Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Auriculotherapy on nurses' stress, anxiety and depression

Protocol summary

Study aim

Determining the Effect of Auriculotherapy on Stress, anxiety and depression among Nursing Staff i n Alzahra hospital of Isfahan

Design

The present study is a single-blind randomized controlled clinical trial . 56 nurses working in Al-Zahra Hospital who have the criteria to enter the research and want to participate in the research are the research samples. Samples with inclusion criteria are selected by the Convenience Sampling. in order to be randomly assigned by the number card method in a closed envelope, they will be placed in two intervention and control groups.

Settings and conduct

After obtaining the necessary permits, informed consent, sampling and random allocation in Al-Zahra Hospital in Isfahan, the DASS-21 stress-anxiety-depression questionnaire will be completed before and immediately and 4 weeks after the intervention in both groups. Data collection and data entry will be analyzed using SPSS software version 19 and statistical tests of t-test, paired t-test and one-way analysis of variance.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 6 months of experience in the hospital, No history of psychological disorders and no use of anti-anxiety, anti-depressant and sedative drugs, not addict, no allergic reaction to the adhesives in the ear

Intervention groups

The intervention in the intervention group will be done by placing adhesives containing seed (Vakaria seeds) on the areas related to stress, anxiety and depression on the ear for 8 sessions over 4 weeks. In the control group, the same intervention will be performed with non-sided adhesives on areas related to stress, anxiety and depression on the ear for 8 sessions over 4 weeks.

Main outcome variables

stress, anxiety and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200622047884N1**
Registration date: **2020-11-01, 1399/08/11**
Registration timing: **prospective**

Last update: **2020-11-01, 1399/08/11**
Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Narges Kheirollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7539

Email address

nargeskheirollahi92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Auriculotherapy on nurses' stress, anxiety

and depression

Public title
The Effect of Auriculotherapy on Stress, anxiety and depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
At least 6 months of experience in the hospital No history of Psychological disorders and no history of using anti-anxiety, anti-depressant and sedative drugs Not addicted
Exclusion criteria:
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to allocate randomly, a simple random method with a number card in a sealed envelope will be used. In this way, 56 cards (in order to have equal chances for research samples, 28 cards with number 1, for the control group and 28 cards with number 2 and for the control group) will be placed in the box. Participants are asked to remove a card from the envelope. Card number one will be placed in the intervention group and card number two will be placed in the control group. In order to create an equal chance for all samples, each card will be returned to the box after being removed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib street, Isfahan, Iran 8174673461
City
Isfahan
Province
Isfehan
Postal code
کد پستی : 8174673461
Approval date
2020-05-04, 1399/02/15
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.060

Health conditions studied

1

Description of health condition studied
stress,anxiety and depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Stress
Timepoint
Before the intervention, immediately after the end of 8 intervention sessions and 4 weeks after the end of the intervention
Method of measurement
Stress-Anxiety-Depression Inventory DASS-21

2

Description
Anxiety
Timepoint
Before the intervention, immediately after the end of 8 intervention sessions and 4 weeks after the end of the intervention
Method of measurement
Stress-Anxiety-Depression Inventory DASS-21

3

Description
Depression
Timepoint
Before the intervention, immediately after the end of 8 intervention sessions and 4 weeks after the end of the intervention
Method of measurement
Stress-Anxiety-Depression Inventory DASS-21

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in the intervention group will be done by placing adhesives containing Seed (Vakaria seeds) on the points related to stress, anxiety and depression on the ear for 8 sessions over 4 weeks.

Category

Treatment - Other

2

Description

Control group: In the control group, the intervention will be performed with non-seeded adhesives on the points related to stress, anxiety and depression on the ear for 8 sessions over 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Educational and Medical Center in Isfahan

Full name of responsible person

Fateme bastani

Street address

Soffeh Blvd., Isfahan, Iran

City

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Phone

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Email

nargeskheirollahi92@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Hezar Jerib street, Isfahan,

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Isfahan

Province

Isfehan

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Iran 8174673461

Phone

+98 31 3792 3071

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice-Chancellery for Research and Technology, Isfahan medical science university

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

Esfahan University of Medical Sciences

Full name of responsible person

Narges Kheirollahi

Position

Faculty member of Isfahan School of Nursing and Midwifery

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboubeh Valiani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

complementary medicine

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valiani@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Narges kheirollahi

Position

Faculty member of Isfahan School of Nursing and Midwifery

Latest degree

Master

Other areas of specialty/work

Nursery

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"No more information"

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of completing the stress, anxiety and depression questionnaire before and after the intervention will be published in the form of an article without mentioning the names of the participants.

When the data will become available and for how long

from 2020

To whom data/document is available

researcher

Under which criteria data/document could be used

For use in research activities

From where data/document is obtainable

Send email to the responsible researcher

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

Review by the responsible author and obtain permission from the Research Center

Comments