Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Uriculotherapy on Depression in Elderly

Protocol summary

Study aim
Determining the effect of uriculotherapy medicine on depression in the elderly in Kashan in 1399

Design
The study is a randomized clinical trial with control group (parallel groups), double-blind, on 52 patients. In the intervention group, uriculotherapy will be performed twice a day for 4 weeks, five days a week, using the DONG BANG brand of Wakaria brand made in Korea on the areas of Shenman, Zero, Hart, Antiperspirant and Master-Cerebral which are associated with depression. In the comparison group, only the seedless label is pasted on the points and no pressure is applied on the points.

Settings and conduct
Randomized clinical trial, with control group, double-blind (participants and outcome assessors) on eligible clients of selected comprehensive health centers in Kashan

Participants/Inclusion and exclusion criteria
Including criteria; Age 60 years and older, Willingness to participate in the study, Get a score higher than 25.5 from the COST tool, Iranian citizenship, Get a score higher than 5 from the GDS-15 tool, Ability to communicate in Persian, Organ health in the earlobe area and excluding criteria; Allergy to glue, Having a serious acute illness, Simultaneous use of other non-pharmacological methods, using of acupuncture or acupuncture for the past three months, addiction to drugs and alcohol, exposure to severe stress from 3 months before the start of the study, using of drugs that affect mood from three weeks before the start of the study, Existence of other known psychiatric disorders and mental retardation

Intervention groups
In the intervention group, uriculotherapy will be performed using the DONG BANG brand of Wakaria Sides. In the comparison group, only the seedless label is pasted on the points and no pressure is applied on the points.

Main outcome variables
score of depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100211003329N6**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**
Update count: **0**

Registration date
2021-04-01, 1400/01/12

Registrant information

Name
Zahra Sooki

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Uriculotherapy on Depression in Elderly

Public title
The Effect of Uriculotherapy on Depression in Elderly
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 years and older Willingness to participate in the study Get a score higher than 25.5 from the COST tool Iranian citizenship Get a score higher than 5 from the GDS-15 tool Ability to communicate in Persian Organ health in the earlobe area
Exclusion criteria:
Allergy to glue (allergies, redness) or any intolerance Having a serious acute illness, hospitalization, lack of access Simultaneous use of other non-pharmacological methods using of acupuncture or acupuncture for the past three months addiction to drugs and alcohol based on the contents of the electronic health record exposure to severe stress (such as death of loved ones) from 3 months before the start of the study using of drugs that affect mood from three weeks before the start of the study Existence of other known psychiatric disorders and mental retardation based on the contents of the electronic health record
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
If subjects are satisfied with participating in the study, the selected qualifying samples will be randomly assigned to each of the two groups (intervention and control) in the form of block randomization in the form of 4 and 6 blocks. Using the Sealed Envelope Ltd software. 2017 Available Through www.sealedenvelope.com 4 -4-block and 6 -6-block, overall 10 blocks were defined that the allocation to groups would be based on the order specified by the software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and outcome assessors are unaware of the nature of the seals pasted on participants' ears.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences Ethics Committee
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan
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kashan
Province
Isfehan
Postal code
8715981151
Approval date
2021-03-01, 1399/12/11
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1399.090

Health conditions studied

1

Description of health condition studied
depression
ICD-10 code
F32.8
ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
score of depression
Timepoint
Before the intervention - 4 weeks after the start of the intervention and 4 weeks after the end of the intervention
Method of measurement
Form 15 Questions for the Elderly Depression Scale (GDS-15)

Secondary outcomes

empty

Intervention groups

1

Description
uriculotherapy will be performed twice a day for four weeks, five days a week. In this group, Korean-made

Vakaria brand DONG BANG will be glued by a researcher on the points of Shenman, Zero, Hart, Antiperspirant, and Master-Cerebral that are associated with depression. The elderly will be instructed to press these sideways twice a day, 60 times each time with the index finger and thumb, according to the intended schedule. During the 4 weeks of the intervention, the labels will be affixed alternately on both ears by the researcher on a weekly basis. The labels are placed on the ear for five days each week and the elderly are instructed to remove them by the end of the fifth day or by those around them to prevent possible allergic reactions. It is also noted that if the Sides are separated during the five-day period, the researcher should be notified by telephone; In that case, the researcher, with the consent of the elderly person, will re-attach the sheets at his home, in the health center or wherever it is convenient for the elderly person. Each participant will be taught how to press the sidewalls by researcher. In addition, during the intervention, a weekly diary will be provided to the elderly person, in which he / she will specify the number of times each time the pressure and use of the new drug. The contents of the diary are organized using visual symbols in a way that can be understood and completed with simple training by all partcipants, including literate and illiterate. During the intervention period, all participants will be visited at the agreed location each week and new seeds will be affixed to them, and a diary will be delivered to them and another sheet will be delivered to them for the following week.

Category

Treatment - Drugs

2

Description

Control group:During the 4 weeks of the intervention, the labels will be affixed alternately on both ears by the researcher on a weekly basis. The labels are placed on the ear for five days each week and the elderly are instructed to remove them by the end of the fifth day or by those around them to prevent possible allergic reactions. It is also noted that if the Sides are separated during the five-day period, the researcher should be notified by telephone; In that case, the researcher, with the consent of the elderly person, will re-attach the sheets at his home, in the health center or wherever it is convenient for the elderly person. In addition, during the intervention, a weekly diary will be provided to the elderly person, in which he / she will specify signs of allergy and use of the new drug. The contents of the diary are organized using visual symbols in a way that can be understood and completed with simple training by all participants, including literate and illiterate. During the intervention period, all participants will be visited at the agreed location each week and new seeds will be affixed to them, and a diary will be delivered to them and another sheet will be delivered to them for the following week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers Sadughi in Kashan

Full name of responsible person

zahra Tagharrobi

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Sponsors / Funding sources

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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
Kashan 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
Kashan University of Medical Sciences
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Zahra Tagharrobi
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Assistant Professor
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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
Not done yet
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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