

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

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

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2246578941

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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.

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Kish

Province

Hormozgan

Postal code

7941775883

Phone

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Email

Info@iaukishint.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

Research expert

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Bahman Hajatnia

Position

Research expert

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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