# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparing the effects of aromatherapy with rosemary essential oil and lavender essential oil on the anxiety of type 2 diabetic patients with recent diagnosis

## Protocol summary

**Study aim**
Determining and comparing the effect of aromatherapy with rosemary essential oil and lavender essential oil on the anxiety of type 2 diabetic patients.

**Design**
A crossover clinical trial that has three groups, each group receives twice the intervention and once the placebo. The sample size is 45 people and the study is single-blind, and randomized blocks are used for the randomization of Celsi.

**Settings and conduct**
Hormoz Clinic, Bandar Abbas Shahid Mohammadi Hospital

**Participants/Inclusion and exclusion criteria**
entry conditions: Having a medical record with confirmed diabetes Diagnosing the patient's diabetes in the last three months. Having moderate to severe anxiety The patient is in the age range of 18 to 65 years Having the physical and mental ability to answer questions, Aware of time, place and person Non-entry conditions: Allergy to scented plants , the patient suffering from nervous and mental problems Having a history of allergies and respiratory disease, Impaired level of consciousness, olfactory disorders, discomfort after inhalation, Hemodynamic instability during intervention (such as symptoms of anaphylactic shock, severe fluctuations in blood pressure, blood sugar, and any severe disorder and the need for immediate intervention in vital signs) , reducing the level of consciousness during the intervention, Participant's unwillingness to continue participating in the study and death and having chronic diabetic complications such as kidney failure, heart failure, visual impairment, and neuropathyNon-entry conditions:

**Intervention groups**
Three groups, in a cross-over manner, each group will be given two stages of aromatherapy with rosemary and rosemary and once as a placebo (odorless oil).

**Main outcome variables**
Find and hide anxiety

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230104057049N1**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

**Registration date**
2023-01-18, 1401/10/28

**Registrant information**

**Name**
Mohammad Hossein Taklif

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 71 3825 3402

**Email address**
hosseintaklif@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-01-08, 1401/10/18

**Expected recruitment end date**
2023-05-08, 1402/02/18

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparing the effects of aromatherapy with rosemary essential oil and lavender essential oil on the anxiety of type 2 diabetic patients with recent diagnosis

**Public title**
Comparing the effects of aromatherapy with rosemary essential oil and lavender essential oil on the anxiety of type 2 diabetic patients with recent diagnosis
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having a medical record with confirmed diabetes Diagnosing the patient's diabetes in the last three months Having moderate to severe anxiety The patient is in the age range of 18 to 65 years Having the physical and mental ability to answer questions Aware of time, place and person
**Exclusion criteria:**
Allergy to scented plants The patient suffers from mental and nervous problems Having a history of allergies and respiratory disease Impaired alertness, olfactory disturbances, dissatisfaction after inhalation Hemodynamic instability during intervention (such as symptoms of anaphylactic shock, severe fluctuations in blood pressure, blood sugar, and any severe disorder and the need for immediate intervention in vital signs) Decreased level of consciousness during intervention Participant's unwillingness to continue participating in the study and death Having chronic diabetic complications such as kidney failure, heart failure, visual impairment and neuropathy
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **45**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The available non-random sampling method is used to select the sample people. In this way, diabetic patients who visit the Hormoz Clinic of Shahid Mohammadi Bandar Abbas Hospital in the period of October 1401, taking into account the criteria for entering the study and completing the patient consent form by the patient or his companion according to the random block method, taking into account Taking the 6 blocks whose extracted codes are given in Table 1, the sample subjects with the same volume are assigned to one of the groups of "mohammady inhalation", "lavender inhalation" and "control group". Table (1): Random sequence generated with 6 blocks in Maine Randomization software
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
This study will be one-sided blind. In this study, in order to prevent the creation of distortion caused by the intervention of aroma therapy in the test and control group and for the purpose of research, the statistician who performs the data analysis is blinded.
**Placebo**
Used
**Assignment**
Crossover
**Other design features**
Non-probability sampling was done based on the entry and exit criteria of the study, then they were randomly assigned into 3 groups: aromatherapy with rosemary essential oil, aromatherapy with lavender essential oil, and control. After receiving the code of ethics and consent form. First, the patients are asked to complete the demographic information questionnaire, which includes: age, sex, marital status, occupation, history of anxiety disorder and type of diabetes, as well as the Spielberger anxiety questionnaire, as well as the working methods for the intervention groups in each session. It is explained. Therefore, people in the group of rosemary essential oil inhalation will get even numbers and people in the lavender inhalation group will get odd numbers.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committee of Hormozgan University of Medical Sciences
**Street address**
End of Imam Hossein Boulevard - Hormozgan University of Medical Sciences
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7919693116
**Approval date**
2022-12-04, 1401/09/13
**Ethics committee reference number**
IR.HUMS.REC.1401.292

## Health conditions studied

### 1

**Description of health condition studied**

Anxiety in diabetic patients

**ICD-10 code**

F15.280

**ICD-10 code description**

Other stimulant dependence with stimulant-induced anxiety disorder

## Primary outcomes

### 1

**Description**

Overt and hidden anxiety scores according to Spielberger's standard questionnaire

**Timepoint**

After filling in the demographic questionnaire and before the aromatherapy as a pre-test and at the end of 20 minutes of aromatherapy as a post-test, anxiety is measured by the Spielberger questionnaire.

