Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Street address
Zand street
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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

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+98 71 3647 4252
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mortezataheri808@gmail.com
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