

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effects of Religious Clinical Cares by Clergymen on Anxiety and Depression of the Patients and their Spiritual Health

#### Protocol summary

##### Summary

The aim of the present study is to determine the effectiveness of clinical religious cares on the anxiety, depression, and spiritual health of hospitalized patients in Qom-Iran. At the beginning of study, the researcher selected 150 hospitalized patients who were not mentally sick and did not receive specific drugs. The samples were divided in two control and intervention groups. A three section questionnaire has been applied to collect data, consisted of 1- demographic data, 2- standardized questionnaire of the Hospital Anxiety and Depression Scale (HADS), and 3-Palutzian& Ellison's 20-item questionnaire of spiritual health. It measures both religious and existential well-being. Then, the subjects were assigned to control and intervention groups, randomly. At the next stage, intervention of a clergyman was applied as a religious care among the intervention group. Intervention type, content and method were designed with regard to the opinions of the religious experts and colleagues at the pre-test results analysis stage. After the educational intervention, mentioned questionnaires were distributed among the participants once more, aiming at comparing the effects of religious intervention on the test group members' Anxiety, depression and spiritual health and those of the control group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060918022N1**

Registration date: **2014-08-22, 1393/05/31**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-22, 1393/05/31

##### Registrant information

###### Name

Sarallah Shojaei

###### Name of organization / entity

Qom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3772 2154

###### Email address

sarallah.shojaei@modares.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Qom University of Medical Sciences

##### Expected recruitment start date

2014-06-21, 1393/03/31

##### Expected recruitment end date

2014-09-21, 1393/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Religious Clinical Cares by Clergymen on Anxiety and Depression of the Patients and their Spiritual Health

##### Public title

Effects of Religious Clinical Cares by Clergymen on Anxiety and Depression of the Patients and their Spiritual Health

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: hospitalized and mature at the time of study; providing the written consent; capability of responding the questions; lack of anti-anxiety and anti-depression drug use at the time of study; and being Muslim. Exclusion criteria: having mental diseases records or being infected by mental retardation and the underlying disorders; lack of willingness to continue participation in the study; leading to some difficulties for the patients concerning their transferring to other hospitals or releasing; and drug abuse records.

#### **Age**

From **15 years** old to **139 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **150**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **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**

Qom university of medical sciences

##### **Street address**

Shahid Lavasani st

##### **City**

Qom

##### **Postal code**

#### **Approval date**

2014-05-11, 1393/02/21

#### **Ethics committee reference number**

3247

### **Health conditions studied**

#### 1

#### **Description of health condition studied**

Anxiety and Depression

#### **ICD-10 code**

F41.2

#### **ICD-10 code description**

Mixed anxiety and depressive disorder

### **Primary outcomes**

#### 1

#### **Description**

stress

#### **Timepoint**

pre and post intervention

#### **Method of measurement**

Questionnaire

#### 2

#### **Description**

depression

#### **Timepoint**

pre and post intervention

#### **Method of measurement**

Questionnaire

#### 3

#### **Description**

spiritual health

#### **Timepoint**

pre and post intervention

#### **Method of measurement**

Questionnaire

### **Secondary outcomes**

#### 1

#### **Description**

disease

#### **Timepoint**

post intervention

#### **Method of measurement**

clinical observation

### **Intervention groups**

#### 1

#### **Description**

the control group receives the usual care of the nurses.

#### **Category**

Other

#### 2

#### **Description**

providing the participants with clergyman face to face interaction and discussion in the hospital for half or one hour, depending on the patient mood and situation;

#### **Category**

Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Nekoei hospital

**Full name of responsible person**

Sarallah Shojaei

**Street address**

Mirzaye ghomi sq; Shahid Taleghani st

**City**

Qom

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Qom univesity of medical sciences

**Full name of responsible person**

Dr.Hosein Saghafi

**Street address**

Shahid Lavasani st

**City**

Qom

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qom univesity of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Qom university of medical sciences

**Full name of responsible person**

Sarallah Shojaei

**Position**

PhD student in health education and promotion.

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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**Web page address**

## Person responsible for updating data

### Contact

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*