Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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) 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
Hafte-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
Semnan

Postal code
6314773955

Phone
+98 23 3239 5054

Email
emamian@shmu.ac.ir

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

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

Street address
Gorganjadid street

City
Gorgan

Province
Golestan

Postal code
4913796855

Phone
+98 17 3268 0347

Email
rezamirafzali@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
Hafte-Tir Square, Shahroud University of Medical Sciences

City
Shahroud

Province
Semnan

Postal code
3617753917

Phone
+98 23 3239 5054

Email
bagheri@shmu.ac.ir

Person responsible for updating data

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

Street address
Gorganjadid street

City
Gorgan

Province
Golestan

Postal code
4913796855

Phone
+98 17 3268 0347

Email
rezamirafzali@shmu.ac.ir

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