

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The impact of religious-spiritual intervention on the elderly's sense of loneliness and sleep quality.

Protocol summary

Summary

Regarding the importance of spiritual and religious care, in order to reduce the feeling of loneliness and improve the quality of sleep of the elderly in old people's house, this study is conducted to investigate the effect of religious and spiritual intervention on loneliness and the quality of sleep in the elderly residents of an old people's home. Study design In this four-stage quasi-experimental study, eligible elderly people are enrolled in study group. Procedure: First of all, qualified elderly people who are willing to participate in the study complete the St. Petersburg quality of life questionnaire and Russell's sense of loneliness, and the eligible people will participate in the study on the basis of the required grade (Stage One). After a month without any intervention, the questionnaires are re-completed and collected (Stage Two), which are considered as their control group in this case. Then the intervention takes place for one month and the questionnaires are completed again immediately after the intervention (Stage Three). In order to track the effectiveness of the intervention, two months after the data are collected, the questionnaires are completed again (Stage Four). Interventions The interventions are based on Ghalbe Salim model, which consists of four sections of communication with God, others and nature. The treatment lasts for a months with four sessions each week totaling 30 hours. Variables Sleep quality and loneliness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081015426N5**

Registration date: **2017-09-22, 1396/06/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2017-12-11, 1396/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of religious-spiritual intervention on the elderly's sense of loneliness and sleep quality.

Public title

The impact of religious-spiritual intervention on the elderly.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The criteria include the person's willingness to participate in the study, physical ability, reading and writing skills, score of sleep disorders above 5 in the St. Petersburg questionnaire, and a sense of loneliness score above 50 in the Russell questionnaire.

Exclusion criteria: They include cognitive and chronic psychiatric disorders (schizophrenia, Alzheimer's disease) as well as the use of sedative medications or other methods of improving sleep such as relaxation and meditation during the study.

Age

From **60 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Postal code

71348-14336

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.SUMS.REC.1396.80

Health conditions studied

1

Description of health condition studied

Senility

ICD-10 code

R54

ICD-10 code description

Old age without mention of psychosis

Primary outcomes

1

Description

Sleep quality

Timepoint

Before, after and 2 month later of intervention

Method of measurement

Pittsburgh sleep quality inventory(PSQI)

2

Description

Loneliness

Timepoint

Before, after and 2 month later of intervention

Method of measurement

Russell's loneliness questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

case group: The interventions are based on Ghalbe Salim model, which consists of four sections of communication with God, others and nature. The treatment lasts for a months with four sessions each week totaling 30 hours.

Category

Other

2

Description

The study does not have a separate control group. Therefore, all elderly people are used as a control group in the first stage, and no interventions are performed on them to determine the impact of confounding factors on the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahandidegan mehr nursing house

Full name of responsible person

Roushan Zamir

Street address

Behind Elmi-karbordi university-Dr dadman blv.

City

Larestan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Hashemi Seyed Basir

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Shiraz

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

Yes

Title of funding source

Shiraz University 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**

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Web page address**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