

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effectiveness of spiritual intervention on pain intensity and quality of life in end-of-life patients

Protocol summary

Study aim

Determining the effectiveness of spiritual intervention on pain intensity and quality of life in end-of-life patients

Design

The statistical sample size is 60 people (30 people in the intervention group and 30 people in the control group). In the present study, the 26-item World Health Organization Quality of Life Questionnaire and the Won Korf Pain Intensity Questionnaire will be used.

Settings and conduct

The study site is Imam Reza Hospital in Mashhad and the sampling method is simple non-random that the target population is patients in the end stage of cancer life of Imam Reza Hospital in Mashhad.

Participants/Inclusion and exclusion criteria

ents at the end of cancer life stage, consent to participate in the study, age 16 years and older, minimum primary education, Shiite religion, level of consciousness above 8

Intervention groups

The intervention group consists of patients who provide spiritual care content based on the titles of the Richards & Bergin protocol sessions over six 60-minute sessions over four months. The control group is patients who receive only routine interventions performed on patients so far and do not receive any spiritual intervention.

Main outcome variables

Reducing pain and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210513051282N1**

Registration date: **2021-07-11, 1400/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**

Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

seyed mahmoud tabatabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 5777

Email address

tabanet@um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of spiritual intervention on pain intensity and quality of life in end-of-life patients

Public title

Evaluation of the effectiveness of spiritual intervention on pain intensity and quality of life in end-of-life patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

According to medical parameters, they are less than 6 months old Has at least a diploma Age 19 years and above Believes in the Shia religion Awareness above 8
Exclusion criteria:
Decrease the patient's level of consciousness to less than 8 during interventions for 4 consecutive days

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Organizational Ethics Committee of Mashhad
University of Medical Sciences

Street address

Mashhad, Azadi Square, Campus, University, School
of Medicine, Department of Medical Ethics

City

mashhad

Province

Razavi Khorasan

Postal code

9194568899

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

1396.814

Health conditions studied

1

Description of health condition studied

Reducing pain and quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce pain

Timepoint

Before the intervention and two weeks after the
intervention

Method of measurement

Von Korf Pain Intensity Questionnaire

2

Description

Quality of Life

Timepoint

Von Korf Pain Intensity Questionnaire

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Spiritual Care Content is based on
the titles of Richards and Bergin Spiritual Intervention
Sessions in six 60-minute sessions over four months.

Category

Rehabilitation

2

Description

Control group: The control group is patients who receive
only routine interventions performed on patients so far
and do not receive any spiritual intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ehsan Izadipour

Street address

Ibn Sina St. Imam Reza Hospital Square Imam Reza
Hospital

City

mashhad

Province

Razavi Khorasan

Postal code

9178787665

Phone

+98 51 3841 5777

Email

lzadipoure2@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Tafqadi

Street address

University Street in front of the University 18 Central
Building of Mashhad 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mahmoud Tabatabaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Ethics

Street address

University Street in front of the University 18 Central
Building of Mashhad University of Medical Sciences
Office of the Leadership Institution

City

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Province

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917786655

Phone

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Email

tabanet@um.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ehsan Izadipour

Position

expert

Latest degree

Bachelor

Other areas of specialty/work

Medical Ethics

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

fatemeh rezaei

Position

Researcher psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Email

rezaeif7@mums.ac.ir

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