

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

Anxiety, quality of life

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

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

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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

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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

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

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Person responsible for scientific inquiries

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Position

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Latest degree

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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