

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation Impact of spiritual care on sleep quality and spiritual health of elderly

Protocol summary

Study aim

Effect of spiritual care on the Quality of Sleep and spiritual health of the Elderly in Isfahan

Design

This interventional study will be conducted on 60 people (30 intervention people and 30 control people), among the elderly referring to health centers in Isfahan, using the available sampling method. Considering the sample size in the present study (less than 100) and to prevent the problem of imbalance between the groups, the studied sample will be allocated to two intervention and control groups using the Block Randomization method.

Settings and conduct

The target community will be the elderly living in Isfahan city. Sampling will be done as available and among the elderly who refer to health centers in Isfahan.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age over 60 years 2. Under the cover of the health center and constantly visiting that health center 3. Physical and mental ability to communicate (to complete the questionnaire) 4. Be able to speak and understand Persian language. Exclusion criteria 1. Unwillingness to continue participating in research 2. Lack of cooperation and satisfaction during the training sessions and not completing the assignments presented in the sessions

Intervention groups

In this study, two measures of active listening and instilling hope will be performed in the form of spiritual care group sessions during 6 weekly sessions of 45 to 60 minutes(39) for the intervention group in the health center. * In order to comply with ethical considerations, the items taught in the training sessions will be given to the control group in the form of a pamphlet as a training package after completing the second stage of the questionnaires.

Main outcome variables

sleep quality, spiritual care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200119046186N2**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **retrospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Majid Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 9821

Email address

rahimi@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Impact of spiritual care on sleep quality and spiritual health of elderly

Public title

Evaluation Impact of spiritual care on sleep quality and spiritual health of elderly

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years Having the ability to orient in relation to place and time . Under the cover of the health center and constantly visiting that health center Physical and mental ability to communicate (to complete the questionnaire) Willingness to participate in the research at the time of the research should not be simultaneously investigated in other experimental researches. Be able to speak and understand Persian language.

Exclusion criteria:

Unwillingness to continue participating in research Simultaneous use of prescribed psychiatric drugs during intervention Lack of cooperation and satisfaction during the training sessions and failure to complete the assignments presented in the sessions

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering the sample size in the present study (less than 100) and in order to prevent the problem of imbalance between the groups, the studied sample will be allocated to two intervention and control groups using the Block Randomization method. For this purpose, at first, all possible combinations of 4 of the two studied groups (A, B) will be considered in the following order. AABB, BBAA, ABAB, BABA, ABBA, BAAB Each of the above 4 blocks will include 2A and 2B. From 1 to 6, a number will be assigned to each of the mentioned blocks. Then, in the table of random numbers, one-digit numbers will be selected randomly (from top to bottom or vice versa, or from left to right or vice versa). Each of the numbers 1 to 6 that appeared in the random number table is the same block.

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 Isfahan University of Medical Sciences

Street address

Hezar_jerib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-05-28, 1402/03/07

Ethics committee reference number

IR.MUI.RESEARCH.REC.1402.084

Health conditions studied**1****Description of health condition studied**

Spiritual health in normal older people

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Spiritual Health

Timepoint

Before and immediately and three months after the intervention

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Sleep Quality

Timepoint

Before and immediately and three months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: In this study, to perform spiritual care, two criteria of active listening and instilling hope will be done through spiritual care group sessions during 6 weekly sessions of 45 to 60 minutes in a group at the health center.

Category

Lifestyle

2

Description

Group: The items taught in educational control sessions in the form of pamphlets in the form of an educational package will be available to the control group after completing the second stage of the questionnaire.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center number one in Isfahan

Full name of responsible person

Dr.Hamid Galedari

Street address

Ebne sina

City

Isfahan

Province

Isfahan

Postal code

81486-53374

Phone

+98 31 3448 5558

Email

moradi136013@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shahin Shirani

Street address

Hezar_jerib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

majidnh79@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Majid Rahimi

Position

Asisstant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Geriatrics

Street address

First Floor, No. 47 Hajian Alley Simin Street

City

Isfahan

Province

Isfahan

Postal code

8176935747

Phone

+98 31 3776 9821

Email

majidnh79@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Majid Rahimi

Position

Asisstant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Geriatrics

Street address

First Floor, No. 47 Hajian Alley Simin Street
City
Isfahan
Province
Isfahan
Postal code
8176935747
Phone
+98 31 3776 9821
Email
majidnh79@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Majid Rahimi
Position
Asisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Geriatrics
Street address
First Floor, No. 47, Hajian Alley, Simin Street
City

Isfahan
Province
Isfahan
Postal code
8176935747
Phone
+98 31 3776 9821
Email
majidnh79@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available