

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of P6 and Yintang Acupressure on anxiety and quality of life in home caregivers of the elderly with Alzheimer

#### Protocol summary

Anxiety, quality of life

##### Study aim

Determining the effect of pressure medicine at P6 and Yintang points on the anxiety and quality of life of home caregivers of the elderly with Alzheimer's disease.

##### Design

A controlled, parallel-group, single-blind, randomized trial on 80 patients.

##### Settings and conduct

Before starting the study, the researcher will review the necessary training to perform pressure medicine intervention under the supervision of a physiotherapist. The intervention will take place in the meeting hall of Hazrat Fatemeh College of Nursing. Before the intervention, demographic information questionnaire, Spielberger anxiety questionnaire and quality of life questionnaire will be completed by both intervention and control groups. The intervention will take place during 4 weeks. After the completion of the intervention, the questionnaires will be completed again by both groups. The participants and interpreters of the questionnaires and data do not know about the allocation of the samples to the intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Experience of direct care and care of the elderly suffering from Alzheimer's for at least 12 months. Age range from 18 to 50 years Having an anxiety score of 43 and above

##### Intervention groups

In the intervention group, acupressure is performed at P6 and Yintang points, and in the control group at ineffective points (the middle point of the forehead and the inner corner of the wrist). The intervention will take place during 4 weeks, three sessions in the first week and then one session per week. In the training sessions, acupressure is given to both groups at the mentioned points so that the clients can perform the intervention during a certain time every day.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120312009267N8**

Registration date: **2022-10-18, 1401/07/26**

Registration timing: **prospective**

Last update: **2022-10-18, 1401/07/26**

Update count: **0**

##### Registration date

2022-10-18, 1401/07/26

##### Registrant information

##### Name

Giti Setoodeh

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4254

##### Email address

setoodeh@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-22, 1401/07/30

##### Expected recruitment end date

2022-11-21, 1401/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of P6 and Yintang Acupressure on anxiety and quality of life in home caregivers of the elderly with Alzheimer

**Public title**

The effect of acupressure on anxiety

**Purpose**

Supportive

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

Experience of direct care and care of an elderly person suffering from Alzheimer's disease for at least 12 months  
Age range from 18 to 50 years old  
Not having any anatomical or skin problem in acupressure points  
Ability to see and hear  
Not having specific mental and physical problems  
Having an anxiety score of 43 and above (medium to high anxiety level)  
Not taking anti-anxiety and sedative drugs during the intervention

**Exclusion criteria:**

Indication of skin disease in acupressure points

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyzer

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: simple. The randomization of participants between two groups is done with random allocation software. In the aforesaid software, the total sample size and the number of groups are entered into the software. The unit of randomization in the mentioned software is a person. The output of the software is a classified list that randomly distributes the samples into two groups. According to the mentioned list, the patients are distributed in two groups according to the time of visit so that the volume reaches the required number in each group. In this study, the researcher helps complete the information related to the software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, for the purpose of blinding, interpretation of the questionnaire, data entry and analysis of information in statistical software will be done by statistical specialists outside the study. The participants have no information about how to assign people to groups; In other words, since the participants in two groups refer for intervention on different days, they will not be informed about the type of interventions performed for

other group. Also, in the control group, in order to compare the place of intervention with the intervention group, a point with the least distance compared to the acupressure points of the intervention group will be used. In addition, data analyzer is unaware about the grouping of the participants.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Ethics Committee of Shiraz University of Medical Sciences, 7th floor, Shiraz University of Medical Sciences, Zand street

**City**

shiraz

**Province**

Fars

**Postal code**

7193613119

**Approval date**

2022-09-09, 1401/06/18

**Ethics committee reference number**

IR.SUMS.NUMIMG.REC.1401.061

**Health conditions studied****1****Description of health condition studied**

Anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**2****Description of health condition studied**

Alzheimer

**ICD-10 code**

G30.1

**ICD-10 code description**

Alzheimer's disease with late onset

**Primary outcomes**

## 1

### Description

Anxiety score in Spielberger questionnaire

### Timepoint

Measurement of anxiety at the beginning of the study, after the first intervention session, one month later

### Method of measurement

Spielberger questionnaire

## 2

### Description

Quality of life score in SF-36 questionnaire

### Timepoint

Measuring the quality of life at the beginning of the study and one month later

### Method of measurement

SF-36 questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: performing acupressure at P6 and Yintang points during one month in the form of three sessions in the first week and one session in the following weeks. Teaching participants to perform the intervention at home during a specific hour in the first sessions.

#### Category

Rehabilitation

### 2

#### Description

Control group: Performing acupressure on ineffective points in acupressure (the middle of the forehead and the inner corner of the wrist) during one month in the form of three sessions in the first week and one session in the following weeks. Teaching the control group to perform intervention in the mentioned points at home during Specific time in the first sessions.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran dementia and Alzheimer's association

##### Full name of responsible person

Giti Setoodeh

##### Street address

After the Quran Gate, Mental Health Park, Fars Province Alzheimer Association

#### City

Shiraz

#### Province

Fars

#### Postal code

7193613119

#### Phone

+98 71 3647 4254

#### Fax

#### Email

Setoodeh@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Janghorban Roxana

##### Street address

Fatemeh School of Nursing and Midwifery, Namazi Square, Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

7193613119

##### Phone

+98 71 3647 4254

##### Email

janghorban@sums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Giti Setoodeh

##### Position

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Fatemeh School of Nursing and Midwifery, Namazi Square, Shiraz

**City**

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**Province**

Fars

**Postal code**

7193613119

**Phone**

+98 71 9647 4254

**Fax****Email**

setoodeh@sums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Giti Setoodeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Giti Setoodeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Fatemeh School of Nursing and Midwifery, Namazi Square, Shiraz

**City**

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**Province**

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**Postal code**

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**Phone**

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**Fax****Email**

setoodeh@sums.ac.ir

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Only the main outcome data can be published

**When the data will become available and for how long**

The access period starts 6 months after the results are published.

**To whom data/document is available**

The data will be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

It will be accessible for use in new researches by mentioning the source.

**From where data/document is obtainable**

The responsible for the project must send an application to setoodeh@sums.ac.ir.

**What processes are involved for a request to access data/document**

The data will be submitted no later than 2 weeks after receiving the email.

**Comments**