Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

City

Birjand

Province

South Khorasan

Postal code

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

Street address

Ghafari

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone
+98 56 3238 1427

Fax

Email
Hosseinrahimi92@yahoo.com

Person responsible for scientific 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

Street address
Ghafari

City
Birjand

Province
South Khorasan

Postal code
9717853577

Phone
+98 56 3238 1427

Fax

Email
Hosseinrahimi92@yahoo.com

Person responsible for updating data

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

Street address
Ghafari

City
Birjand

Province
South Khorasan

Postal code
9717853577

Phone
+98 56 3238 1427

Fax

Email
Hosseinrahimi92@yahoo.com

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