

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Investigating the effectiveness of the acupressure combination of Sanyinjiao (SP6) and Shenmen (HT7) points on the sleep quality of the elderly: A family-oriented three parallel group clinical trial

#### Protocol summary

##### Study aim

Determining the effectiveness of the acupressure combination of Sanyinjiao and Shenmen points on the sleep quality of the elderly

##### Design

Clinical trial of three groups without control group, with parallel groups, randomized, without blinding

##### Settings and conduct

The location of the study will be the clinics of Shahroud city. In a face-to-face meeting, the researcher teaches the elderly caregiver how to press the mentioned points, and they must perform this action on the elderly once a day at night time at 10-11 pm. Before and one week after the intervention, Pittsburgh questionnaire will be completed for all three groups.

##### Participants/Inclusion and exclusion criteria

Entering criteria for elderly: age > 60 years, informed consent, MMSE>22 in literate people and AMTS>7 in illiterate people, unfavorable sleep quality based on Pittsburgh questionnaire. Exclusion criteria for elderly: receiving other sleep-related treatments within 2 weeks before the study, history of mental illness, dependence or addiction to any narcotic, painkiller, antidepressant. Inclusion criteria for the elderly caregiver: having the most contact with the elderly, the health literacy score more than 66.1 from the HELIA questionnaire. Exclusion criteria for the elderly caregiver: Having any physical disease related to the fingers

##### Intervention groups

In group A (Shenmen), B (Sanyinjiao) and C (combination of Shenmen and Sanyinjiao), in a face-to-face meeting, the researcher will teach the person accompanying the elderly to press the mentioned points, and they should do it once a day for a week at 10-11 pm, for elderly. This study has no control group.

##### Main outcome variables

Sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230222057494N1**

Registration date: **2023-04-05, 1402/01/16**

Registration timing: **prospective**

Last update: **2023-04-05, 1402/01/16**

Update count: **0**

##### Registration date

2023-04-05, 1402/01/16

##### Registrant information

##### Name

Reza Mirafzali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3268 0347

##### Email address

rezamirafzali@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-13, 1402/01/24

##### Expected recruitment end date

2023-11-11, 1402/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Investigating the effectiveness of the acupressure combination of Sanyinjiao (SP6) and Shenmen (HT7) points on the sleep quality of the elderly: A family-oriented three parallel group clinical trial

**Public title**

Acupressure combination of Sanyinjiao (SP6) and Shenmen (HT7) points and sleep quality of the elderly

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

age over 60 years old Having full awareness and listening and speaking ability suitable for learning research intervention MMSE score more than 22 in literate people and AMTS score more than 7 in illiterate people Unfavorable sleep quality based on answers to the Pittsburgh sleep quality questionnaire (a score of 5-21 is considered as unfavorable sleep quality) Entry criteria for the person accompanying the elderly: 1- To have the most contact with the elderly. To have the ability to correctly implement the intervention on the elderly The health literacy score is more than 66.1 from the HELIA questionnaire

**Exclusion criteria:**

Secondary insomnia caused by physical illness or mental disorder Those who received other sleep-related treatments within 2 weeks before the study. History of mental illness (based on the elderly's self-report) Dependence or addiction to any drug, pain reliever, anti-depressant, sleeping pill and alcohol Having sleep-related diseases such as obstructive sleep apnea or restless legs syndrome Regarding the person accompanying the elderly: Having any physical disease related to the fingers

**Age**

From **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **126**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into three groups through randomization and based on the production of random numbers strings through software. ([www.randomizer.org](http://www.randomizer.org)) In order for the number of assignments to each group to be equal, the block method of volume 6 is used to create a random allocation sequence because participants are gradually entered into the study. The allocation concealment will be done centrally. In this way, the assignment sequence will be done by someone outside the research team. Upon each person entering the study, the researcher will contact the person and assign the person to the group.

**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, Hafte-Tir Sq., Tehran Street

**City**

Shahroud

**Province**

Semnan

**Postal code**

3614773955

**Approval date**

2023-02-05, 1401/11/16

**Ethics committee reference number**

IR.SHMU.REC.1401.219

**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 Based on Pittsburgh Sleep Quality Test Score

**Timepoint**

Before and one week after the intervention

**Method of measurement**

Pittsburgh Sleep Quality Questionnaire

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group 1: In this group (group A), first in a face-to-face session, pressing the Shenmen point (HT7) (on the ulnar side, the distal volar bands of the wrist and the radial border of the flexor carpi ulnaris tendon in the anterior region of the wrist) with A pressure of 3 to 4 kg using a circular motion with a speed of two revolutions per second in a firm and uniform way for one minute pressure 30 seconds rest up to 3 times with the thumb by the researcher is taught to the person with the intervention group and they must do it once every day at night at 10-11 for a week. Perform this procedure on the elderly themselves and repeat it.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: In this group (group B), first, in a face-to-face session, pressing the Sanyinjiao point (SP6) (directly to the tip of the medial malleolus, the posterior margin of the medial leg of the leg) with a pressure of 3 to 4 kg using A circular movement with a speed of two revolutions per second in a firm and uniform way for one minute, pressure for 30 seconds, rest up to 3 times with the thumb is taught by the researcher to the person accompanying the people of the intervention group, and they should do this procedure on the elderly themselves for a week, once every day at night time at 10-11 and repeat.

#### Category

Treatment - Other

### 3

#### Description

Intervention group 3: In this group (group C), first in a face-to-face meeting, pressing the Shenmen point (HT7) (on the ulnar side, the distal volar bands of the wrist and the radial border of the flexor carpi ulnaris tendon in the anterior region of the wrist) and the Sanyinjiao point (SP6) (straight up to the tip of the medial malleolus, the posterior border of the inner leg of the leg) with a pressure of 3 to 4 kg using a circular motion at a speed of two rotations per second in a firm and uniform manner for one minute of pressure and 30 seconds of rest. Up to 3 times, the person accompanying the intervention group will be trained by the researcher with the thumb up to 3 times, and they They should perform and repeat this procedure on the elderly once every day at night at 10-11 for a week and repeat.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinics in Shahroud city

##### Full name of responsible person

Dr. Hossein Bagheri

##### Street address

Haft-Tir Sq.,Tehran Street

##### City

Shahroud

##### Province

Semnan

##### Postal code

3614773955

##### Phone

+98 23 3239 5054

##### Email

bagheri@shmu.ac.ir

##### Web page address

<http://eh.shmu.ac.ir/home.html>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Mohammad-Hassan Emamian

##### Street address

Haft-Tir Square, Shahroud University of Medical Sciences

##### City

Shahroud

##### Province

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##### Postal code

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##### Phone

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##### Email

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##### Web page address

<http://research.shmu.ac.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

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Reza Mirafzali

**Position**

Master's student in geriatric nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

Master's student in geriatric nursing

**Latest degree**

Bachelor

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## 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**

Hafte-Tir Square, Shahroud University of Medical Sciences

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**Province**

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**Postal code**

3617753917

**Phone**

## 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