

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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  
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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  
**City**  
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**Province**  
Razavi Khorasan  
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lzadipoure2@mums.ac.ir  
**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  
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## 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  
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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