# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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)

**Phone**
+98 23 3239 5054

**Email address**
bagheri@shmu.ac.ir

**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

**City**
Amol

**Province**
Mazandaran

**Postal code**
4615861468

**Phone**
+98 11 4422 1919

**Email**
bagheri@shmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Shahroud University of Medical Sciences

**Full name of responsible person**
Dr. Hossein Ebrahimi

**Street address**
Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

**City**
Shahroud

**Province**
Semnan

**Postal code**
6314773955

**Phone**
+98 23 3239 5054

**Email**
vcr@shmu.a.ir

**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

**Street address**
Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

**City**
Shahroud

**Province**
Semnan

**Postal code**
3614773955

**Phone**
+98 23 3239 5054

**Email**
bagheri@shmu.ac.ir

## Person responsible for scientific 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

**Street address**
Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

**City**
Shahroud

**Province**
Semnan

**Postal code**
3617753917

**Phone**
+98 23 3239 5054

**Email**
bagheri@shmu.ac.ir

**Web page address**

## Person responsible for updating data

**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

**Street address**
Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

**City**
Shahroud

**Province**
Semnan

**Postal code**
36147753917

**Phone**
+98 23 3239 5054

**Email**
bagheri@shmu.ac.ir

## 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