals in Tehran, and the intervention protocol included 6 sessions of 15 to 20 minutes of face-to-face training and the presentation of an educational booklet containing the topics presented in the training. And in this study, the blinding process was done on the study participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Seniors 60 years and older with a cancer diagnosis confirmed by a specialist doctor. • Having complete alertness. • Familiarity with Persian language. Exclusion criteria: • Having visual impairment. • Having hearing impairment. • Having an active mental illness. • Treatment with sedatives (according to the patient herself).

Intervention groups

The spiritual care training intervention group will be derived from the spiritual-religious strategies of Richard and Bergin, which will be in-person training in 6 training sessions of 15-20 minutes and provide a training booklet containing the topics presented in the training sessions. And the control group will not receive any educational intervention.

Main outcome variables

Resilience, self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057845N1**
Registration date: **2023-10-13, 1402/07/21**
Registration timing: **prospective**

Last update: **2023-10-13, 1402/07/21**
Update count: **0**

Registration date

2023-10-13, 1402/07/21

Registrant information

Name

Shiva Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7792 5821

Email address

shivabayat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care on resilience and self-efficacy of patients with cancer referred to oncology ward of shahid beheshti related hospitals

Public title
The effect of spiritual care on resilience and self-efficacy of patients with cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with cancer must be confirmed by a specialist doctor. Having full consciousness Getting to know the Persian language
Exclusion criteria:
Having visual impairment Having hearing impairment Having an active mental illness Treatment with sedatives
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The initial sampling will be based on the available method and the main sampling of the present study will be in the form of block randomization. Patients who meet the inclusion criteria were randomly divided into two groups, the intervention group and the control group. Sealed Envelope Ltd 2019 online randomization service was used to generate the randomization list.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
No. 286, Rodbari St., Dardasht St., Narmak
City
Tehran
Province
Tehran
Postal code
1649848565
Approval date
2022-09-10, 1401/06/19
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.122

Health conditions studied

1

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

2

Description of health condition studied
Cancer
ICD-10 code
C17
ICD-10 code description
Malignant neoplasm of small intestine

3

Description of health condition studied
Cancer
ICD-10 code
D29.1
ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
Resilience
Timepoint
2 and 4 weeks after the intervention
Method of measurement
Connor and Davidson Resilience Questionnaire (CD-RISC)

2

Description
Self-efficacy
Timepoint
2 and 4 weeks after the intervention
Method of measurement
General Self-Efficacy Scale (GSE-10)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention in the present study for the people of the intervention group will include providing spiritual care, derived from the spiritual-religious strategies of Richards and Bergin, who will receive 6 sessions in groups of 10 people 2 days a week (4 days apart) for 3 weeks. The duration of the intervention is 15-20 minutes, and the topics of spiritual care will be in the form of a face-to-face conversation and the presentation of a pamphlet containing the topics presented in the sessions. The sessions will include counseling, lectures, PowerPoint presentations, questions and answers, and group discussions, expressing experiences related to the topic and contents of the session between the researcher, patients, and their home caregivers. The phone and SMS system will be available to the participants during the study period to solve their questions and concerns. After the intervention, resilience and self-efficacy questionnaires will be completed by patients in both intervention and control groups.

Category
Lifestyle

2

Description
The group in which no intervention is used, so the level of resilience and self-efficacy of the participants will be evaluated at the beginning and three weeks later. Participants in this group will not receive any palliative care program. Like the participants in the intervention group, these patients will follow all the doctor's prescriptions and usual care such as taking anti-nausea drugs, corticosteroids, benzodiazepines and other drugs according to the doctor's request.

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Nasrin Azad
Street address
Tehran, Tajrish, Qods Square, Shahradari St., Shahada Tajrish Hospital
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Fax
Email
pr-shohada@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Leila Dadvar
Street address
Tehran - Shahid Madani St. - Imam Hossein Medical Research Training Center
City
Tehran
Province
Tehran
Postal code
6314116177
Phone
+98 21 7343 3000
Email
info@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behrouz Abtahi
Street address
Tehran - Shahid Chamran Highway, Yemen Street - Shahid Arabi Street, Next to Ayatollah Taleghani Hospital
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shiva Bayat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 286, Rodbari St., Dardasht St., Narmak

City

Tehran

Province

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Email

shivabayat0@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shiva Bayat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data related to demographic questionnaires and Connor and Davidson Resilience Questionnaire (CD-RISC) and General Self-Efficacy Scale (GSE-10) are presented as a summary, separately and in a file.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Clients, advisors, guides and all researchers

Under which criteria data/document could be used

General researchers are allowed to use any type of analysis.

From where data/document is obtainable

To receive documents, send to shivabayat0@gmail.com.

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

Send to the recipient's email address.

Comments