Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Spiritual Self-Care Training on Perceived Stress and care burden in Family Caregivers of Patients with blood cancers

Protocol summary

Study aim

Main objectives of the plan: Determine the impact of spiritual self-care education on perceived stress and caregiver burden among family caregivers of patients with blood cancers. Sub-objectives of the plan: Determine and compare perceived stress between the intervention and control groups before and after spiritual self-care education in family caregivers of patients with blood cancers. Determine and compare caregiver burden between the intervention and control groups before and after spiritual self-care education in family caregivers of patients with blood cancers.

Design

The clinical trial has two groups, an intervention group and a control group, without blinding, randomisation of quadruple blocks, and randomisation was performed using the Random Allocation Software.

Settings and conduct

The study recruits caregivers of hematologic cancer patients from Tehran's Valiasr Hospital. Participants are randomized in blocks of four with concealed allocation. Both groups complete the questionnaires; the intervention group receives six online spiritual care sessions with assignments and feedback, while the control group receives standard nursing care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18–65 years Primary caregiver of a patient with hematologic cancer with a confirmed diagnosis, within two months after chemotherapy Ability to read and write in Persian Willingness to participate in the study and sign informed consent Exclusion criteria: Participation in other psychological or spiritual intervention programs History of diagnosed psychiatric disorders

Intervention groups

The intervention group receives spiritual care training through online sessions. The control group receives routine nursing care and, after the sessions, also receives an educational video.

Main outcome variables

perceived stress; caregiver burden.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251022067729N1**
Registration date: **2026-05-18, 1405/02/28**
Registration timing: **prospective**

Last update: **2026-05-18, 1405/02/28**
Update count: **0**

Registration date

2026-05-18, 1405/02/28

Registrant information

Name

Zahra Kafshgar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3236 6310

Email address

zahrakafshgar.edu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Spiritual Self-Care Training on Perceived Stress and care burden in Family Caregivers of Patients with blood cancers

Public title

Investigating the Effect of Spiritual Self-Care Training in Family Caregivers of Patients with blood cancers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 65-18 years The main caregiver of a patient with blood cancers with a definite diagnosis and two months after chemotherapy Ability to read and write in Persian Willingness to participate in the study and sign the informed consent

Exclusion criteria:

Participation in other psychological or spiritual intervention programs History of diagnosed psychiatric disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the samples are included in the study after checking the criteria for entering the available sampling method. Then randomization is done in blocks of four in two control and test groups, RAS (Random Allocation Software) is used for randomization and the results are placed in sealed envelopes to hide the random allocation.

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 Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, corner of Ghods Street, Central Headquarters of Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

14176-13151

Approval date

2025-12-30, 1404/10/09

Ethics committee reference number

IR.TUMS.FNM.REC.1404.237

Health conditions studied

1

Description of health condition studied

Family Caregivers of Patients with blood cancers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Perceived Stress in the Cohen Questionnaire

Timepoint

Perceived stress scores at the beginning of the study (before the intervention started) and one week after the end of the training sessions.

Method of measurement

Cohen's Perceived Stress Questionnaire

2

Description

Caregiver Burden in the Zarit scale

Timepoint

Caregiver Burden scores at the beginning of the study (before the intervention started) and one week after the end of the training sessions.

Method of measurement

Zarit caregiver burden scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Recipients of six online spiritual self-care training sessions, each session lasting 60 minutes, delivered over three weeks (two sessions per week) by a trained spiritual care provider. Session descriptions: First: Introduction to spirituality in the family. Second: Meaning in suffering and the role of the family. Third: Hope and resilience. Fourth: Forgiveness and freedom from guilt. Fifth: Connection and mutual support. Sixth: Summary and self-care. At the end of each session, participants will be given a task to complete, and at the beginning of each session, feedback will be gathered on the previous session's task and content. At the end of all the sessions, participants will receive a file containing the training sessions.

Category
Other

2

Description
Control group: They are receiving routine medical care. At the end of the study, they will be provided with a file of the training sessions.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Zahra Panahi

Street address
End of Keshavarz Boulevard, Imam Khomeini Hospital Complex, Valiasr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

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Keshavarz Boulevard, corner of Qods, Central Headquarters of Tehran University of Medical Sciences

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Zahra Kafshgar

Position
Master student

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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