Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Examining the effect of a spiritual self-care program through podcasts on sleep quality and feelings of loneliness of elderly: A parallel randomized clinical trial

Protocol summary

Study aim
Determining the effect of a spiritual self-care program using podcasts on sleep quality and feelings of loneliness in the elderly

Design
A controlled, parallel-group, non-blinded, randomized, phase 2 clinical trial on 200 elderly people. Randomization was performed by computer with a concealed randomization sequence.

Settings and conduct
A total of 200 eligible elderly people will be selected from comprehensive health service centers affiliated with Mazandaran University of Medical Sciences, and the Pittsburgh Sleep Quality questionnaire and the UCLA Scale will be completed for them. They will be randomly assigned to an experimental group (100 people) and a control group (100 people). The present study is unblinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 65 years and older, possessing a mobile phone equipped with either the Eitaa, WhatsApp, or Telegram application, Obtaining a score of above average on the Spiritual Well-Being Scale Exclusion criteria: Simultaneous participation in a similar spiritual care program, Having speech, vision, or hearing disorders according to the patient's own statement, Having severe mental disorders

Intervention groups
Intervention group: Participants undergoing spiritual therapy intervention in virtual space (Eitaa, WhatsApp, or Telegram software) will be exposed to 10-15 minute podcasts with spiritual therapy content. For 6 weeks, one episode will be sent to each participant weekly via the virtual space. Each patient in the intervention group will join a pre determined group in one of the accessible software programs installed on the patients' smartphones, where the spiritual therapy episodes will be shared. Control group: The same routine care will be implemented at home for the control group.

Main outcome variables
Sleep quality, feelings of loneliness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100114003064N18**
Registration date: **2025-10-11, 1404/07/19**
Registration timing: **prospective**

Last update: **2025-10-11, 1404/07/19**
Update count: **0**

Registration date
2025-10-11, 1404/07/19

Registrant information

Name
Hossein Bagheri

Name of organization / entity
Shahroud University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-04-04, 1405/01/15

Expected recruitment end date
2027-09-23, 1406/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Examining the effect of a spiritual self-care program through podcasts on sleep quality and feelings of loneliness of elderly: A parallel randomized clinical trial

Public title
Examining the effect of a spiritual self care program through podcasts on sleep quality and feelings of loneliness of elderly
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 65 years and above Having a mobile phone equipped with either Eitaa, WhatsApp, or Telegram Obtaining a medium to high score on the Spiritual Well-Being Scale (SWBS)
Exclusion criteria:
Concurrent participation in a similar spiritual care program Self reported speech, vision, or hearing impairments Severe mental disorders Use of sleeping pills
Age
From **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, the elderly will be selected based on the criteria desired by the researcher and by sequential sampling method, and based on the random software, the elderly will be grouped into blocks of 4 and divided into two groups: experimental and control. The replacement order will be done blindly or secretly, meaning that 200 envelopes will be prepared in a package, each with a code. After it is determined that the desired person will participate in the study, the researcher will take the desired envelope in a specific order and act based on the group recorded in the envelope.
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 Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences, Haft Tir Square, Shahroud
City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2025-08-17, 1404/05/26
Ethics committee reference number
IR.SHMU.REC.1404.068

Health conditions studied

1

Description of health condition studied
Sleep quality
ICD-10 code
G47.9
ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
Sleep quality
Timepoint
Before, immediately after, and two months after the end of the intervention
Method of measurement
Pittsburgh Sleep Quality questionnaire

2

Description
Loneliness
Timepoint
Before, immediately after, and two months after the end of the intervention
Method of measurement
Russell questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the experimental group, participants will undergo a spiritual therapy intervention in cyberspace (ETA software, WhatsApp or Telegram) in the form of a podcast. Each of the podcasts will be prepared in the form of 10 to15 minute episodes with spiritual therapy content according to Table 1 and under the supervision of a psychological specialist with sufficient experience, and for 6 weeks, one episode will be sent to each participant every week through a predetermined cyberspace . Each patient in the intervention group will join a predetermined group in one of the available software installed on the patients' smartphones , in which spiritual therapy episodes will be shared.

Category
Behavior

2

Description
Control group: Participants in the control group will receive the same routine treatments and care recommended by healthcare centers for the control group at home

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Selected comprehensive health service centers in Amol city

Full name of responsible person
Dr. Hossein Bagheri

Street address
Next to the Hilal Ahmar, Hilal Ahmar Street, Amol

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Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Dr. Hossein Bagheri

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No decision has been taken at this time. There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available