

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Lavender herbal tea on Anxiety and Depression in the Elderly

Protocol summary

Study aim

Determination of the Effect of Lavender on Anxiety and Depression in the Elderly

Design

Clinical Trial with community based and control group, with parallel groups without blindness, randomized, follow up immediately after the end of the intervention

Settings and conduct

This study is conducted in elderly people of senior home in Shiraz city

Participants/Inclusion and exclusion criteria

Signing informed consent to participate in research; ability to swallow and not have problems with oral and digestive tract that interfere with oral intake; having the consciousness to complete the questionnaires; depression and anxiety disorders are not due to physical problems such as hypothyroidism.

Intervention groups

In this study, 30 of the intervention group consisted of 5 grams of lavender herbal tea twice in day at morning and night during two weeks, 2 cups of lavender. The control group does not receive any intervention.

Main outcome variables

Depression and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090304001742N4**

Registration date: **2019-06-15, 1398/03/25**

Registration timing: **prospective**

Last update: **2019-06-15, 1398/03/25**

Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name

mohammadrafi bazrafshan

Name of organization / entity

shiraz university medical science

Country

Iran (Islamic Republic of)

Phone

+98 917 382 1959

Email address

mrbazr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2019-12-20, 1398/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Lavender herbal tea on Anxiety and Depression in the Elderly

Public title

Effect of Lavender on Anxiety and Depression

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to participate in research
Ability to swallow and not have problems with oral and digestive tract that interfere with oral intake
Having the consciousness to complete the questionnaires
Depression and anxiety disorders are not due to physical problems such as hypothyroidism

Exclusion criteria:

Were reluctant to stay in the study Having sensitivity to
Lavender

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method, Using Excel software, a random sequence of numbers was formed and then randomly, sub-sub groups in the intervention group and above half in the control group were placed.

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 Larestan University of Medical Sciences

Street address

Emam Khomeini square, Velayat blvd.

City

Larestan

Province

Fars

Postal code

74319-75566

Approval date

2019-04-08, 1398/01/19

Ethics committee reference number

IR.LARUMS.REC.1398.006

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Anxiety

2

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Depression

Primary outcomes

1

Description

Depression

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Beck Depression Inventory

2

Description

Anxiety

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consists of 5 grams of lavender aerated aerial parts, which is used in 2 roasted meals in the morning and at night, in the form of 2 cups of lavender, in two weeks.

Category

Treatment - Drugs

2

Description

Control group: they are not received any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Mehr Nursing Home, Lar
Full name of responsible person
Dr Mohammad rafi Bazrafshan
Street address
Dadman Blvd
City
Larestan
Province
Fars
Postal code
74319-75566
Phone
+98 71 3228 8613
Email
mrbazr@sums.ac.ir

Full name of responsible person
Dr. Mohammad rafi Bazrafshan
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Emam khomeini square, velayat blv, postal code
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Email
mrbazr@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Larestan University of Medical Sciences
Full name of responsible person
Dr Mohammad Hossein Karimi
Street address
Emam Khomeini square, Velayat blvd.
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Phone
+98 71 5234 2877
Email
mrbazr@sums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Larestan 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
Larestan University of Medical Sciences

Person responsible for scientific inquiries

Contact

Name of organization / entity
Larestan University of Medical Sciences
Full name of responsible person
Dr. Mohammad rafi Bazrafshan
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Emam khomeini square, Velayat blv, postal code
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mrbazr@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Larestan University of Medical Sciences
Full name of responsible person
Mohammad rafie Bazrafshan
Position
Faculty member-assistant professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursery

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Phone

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Email

mr bazr@sums.ac.ir

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

It can be shared by unidentifiable participants

When the data will become available and for how long

Access begins a year after the publication of results

To whom data/document is available

People who are working in the academic and scientific institutions

Under which criteria data/document could be used

It needs the agreement of Larestan Medical School

From where data/document is obtainable

mohammad rafi bazrafshan, faculty member of larestan medical school, mr bazr@sums.ac.ir, tell phone:07152255278, cell phon number:09173821959

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

Written and formal request to the vice chancellor for research of Larestan University of Medical Sciences

Comments