

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Development, Validation and Evaluation of the Effectiveness of the native Spiritual Care Protocol Based on Iranian-Islamic Culture to increase spiritual health of Advance Cancer Patients and Their Caregivers Suitable for Covid-19 pandemic conditions

Protocol summary

Study aim

Implementing and evaluating the effectiveness of the spiritual care model to increase the spiritual health of patients with advanced cancer and their caregivers

Design

The sample group will be available based on sampling and will include 5 patients and 5 caregivers.

Settings and conduct

Patients with advanced cancer and their caregivers referred to the MACSA Cancer Control Center will receive individual spiritual care intervention.

Participants/Inclusion and exclusion criteria

Belief in God - Belief in the resurrection - Age range of 40 to 60 years in patients - Caregiver membership as a first-class member of the patient's family (spouse, parent, child, sibling). - The caregiver should be recognized as the main person caring for the patient who has the main duty. - History of not having psychotic psychiatric disorders in caregivers and patients. Criteria for excluding people from the research are as follows: Existence of brain metastasis or any other type of disease or treatment complication that has led to brain damage or lack of speech in the patient. - Neurological-cognitive diseases that affect the correctness of the answers

Intervention groups

In the intervention group, the spiritual care protocol will be implemented for 5 patients with advanced cancer and their caregivers.

Main outcome variables

spiritual health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220509054792N1**

Registration date: **2022-11-14, 1401/08/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-14, 1401/08/23**

Update count: **0**

Registration date

2022-11-14, 1401/08/23

Registrant information

Name

Nooramad Latifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 4957

Email address

dr.noorahmadlatifi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development, Validation and Evaluation of the

Effectiveness of the native Spiritual Care Protocol Based on Iranian-Islamic Culture to increase spiritual health of Advance Cancer Patients and Their Caregivers Suitable for Covid-19 pandemic conditions

Public title

Development, Validation and Evaluation of the Effectiveness of the native Spiritual Care Protocol Based on Iranian-Islamic Culture in Advance Cancer Patients and Their Caregivers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Belief in God Belief in the resurrection Age range of 40 to 60 years in patients Caregiver membership as a first-degree member of the patient's family (spouse, parent, child, sibling). The caregiver should be recognized as the main person caring for the patient who has the main duty History of non-occurrence of psychiatric disorders in caregivers and patients.

Exclusion criteria:

Presence of brain metastasis or any other disease or therapeutic complication that has resulted in brain injury or non-speech in the patient Having neurocognitive diseases that affect the correctness of the responses.

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran Hemat Highway next to Milad Tower. 14535

City

tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-03-12, 1400/12/21

Ethics committee reference number

IR.IUMS.REC.1400.1210

Health conditions studied

1

Description of health condition studied

advance cancer

ICD-10 code

C80

ICD-10 code description

Malignant neoplasm without specification of site

Primary outcomes

1

Description

spiritual health

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

politson & ellison spiritual health questionnaire (1982)

Secondary outcomes

empty

Intervention groups

1

Description

There is an intervention in cancer patients and their caregivers which is done first and last and will be examined as the third phase. The details of the intervention's content will be the outcome of the results of phases 1 & 2 of this research. Consequently, the details will be determined after the fulfillment of the previous phases. The intervention's content is spiritual care which will be done in 8 to 12 sessions. Meetings will be held individually. The content of the intervention focused on the relationship with self, others, nature, and God.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

MACSA

Full name of responsible person

Neda Shahvaroughi Farahani

Street address

MACSA Clinic, Hazrat Fatemeh Hospital, 21st Street, Yousefabad, Tehran

City

Tehran

Province

Tehran

Postal code

۱۳۴۶۶۶۷۴۵۱

Phone

+98 21 8872 0035

Email

info@macsa.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Iran University Campus, Hemmat freeway, next to Milad tower, Tehran,

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Email

latifi.na@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Noor Ahmad Latifi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Plastic & Reconstructive Surgery

Street address

Hazrat Fatemeh Hospital, 21st Street, Yousefabad, Tehran

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14339 33111

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Person responsible for scientific inquiries

Contact

Name of organization / entity

MACSA

Full name of responsible person

Seyede Hasti Tamaddon

Position

Psychologist, spiritual caregiver

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Noor Ahmad Latifi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Plastic & Reconstructive Surgery

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be presented in the form of a final report to the relevant organization.

When the data will become available and for how long

After the publication of the article extracted from the study

To whom data/document is available

After the publication of the article, the study is open to the public

Under which criteria data/document could be used

by email of corresponding author

From where data/document is obtainable

by email of corresponding author

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

After receiving the request via email, the data will be provided to the applicants while maintaining the confidentiality.

Comments