# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## The effect of lavender aromatherapy on boredom, severity of anxiety, cognitive function, clinical factors in smokers users

## Protocol summary

**Study aim**

Determining the effect of lavender scent on impatience, anxiety intensity, cognitive function, clinical factors in smokers in Kashan city.

**Design**

A clinical trial with a control group and a sample size of 80 participants, with parallel groups, double-blind, randomized with Trek software and based on the random number table method.

**Settings and conduct**

This study is an experimental method (pre-test and post-test) and a double-blind intervention. The sample size is 80 people. The selected people will be divided into two groups of 40 people, test and control. In the experimental group, for a period of 15 days, patients are asked to inhale 2% lavender essential oil every night before going to bed. In the control group, distilled water is used to compare the results with the experimental group.

**Participants/Inclusion and exclusion criteria**

Entry criteria: 1- Willingness of the participants to enter the experiment 2- Age range of 18-49 years old 3- Not having a chronic disease such as mental illness or diabetes, blood pressure or heart disease and hepatitis etc. 4- All people who are smoking Or, not much time has passed since they stopped using them and their Fagerstrom score is at least 4 Exclusion criteria: non-cooperation 2- using any kind of drugs 3- having any newly diagnosed chronic physical disease

**Intervention groups**

Intervention group: includes 40 participants. Using two drops of lavender essential oil on a cotton gauze and breathing for 20 minutes Control group: includes 40 participants. Distilled water is used to compare the results with the experimental group.

**Main outcome variables**

Primary outcomes: It includes impatience and cognitive assessment, sleep quality, anxiety intensity and cognitive assessment. Secondary consequences: It includes markers related to blood pressure, blood oxygen levels, and heart rate.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230320057758N1**
Registration date: **2023-03-28, 1402/01/08**
Registration timing: **prospective**

Last update: **2023-03-28, 1402/01/08**
Update count: **0**

**Registration date**

2023-03-28, 1402/01/08

**Registrant information**

**Name**

peyman Esmaili-Shahzade-Ali-Akbari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 3457 4191

**Email address**

esmaeili-p@kaums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-07-21, 1402/04/30

**Expected recruitment end date**

2023-10-22, 1402/07/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
The effect of lavender aromatherapy on boredom, severity of anxiety, cognitive function, clinical factors in smokers users

**Public title**
Investigating the effect of lavender scent on the side effects of smoking

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Willingness of participants to enter the experiment Age range 18-49 years Not having a chronic disease, including mental illness or diabetes, blood pressure or heart disease, hepatitis, etc. All people who are smoking or have not quit smoking for a long time and their Fagerstrom score is at least 4.

**Exclusion criteria:**
Unwillingness to participate in the study Taking any kind of drugs Any chronic physical disease that is newly diagnosed and interferes with the test results, including diabetes, high blood pressure, etc.

**Age**
From **18 years** old to **49 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
In order to blind the presenters and patients, oil and placebos are placed in separate packages with codes 1 and 2.

**Placebo**
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**
Kashan University of Medical Sciences, Faculty of Medicine, Kashan, Iran

**City**
kashan

**Province**
Isfehan

**Postal code**
8715981151

**Approval date**
2023-03-12, 1401/12/21

**Ethics committee reference number**
IR.KAUMS.MEDNT.REC.1401.245

## Health conditions studied

### 1

**Description of health condition studied**
Nicotine dependence

**ICD-10 code**
F17.21

**ICD-10 code description**
Nicotine dependence, cigarettes

## Primary outcomes

### 1

**Description**
Boredom score of MSBS questionnaire

**Timepoint**
Completing the questionnaire before the intervention and on the 15th day of the intervention

**Method of measurement**
MSBS questionnaire

### 2

**Description**
Expression intensity by Hamilton questionnaire

**Timepoint**
Completing the questionnaire before the intervention and on the 15th day of the intervention

**Method of measurement**
Hamilton Anxiety Severity Questionnaire

### 3

**Description**

Cognitive performance score of MoCA questionnaire

**Timepoint**

Completing the questionnaire before the intervention and on the 15th day of the intervention

**Method of measurement**

MoCA Cognitive Function Questionnaire

**4**

**Description**

Sleep quality score of Petersborg Sleep Disorder Questionnaire

**Timepoint**

Completing the questionnaire before the intervention and on the 15th day of the intervention

**Method of measurement**

Petersburg Sleep Disorder Questionnaire

**5**

**Description**

Blood pressure measurement

**Timepoint**

Measurement before the intervention and day 15 of the intervention

**Method of measurement**

Blood pressure measuring device

**6**

**Description**

Heart rate measurement

**Timepoint**

Measurement before the intervention and day 15 of the intervention

**Method of measurement**

Heart rate monitor

**7**

**Description**

Blood oxygen measurement

**Timepoint**

Measurement before the intervention and day 15 of the intervention

**Method of measurement**

Blood oxygen measuring device

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Intervention group: includes 40 participants. In this group, before the intervention, tests of impatience, anxiety, cognitive function, as well as clinical factors including blood pressure, heart rate and blood oxygen are taken from the participants. Then, patients are given vials containing lavender essential oil, which is provided by Barij Essential Oil Company, and they are asked to put two drops of it on a cotton ball every night before going to sleep for 15 days and breathe slowly for 20 minutes. slow At the end, the intervention tests of impatience, anxiety, cognitive function, as well as clinical factors including blood pressure, heart rate and blood oxygen are received from the participants again.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: includes 40 participants. In this group, before the intervention, tests of impatience, anxiety, cognitive function, as well as clinical factors including blood pressure, heart rate and blood oxygen are taken from the participants. Then vials containing distilled water, which are in the shape and size of the vials of the intervention group, are obtained from Barij Essans Company, are given to the patients and they are asked to drink two drops of them every night before going to bed for 15 days. Put it on cotton and breathe slowly for 20 minutes. At the end, the intervention tests of impatience, anxiety, cognitive function, as well as clinical factors including blood pressure, heart rate and blood oxygen are received from the participants again.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Health centers of Kashan city

**Full name of responsible person**

amir ghaderi

**Street address**

Kashan University of Medical Sciences, Faculty of Medicine

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peyman.esmaely@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

DR gholamali hamidi

**Street address**

Kashan University of Medical Sciences, Vice President of Research and Technology

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hamiidi@yahoo.com

**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

**Full name of responsible person**

Amir ghaderi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

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## Person responsible for scientific inquiries

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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Kashan University of Medical Sciences

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peyman esmaili

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Toxicology

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable