Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Investigation of auricular acupressure effects on the constipation and that related quality of life among the elderlies in residential care home

Protocol summary

Study aim
Determine of effect of auricular acupressure on the constipation and that related quality of life among the elderlies in residential care home

Design
This study is a clinical trial with two groups (intervention and control), double blinded (the data analysis and participants) and randomized, with 25 patients in each group.

Settings and conduct
This study will be performed in a nursing home under the auspices of the Kerman Welfare Organization. In the intervention group, the auricular acupressure intervention will be performed for 10 days. Constipation and that related quality of life will be measured before the intervention, after the intervention and 10 days after the intervention in the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient age between 65_85 years , Patient with constipation according to ROME IV diagnostic criteria , The patient's cognitive status score according to the Abbreviated Mental Test criteria is equal to or greater than 6 Exclusion criteria: who had local lesions/infection of the ears, or absence of ear , Doing a treatment program other than taking laxatives to relieve constipation , has had an abdominal operation in the past 6 months , Suffering from Alzheimer's disease, dementia or delirium disorder according to the physician's diagnosis and inclusion in the medical record

Intervention groups
the intervention includes was applied to seven auricular acupoints for 10 days using vaccaria seeds for the intervention group. After 5 days, auricular plasters with vaccaria seeds were directly removed and we attach new auricular plasters with vaccaria seeds on the other ear.participants in control group received only auricular plasters without vaccaria seeds for 10 days in seven auricular acupoints and no intervention will be made on them.

Main outcome variables
Constipation and that related quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151107024919N10**
Registration date: **2020-09-30, 1399/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-30, 1399/07/09**
Update count: **0**

Registration date
2020-09-30, 1399/07/09

Registrant information

Name
Batoul Tirgari
Name of organization / entity
Kerman Medical University of Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Investigation of auricular acupressure effects on the constipation and that related quality of life among the elderlies in residential care home

Public title

effect of auricular acupressure on the constipation and that related quality of life among the elderlies in residential care home

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient age between 65_85 years Patient with constipation according to ROME IV diagnostic criteria The patient's cognitive status score according to the Abbreviated Mental Test is equal to or greater than 6 Possibility to participate in the project for 20 days Ability to speak and understand Persian

Exclusion criteria:

who had local lesions/infection of the ears, or absence of ear Previous experience with auricular acupressure over the past year Doing a treatment program other than taking laxatives to relieve constipation Has had abdominal surgery for the past six months Suffering from Alzheimer's disease, dementia or delirium disorder according to the physician's diagnosis and inclusion in the medical record Suffering from a wide range of physical and mental diseases affecting the constipation variable according to the physician's diagnosis and inclusion in the medical record

Age

From **65 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign the participants to the intervention and control groups, the stratified randomization method is used, so we use the stratified randomization method based on the consumption of liquids, fruits and laxatives, and then a simple random assignment.first all participants are classified according to the collected information based on the consumption of liquids, fruits and laxatives and then we list and number the sample participants and using SPSS software, participants are randomly divided into two groups and Controls are divided.So that men and women are divided into groups separately; Then, in each group, men and women are used in a stratified random and simple random method, and half of the men are in the intervention group and the other half are in the control group (the same will be done for women).

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are randomly assigned to one of the intervention and control groups by a statistician who is blind to the study and the data analyst does not know which data is related to the intervention group and which data is related to the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.KMU.REC.1399.374

Health conditions studied

1

Description of health condition studied

constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

constipation

Timepoint

Constipation will be measured before the intervention

and after the intervention and 10 days after the end of the intervention

Method of measurement

Patient Assessment of Constipation–symptoms questionnaire (PAC-SYM)

2

Description

constipation related quality of life

Timepoint

constipation related quality of life will be measured before the intervention and after the intervention and 10 days after the end of the intervention

Method of measurement

Patient Assessment of Constipation–Quality of Life Questionnaire (PAC-QOL)

Secondary outcomes

empty

Intervention groups

1

Description

the intervention includes was applied to seven auricular acupoints for 10 days using vaccaria seeds for the intervention group. Thus, to apply constant pressure on the ear during the day and night, we use Vaccaria seeds at seven specific points on the ear, and the researcher gently presses the vaccaria seeds three to four times a day until the elderly feel a slight pain. First, we clean the marked points on the patient's ear with 70% alcohol, then to apply continuous pressure on the ear during the day and night, auricular plasters with vaccaria seeds (0.5 * 0.5 cm) are used on the marked points. After 5 days, auricular plasters with vaccaria seeds were directly removed and we attach new auricular plasters with vaccaria seeds on the other ear , so we will have two 5-day periods, each ear alternately under auricular acupressure. if auricular plasters with vaccaria seeds are removed from the ear earlier than five days, the elderly are asked to immediately inform until apply new auricular plasters with vaccaria seeds. HuanQiu brand auricular plasters with vaccaria seeds made in China are used for acupressure.

Category

Other

2

Description

Control group: For the control group, participants in control group received only auricular plasters without vaccaria seeds for 10 days in seven auricular acupoints and only their receive usual daily care and no intervention will be made on them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
The Kerman Welfare Organization
Full name of responsible person
Alireza Asadi
Street address
No. 27, Jomhuri Eslami Blvd., Kerman
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Kerman
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7618816359
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Web page address
http://www.behzisti-kr.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
No 2, Research and Technology Dept., Ibnsina Ave., Kerman
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Province
Kerman
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7616913555
Phone
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Email
abpardakhty@kmu.ac.ir
Web page address
http://kmu.ac.ir/fa/vcrt

Grant name

Grant code / Reference number

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

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Batool Tirgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

Kerman University of Medical Sciences

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Position

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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