

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of aromatherapy with extract salix aegyptiaca on hypertension and quality of sleeping elderly referring to selected health centers of rafsanjan city at 2019

Protocol summary

Study aim

The effect of aromatherapy with extract salix aegyptiaca on hypertension and quality of sleeping elderly

Design

Two arm parallel-group randomized trial with blinded and outcome assessment. hypertension and quality of sleeping elderly will be measured in intervention and control group.

Settings and conduct

This study is a randomized, double blind clinical trial performed. One day before the intervention, the blood pressure of the elderly is measured with a Mercury blood pressure device and Their sleep quality by the Pittsburgh Questionnaire. Blood pressure measurement is performed on days 2, 5, 9, 12, and 16 (Mondays, Thursdays, Mondays, Thursdays, and Mondays). Measurement of sleep quality score is also done after the intervention by completing the sleep questionnaire again.

Participants/Inclusion and exclusion criteria

Being 60 years old or older, The fact that hypertension is detected by Diagnosis of the treating physician and available medical records, Having primary blood pressure Having a sleep disorder based on a score above 5 in the Pittsburgh Questionnaire, Healthy feeling, Not having sensitivity to the extract salix aegyptiaca, Not having sensitivity to the aromatic substances, Not having a history of allergies or respiratory diseases

Intervention groups

In the intervention group, the extract salix aegyptiaca is diluted. The elderly in the intervention group undergo aromatherapy at a distance of 5 cm from the nose for 2 minutes and for 2 weeks by inhalation. Control group: In the control group, will be used a placebo.

Main outcome variables

hypertension and quality of sleeping

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N23**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **retrospective**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-11, 1399/03/22

Expected recruitment end date

2020-07-02, 1399/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with extract salix aegyptiaca on hypertension and quality of sleeping elderly referring to selected health centers of rafsanjan city at 2019

Public title

The effect of aromatherapy with extract salix aegyptiaca on hypertension and quality of sleeping elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being 60 years old or older, The fact that hypertension is detected by Diagnosis of the treating physician and available medical records, Having primary blood pressure, Having a sleep disorder based on a score above 5 in the Pittsburgh Questionnaire, Not having sensitivity to the extract salix aegyptiaca, Not having sensitivity to the aromatic substances, Not having a history of allergies or respiratory diseases, Healthy sense of smell

Exclusion criteria:

Age

From **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

according to the simple randomization, patients were divided into 35 groups, the intervention group and the control group. Patients were divided into two groups of 35 people, A and B, based on a table of random numbers, and finally, groups A and B were divided into intervention and control groups based on the lottery.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and researcher colleague do not aware of the type of group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences ethics committee

Street address

School of Nursing and Midwifery, Nurse Avenue, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.RUMS.REC.1398.209

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

IX 110

ICD-10 code description

Essential (primary) hypertension Incl.: High blood pressure

2

Description of health condition studied

Sleep quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

hypertension

Timepoint

Before the intervention, 2,5,9,12 days after, two days after intervention

Method of measurement

Blood pressure in millimetres of mercury using a Mercury blood pressure

2

Description

Sleep quality

Timepoint

sleep quality measured in control and intervention

groups (before and after the intervention) using the Pittsburgh Sleep Quality Index.

Method of measurement

the Pittsburgh Sleep Quality Index.

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the extract salix aegyptiaca produced in exir hayat Company with a concentration of 20% is used. The elderly in the intervention group are given a dropper containing extract salix aegyptiaca for two weeks. The elderly in the intervention group undergo aromatherapy at a distance of 5 cm from the nose for 2 minutes and for 2 weeks by inhalation. One day before the intervention, the elderly are explained exactly how to do the plan and the consent form is completed by the elderly and on the same day their blood pressure is measured with a mercury blood pressure monitor and their sleep quality is measured with the Pittsburgh questionnaire. To prevent forgetting the aromatherapy sessions, it is recommended that the elderly perform aromatherapy when performing the morning and evening prayers (morning and evening). Elderly people are asked to take medications for high blood pressure and insomnia within two weeks of the intervention at specific times so that the time of medication does not affect blood pressure and sleep quality. Also, standard conditions for controlling blood pressure include ten minutes of rest before taking blood pressure, inactive physical activity before going to the health center, empty bladder, sitting position evenly and placing the hand on the level of the heart. These cases are registered in the blood pressure registration form before taking the blood pressure. Blood pressure measurement is performed on days 2, 5, 9, 12, and 16 (Mondays, Thursdays, Mondays, Thursdays, and Mondays), and is followed by ten minutes of rest by a specific person at the clinic. Measurement of sleep quality score is also done after the intervention by completing the sleep questionnaire again. To ensure extract consumption, the exact checklist for aromatherapy is completed by the elderly and delivered to the researcher.

Category

Treatment - Other

2

Description

Control group: In the control group, water will be used as a placebo. In the control group, the dropper head is impregnated with extract salix aegyptiaca to disperse some of the smell in the space when opened. This is done in order to continue the cooperation of the elderly in the control group and not to realize that they have a placebo. The elderly in the control group also will be asked to undergo aromatherapy for 2 minutes twice a

day for 2 weeks by inhaling three drops of placebo on cotton at a distance of 5 cm from the nose. In the control group also one day before the intervention, the elderly are explained exactly how to do the plan and the consent form is completed by the elderly and on the same day their blood pressure is measured with a mercury blood pressure monitor and their sleep quality is measured with the Pittsburgh questionnaire. To prevent forgetting the aromatherapy sessions, it is recommended that the elderly perform aromatherapy when performing the morning and evening prayers (morning and evening). Elderly people are asked to take medications for high blood pressure and insomnia within two weeks of the intervention at specific times so that the time of medication does not affect blood pressure and sleep quality. Also, standard conditions for controlling blood pressure include ten minutes of rest before taking blood pressure, inactive physical activity before going to the health center, empty bladder, sitting position evenly and placing the hand on the level of the heart. These cases are registered in the blood pressure registration form before taking the blood pressure. Blood pressure measurement is performed on days 2, 5, 9, 12, and 16 (Mondays, Thursdays, Mondays, Thursdays, and Mondays), and is followed by ten minutes of rest by a specific person at the clinic. Measurement of sleep quality score is also done after the intervention by completing the sleep questionnaire again. To ensure placebo consumption, the exact checklist for aromatherapy is completed by the elderly and delivered to the researcher.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 3 Rafsanjan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tayebeh Mirzaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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