

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Acupressure on anxiety, depression and stress of primary Family Caregivers of Stroke Survivors

Protocol summary

Study aim

Determining the effect of acupressure on the anxiety, depression, and stress of main family caregivers of stroke patients.

Design

This study is a clinical trial with a control group, with parallel groups, single-blind, randomized with a table of random numbers, a sample size of 96 people.

Settings and conduct

Depression, anxiety, and stress are common problems for primary care patients with stroke. Interventions are necessary to improve these complications. 96 participants will be randomly assigned to two groups according to inclusion criteria. In the intervention group, the acupressure will be applied at Yintang and Shenmen acupoints for one month. In the sham group, acupressure will be applied at CV24 and TB5 acupoints for one month. DASS42 questionnaire will be completed before and one day after the intervention. The data analyst will not be aware of the groups and the type of intervention in each group. Blinding will be done by coding the questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years, Ability to read and write. Exclusion criteria: Lack of physical ability, lack of desire to continue participating in research, Change the main caregiver.

Intervention groups

Intervention group: Participants in this group will press HT7 and GV29 acupoints. The intervention will be performed every morning for 15 minutes (5 minutes on each hand and 5 minutes on the third eye) for one month. Sham Group: The CV24 and TB5 acupoints will be pressed.

Main outcome variables

Depression; Anxiety; Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190515043601N6**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

Registration date

2020-05-06, 1399/02/17

Registrant information

Name

Hossein Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1427

Email address

hosseinrahimi92@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acupressure on anxiety, depression and stress of primary Family Caregivers of Stroke Survivors

Public title

The Effect of Acupressure on anxiety, depression and stress of primary Family Caregivers of Stroke Survivors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of primary caregiver 60-18 year Ability to read and write

Exclusion criteria:

Lack of physical ability Lack of desire to continue participating in research Change the main caregiver Eliminate the role of the main caregiver

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind clinical trial. Those who evaluate the outcome and analyze the data will be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Science

Street address

Ayatollah Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.BUMS.REC.1398.268

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F43.9

ICD-10 code description

Reaction to severe stress, unspecified

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3

Description of health condition studied

Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description

The level of stress in primary caregivers of patients with stroke.

Timepoint

Before and one day after the end of intervention

Method of measurement

Stress score from the depression, anxiety and stress scale-42

2

Description

The level of anxiety in primary caregivers of patients with stroke.

Timepoint

Before and one day after the end of intervention

Method of measurement

Anxiety score from the depression, anxiety and stress scale-42

3

Description

The level of depression in primary caregivers of patients with stroke.

Timepoint

Before and one day after the end of intervention

Method of measurement

Depression score from the depression, anxiety and stress scale-42

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants in this study will be the primary caregiver of patients with stroke in birjand city. 46 patients will be included in the intervention group. Participants will press the HT7 and GV29 acupressure points. The intervention will be for 15 minutes each morning (5 minutes for each hand and 5 minutes for the third eye) for one month. The DASS 42 questionnaire will be completed one day after the end of the intervention.

Category

Treatment - Other

2

Description

Sham group: 46 patients will be included in the sham group. Participants will press the CV24 and TB5 acupressure points. The intervention will be for 15 minutes each morning (5 minutes for each hand and 5 minutes for the third eye) for one month. The DASS 42 questionnaire will be completed one day after the end of the intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Alireza Mahmoudirad

Street address

Ayatollah Ghafari Street

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South Khorasan

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9717853577

Phone

+98 56 3204 1088

Email

dr_mahmoodi_rad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Hossein Dehghani Firoozabadi

Street address

ghafari

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1400

Email

drdehghani@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Hossein Rahimi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Position

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

All potential data can be shared after unidentifiable participants

When the data will become available and for how long

Start of access period 12 months after printing results

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to access the data, researchers can request access to the information 12 months after the results are published. Within two weeks, the information will be sent to them. It should be noted that applicants must be faculty members of the Ministry of Health.

From where data/document is obtainable

After verifying the identity of the applicant, the data will be submitted to the researcher within 2 weeks.

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

Applicants can apply to the Birjand University of Medical Sciences School of Nursing and Midwifery for information.

Comments