

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of spiritual group therapy on perceived stress, mental rumination and sleep quality of the elderly referring to comprehensive health service centers in Rafsanjan in 2023

Protocol summary

Study aim

Determining the effect of spiritual group therapy on perceived stress, mental rumination and sleep quality of the elderly

Design

44 eligible elderly people will be divided into two equal groups by simple randomization method and the intervention will be done on one of the groups based on random selection.

Settings and conduct

The intervention on the elderly with sleep disorder referring to Rafsanjan health centers is done in the form of spiritual group therapy at the nursing school.

Participants/Inclusion and exclusion criteria

Entry conditions: age 60 years or older; absence of acute physical and mental illness; ability to participate in research; not having cognitive problems such as Alzheimer's disease; willingness to participate in the study; minimal reading and writing literacy and absence of hearing impairment according to the individual's own statement. Exit conditions: including the individual's refusal to participate in spiritual care programs and not participating in four sessions of the programs and the death of the elderly

Intervention groups

For the intervention group, spiritual care sessions will be held twice a week for 45 to 60 minutes in 8 sessions by the researcher, and for the control group, no special intervention was done, and only before and after the implementation of the intervention and one month later in the questionnaire test group by them. will also be completed.

Main outcome variables

Perceived stress; sleep quality; rumination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N28**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-06-14, 1402/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		<u>1</u>	
Scientific title The effect of spiritual group therapy on perceived stress, mental rumination and sleep quality of the elderly referring to comprehensive health service centers in Rafsanjan in 2023 Public title Investigating the effect of spiritual group therapy on perceived stress, mental rumination and sleep quality of the elderly Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: Age 60 years old or older Not having acute physical and mental illness Ability to participate in research Not having cognitive problems such as Alzheimer's disease, stroke, and transient brain attack Willing to participate in the study At least literate in reading and writing Not having hearing impairment according to the individual's self-report of having a sleep disorder based on getting a score higher than 5 in the Pittsburgh Questionnaire Exclusion criteria: A person's refusal to participate in spiritual care programs Not attending three sessions of the programs and the death of the elderly Age From 60 years old to 80 years old Gender Both Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 44 Randomization (investigator's opinion) Randomized Randomization description Simple randomization. Sampling will be done in an accessible (easy) method, and the allocation of research units to two intervention and control groups will be random using a simple randomization method (random number table). Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees		Ethics committee Name of ethics committee Research Ethics Committee of Rafsanjan University of Medical Sciences Street address Rafsanjan, Imam Ali Blvd. Central Office of Rafsanjan University of Medical Sciences City rafsanjan Province Kerman Postal code 7718796755 Approval date 2022-10-08, 1401/07/16 Ethics committee reference number IR.RUMS.REC.1401.128	
		Health conditions studied	
		<u>1</u>	Description of health condition studied Sleep disorder ICD-10 code ICD-10 code description
		<u>2</u>	Description of health condition studied perceived stress ICD-10 code ICD-10 code description
		<u>3</u>	Description of health condition studied rumination ICD-10 code ICD-10 code description
		Primary outcomes	
		<u>1</u>	Description Response score to Cohen's perceived stress scale Timepoint Before, immediately and one month after the end of the intervention Method of measurement Cohen's Perceived Stress Questionnaire
		<u>2</u>	Description Response score to Nolen Hoeksma's mental rumination questionnaire Timepoint Before, immediately and one month after the end of the intervention

Method of measurement

Nalan Hoeksma mental rumination questionnaire

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Description

Sleep quality

Timepoint

Before, immediately and one month after the end of the intervention

Method of measurement

Elderly Sleep Quality Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The researcher will start the work after stating the goals and method of the study and obtaining the consent of the people to participate in the study. Data collection tools include: 1. Demographic Information Questionnaire 2. Nolen Hoeksma's Mental Rumination Questionnaire 3. Cohen's Perceived Stress Scale 4. Pittsburgh Sleep Quality Index Questionnaire For the intervention group, spiritual care sessions will be held twice a week for 45 to 60 minutes in 8 sessions by the researcher. Holding 8 sessions for 4 weeks and two sessions each week: First session: introduction and getting to know the participants and distribution of demographic information questionnaires, mental rumination, perceived stress and sleep quality. Getting the contact number and setting the next appointment, building trust to establish contact. The second session: talking and discussing about spiritual issues and how it affects life and coping with life's problems and concerns. The third session: talking about existential truth and meaning in life. , challenging irrational thoughts, talking about God and any higher power that the client believes in. The fourth session: Examining religious and spiritual teachings regarding stress and connection with the saints. The fifth session: Examining irrational thoughts about feelings of guilt and resentment and The lack of self-forgiveness and the role of the sound of the Qur'an in sound sleep. The sixth session: Faith and trust in God and its role in reducing stress. Summarizing the contents of the previous sessions, re-completing the rumination questionnaire and perceived stress and sleep quality, and the last 10 minutes of each session are spent reviewing the reports related to these tasks and answering the questions.

Category

Treatment - Other

2

Description

Control group: The control group will be formed by the Whats App group for 4 weeks by the researcher and will

explain the problems that will occur in the aging process and will answer their medical questions and problems.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Rafsanjan

Full name of responsible person

Dr.Tayebeh Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Tayebeh Mirzaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available