Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 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

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Iran (Islamic Republic of)

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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

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7919693116
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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
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At the end of Imam Hossein Boulevard, Hormozgan University of Medical Sciences
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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
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Person responsible for scientific inquiries

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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
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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