Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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 analyser

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
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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
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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
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Other areas of specialty/work
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Person responsible for updating data

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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