Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effectiveness of Spirituality Therapy and Acceptance and Commitment therapy on Sleep Quality, Resilience and Death Anxiety in the Elderly

Protocol summary

Study aim
Comparing the Effectiveness of Spirituality Therapy and Acceptance and Commitment therapy on Sleep Quality, Resilience and Death Anxiety in the Elderly

Design
A randomized controlled clinical trial with parallel groups, Randomized block, sample size 45 (15 persons per group)

Settings and conduct
Before starting the sessions and obtaining permission, all three groups completed questionnaires of resilience, anxiety, and sleep quality. Experimental group A (spirituality therapy) and experimental group B (acceptance and commitment therapy) were trained weekly in the nursing home for the elderly men and women. The control group received no intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria were: having at least 60 years of age, having at least secondary education, not receiving psychological treatment since diagnosis. Exclusion criteria include acute or chronic medical illnesses such as epilepsy, skeletal diseases, heart and respiratory failure, etc. which can cause long-term problems, severe mental illnesses such as psychotic disorders, psychotropic medications or abuse in present.

Intervention groups
For the first group spirituality therapy, for the second group acceptance and commitment therapy, and in the third group no intervention will be performed.

Main outcome variables
Sleep Quality; Resilience; Death Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200210046450N1**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**
Update count: **0**

Registration date
2020-04-06, 1399/01/18

Registrant information

Name
Bahman Hajatnia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 4686 4886

Email address
b.hajatnia@iaukishint.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-15, 1398/09/24

Expected recruitment end date
2020-05-10, 1399/02/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effectiveness of Spirituality Therapy and Acceptance and Commitment therapy on Sleep Quality, Resilience and Death Anxiety in the Elderly

Public title
Comparing the Effectiveness of Spirituality Therapy and Acceptance and Commitment therapy on Sleep Quality, Resilience and Death Anxiety in the Elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Minimum age 60 Minimum high school education Lack of psychological treatment since diagnosis
Exclusion criteria:
Acute or chronic medical illnesses such as epilepsy, skeletal diseases, heart and respiratory failure, etc. which can cause problems in long sessions. severe mental illness such as psychotic disorders psychotropic drugs or substance abuse at present
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method is performed by the statistical consultant as follows: randomization is performed in three groups: Spirituality Therapy, Acceptance and Commitment therapy, and control: First, a list of eligible individuals is provided and coded. In block randomization, the number of participants in all groups will be very close together by making blocks of sequences so that the same number of participants are assigned to study groups within each group. We first code the groups in Latin letters as follows: A = Spirituality Therapy, B = Acceptance and Commitment therapy, and C control group In this study with three groups A, B and C we create the following six groups and assign 1 to 6 each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the random number table, we choose one of these blocks whenever the numbers 1, 2, 3, 4, 5, 6 appear, and if the other number appears, consider null and go to the next choice. . In fact, we have obtained a random sequence of numbers with a random number table that we consider the order of assignment for each number. This way the number of people in the groups will be approximately equal.
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 Hormozgan University Of Medical Sciences
Street address
No. 64, Janbazan Ave., North Karegar Street
City
Tehran
Province
Tehran
Postal code
1437697419
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.HUMS.REC.1398.339

Health conditions studied

1

Description of health condition studied
Elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Resiliency
Timepoint
Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement
Connor-Davidson Resiliency Questionnaire

2

Description
Death Anxiety
Timepoint
Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement
Cult-Leicester Death Anxiety Scale

3

Description
Sleep Quality
Timepoint
Measurement will be done in pre-test, post-test and

follow-up three months after post-test

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the present study, the purpose of group spirituality therapy is 8 sessions based on Ahmadi et al. (2014) spiritual therapy intervention, which was held two sessions per week (for one month) and each session for 90 minutes.

Category

Treatment - Other

2

Description

Intervention group II: Acceptance and commitment therapy and a 90-minute 9-session treatment plan twice a week (for a month and a half) based on ACT Hayes (2004) protocol and designed as a group experimental group subjects are provided.

Category

Treatment - Other

3

Description

Control group: No Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz nursing home

Full name of responsible person

Bahman Hajatnia

Street address

No. 61, 24th Ave., Janbazan Street, South Kurdistan Highway.

City

Tehran

Province

Tehran

Postal code

2246578941

Phone

+98 21 2288 1908

Email

b.hajatnia@iaukishint.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Kish Island, Sana'i Boulevard, Free Zone Organization Square, Islamic Azad University of Kish International Branch.

City

Kish

Province

Hormozgan

Postal code

7941775883

Phone

+98 76 4442 2720

Email

Info@laukishint.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Bahman Hajatnia

Position

Reasearch expert

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No. 44, Marvdasht Ave., Police Blvd

City

Shiraz

Province

Fars

Postal code

7941775883

Phone
+98 71 4686 4886

Fax

Email
bahmanhajatnia48@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Bahman Hajatnia

Position
Reasearch expert

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Other areas of specialty/work
Psychology

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bahmanhajatnia48@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

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bahmanhajatnia48@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
Any type of analysis on the data delivered is permitted

From where data/document is obtainable
Bahman Hajatnia Before the Shiraz Marvdasht Road Police after the Faculty of Pharmacy postal code: 7941775883 Tel: +98 71 4686 4886

What processes are involved for a request to access data/document
The request will be sent by email to: b.hajatnia@iaukishint.ac.ir

Comments