**Method of measurement**

Spielberger questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

This study is cross-sectional in three groups, where each group is conducted in two stages as an intervention and one stage as a control group. The intervention in the first group is as follows: First stage: Inhalation therapy with 10% rosemary essential oil. two drops on the pad) is done at a distance of 20 cm from the patient's nose for 20 minutes and before and immediately after the end of the post test. (wash out period) and then the second stage is performed for the first group. The second stage: therapeutic inhalation with 10% lavender essential oil (two drops on a pad) is performed at a distance of 20 cm from the patient's nose for 20 minutes. And before and immediately after the end of the intervention, the post test is done. After the second stage, in order to clean the effect of the second intervention, we have a one-week wash out period, and then the third stage is done for the first group. The third stage: At this stage, the first group becomes the control group. Inhalation therapy with odorless oil (two drops on a pad) is performed at a distance of 20 cm from the patient's nose for 20 minutes. After the completion of the intervention, the post test is done.

**Category**

Rehabilitation

### 2

**Description**

The intervention in the second group is as follows: First stage: therapeutic inhalation with 10% lavender essential oil (two drops on a pad) at a distance of 20 cm from the patient's nose for 20 minutes and before and immediately after the end of the post-test intervention After the first stage, in order to clean the effect of the first intervention, we have a wash out period, and then the second stage is done for the second group. Second stage: In this stage, the first group is controlled. come Inhalation therapy with odorless oil (two drops on the pad) is performed at a distance of 20 cm from the patient's nose for 20 minutes, and before and immediately after the end of the post-test intervention. After the second stage, in order to clean The effect of the second intervention is a one-week wash out period, and then the third stage is performed for the second group. The patient's nose is done for 20 minutes and the post-test is done before and immediately after the end of the intervention

**Category**

Rehabilitation

### 3

**Description**

Intervention group: The intervention in the third group is as follows: First stage: In this stage, the third group becomes the control. Therapeutic inhalation with odorless oil (two drops on the pad) is performed at a distance of 20 cm from the patient's nose for 20 minutes. and before and immediately after the end of the intervention, the post test is done. After the first stage, in order to clean the effect of the first intervention, we have a wash out period, and then the second stage is done for the third group. The second stage : Inhalation therapy with 10% rosemary essential oil (two drops on a pad) is performed at a distance of 20 cm from the patient's nose for 20 minutes, and a post-test is performed before and immediately after the end of the intervention. After the second stage In order to clean the effect of the second intervention, we have a wash out period of one week, and then the third stage is performed for the third group. A meter is taken from the patient's nose for 20 minutes and a post-test is performed before and immediately after the end of the intervention.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Hormoz Clinic, Bandar Abbas Shahid Mohammadi Hospital

**Full name of responsible person**

Dr. Abdullah Gharibzadeh

**Street address**

Hormozgan Province, Bandarabbas, Kuy e Farhangiyan, Jomhoori-e Eslami Blvd, 57VW+CP9

**City**

Bandar Abbas

**Province**

Hormozgan
**Postal code**
7919693116
**Phone**
+98 76 2501 5033
**Email**
info@hums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Dr. Gholam Ali Javadan
**Street address**
At the end of Imam Hossein Boulevard, Hormozgan University of Medical Sciences
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7916613885
**Phone**
+98 76 3333 3280
**Email**
info@hums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Bandare-abbas 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**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Mohammad Hossein Taklif
**Position**
University student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Bandar Abbas, Shahid Chamran Boulevard, Hormozgan University of Medical Sciences and Health Services
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
1388579166
**Phone**
+98 76 3333 3280
**Email**
info@hums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Mohammad Hossin Taklif
**Position**
University student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Bandar Abbas, Shahid Chamran Boulevard, Hormozgan University of Medical Sciences and Health Services
**City**
Bandafr Abbas
**Province**
Hormozgan
**Postal code**
1388579166
**Phone**
+98 76 3333 3280
**Email**
info@hums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Mohammad Hossein Taklif
**Position**
university student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Bandar Abbas, Shahid Chamran Boulevard, Hormozgan University of Medical Sciences and Health Services
**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

1388579166

**Phone**

+98 76 3333 3280

**Email**

info@hums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Due to confidentiality and keeping secrets

**Study Protocol**

Yes - There is 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**

No - There is not 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**

Not applicable

**Title and more details about the data/document**

Information obtained from patients (change in patients' anxiety due to aromatherapy)

**When the data will become available and for how long**

There is no specific limit

**To whom data/document is available**

No limitation has been stated by the researcher

**Under which criteria data/document could be used**

No limitation has been stated by the researcher

**From where data/document is obtainable**

Refer to the corresponding author hosseintaklif@gmail.com

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

There is no special process

**Comments**