Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

: The Effect of Uriculotherapy on Pain, Sleep Quality, and Functional Disability in Elderly People with Chronic Low Back Pain

Protocol summary

Study aim
Determining the effect of uriculotherapy on pain, sleep quality, and functional disability in elderly people with chronic low back pain

Design
A clinical trial with two groups of control and intervention, has been randomized, without blindness. The sample size is 70,

Settings and conduct
This study was conducted at the Taleghani and Akramian comprehensive health center of Kashan. Qualified samples were randomly divided into two intervention and control groups. Uriculotherapy was performed three times a day for 4 weeks and five days a week. Which points are different in both groups.At the end of the data, descriptive and inferential statistics will be analyzed and analyzed.

Participants/Inclusion and exclusion criteria
Entry requirements: Age 60 and older, Lower back pain for at least 3 months, Health in the tulip ear,The desire to participate in the study Non-arrival conditions: Lower back pain for some reason like a back injury, Acute low back pain, Those who get information from them are difficult

Intervention groups
In the intervention group, four times a week, five days a week, three times a day, and at the same time, pain will be done; In this group, the Vacheria Marc DONG BANG cheeses made by Korea on the sites of Shengman, Sympathetic, Subcortex and Lumbar were studied by the researcher. The elderly person will be instructed to follow these aids each time for three minutes with his index finger and thumb according to the schedule. In the comparison group, the uriculotherapy with a similar protocol, but on the kidney, stomach, mouth and duodenum, which is not proven to be pain-related will be performed. It should be noted that in both groups, during the 4 weeks of intervention, the Vakaria syndrome by the researcher will be alternately fastened to both ears within a week.

Main outcome variables
Severity of pain, Sleep quality, Functional disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190303042891N1**
Registration date: **2019-07-01, 1398/04/10**
Registration timing: **retrospective**

Last update: **2019-07-01, 1398/04/10**
Update count: **0**

Registration date
2019-07-01, 1398/04/10

Registrant information

Name
Maryam Pourmohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: The Effect of Uriculotherapy on Pain, Sleep Quality, and Functional Disability in Elderly People with Chronic Low Back Pain

Public title

: The Effect of Uriculotherapy on Pain, Sleep Quality, and Functional Disability in Elderly People with Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 and above Having a back pain for at least 3 months 3) willingness to participate in the study Gain score more than 5/25 of the COST tool Iranian citizenship Get a 4 up score from the VAS tool Get a 5 up score from Pittsburgh Sleep Quality Tool Acquire the maximum 25-point rating of Oswestry functional disability tool Ability to communicate in Farsi Health in the Auricle

Exclusion criteria:

Lower back pain for some reason like a back injury Acute low back pain Those who get information from them are difficult Known mental illness based on the contents of the electronic health record Known mental retardation based on the contents of the electronic health record Autoimmune and malignant diseases is confirmed by a specialist Congenital anomalies (with the exception of mild lordosis and scoliosis), fracture or infection in the spine, confirmed by a specialist physician Use of acupuncture or needles during the last three months Surgery in the spine History of bump in the back during the past month drug and alcohol addiction Do sports in a professional manner

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocks randomization in the form of blocks 4, 6 and 8 will be assigned to each of the two intervention and comparison groups. Using the Sealed Envelope Ltd. software. 2017 available through the site www.sealedenvelope.com blocks 4, 4 blocks 8 and 5 blocks 6, a total of 11 blocks were defined, which will be allocated to the groups according to the order specified by the tool.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

Ghotbe ravandi Boulevard

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1397.064

Health conditions studied

1

Description of health condition studied

Chronic low back pain in the elderly

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Chronic low back pain

Timepoint

Measured at the beginning of the study, during the intervention (end of each week), the end of the intervention, and 4 weeks after the end of the intervention.

Method of measurement

The short form of the McGill Pain questionnaire and the Visual analogue tool for pain assessment

2

Description

Sleep quality

Timepoint

Measured at the beginning of the study and after the end of the intervention and 4 weeks after the end of the intervention.

Method of measurement

Pittsburgh sleep quality questionnaire

3

Description

Functional disability

Timepoint

Measured at the beginning of the study and after the end of the intervention and 4 weeks after the end of the intervention.

Method of measurement

Functional disability questionnaire Oswestry

Secondary outcomes

1

Description

Allergy to Vacheria glue

Timepoint

Daily

Method of measurement

See red, inflammation, or feeling itching in the ear by elderly

Intervention groups

1

Description

Intervention group: In the intervention group Uriculotherapy will be done at the time of pain, three times a day and five days a week during 4 weeks. In this group, the Vacheria seeds (with brand name Dong Bang made by Korea) are pasted by the researcher on the points of Shenman, Sympathetic, Subcortex and Lumbar. Participants will be taught by the researcher that seeds would be pressed with index and thumb finger for three minutes each time.

Category

Treatment - Devices

2

Description

Control group: In the Control group, Uriculotherapy will be done at the time of pain, three times a day and five days a week during 4 weeks too. In this group, the Vacheria seeds (with brand name Dong Bang made by Korea) are pasted by the researcher on the points of the stomach; kidney, mouth and duodenum that have been proven these points are not related to pain. Participants will be taught by the researcher that seeds would be pressed with index and thumb finger for three minutes each time.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health center of Taleghani

Full name of responsible person

Tagharrobi Zahra

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Taleghani street,-Kashan

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research assistance of Kashan university of medical sciences

Full name of responsible person

Hamid Reza Banafshe

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81151-87159
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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
Research assistance of 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
Full name of responsible person
Tagharrobi Zahra
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University professor
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

Analytic Code
Undecided - It is not yet known if there will be a plan to

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