Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effects of Lavender Aromatherapy with Virtual Reality on the Quality of Sleep in Type 2 Diabetic Patients

Protocol summary

Study aim

The Comparison of the Effects of Lavender Aromatherapy and Virtual Reality on the Sleep Quality of Patients with Type 2 Diabetes.

Design

A clinical trial with a control group, two parallel intervention groups, and a single-blind design.90 patients were randomized using a random number table.

Settings and conduct

In this single-blind clinical trial, 90 type 2 diabetic patients at Hazrat Zahra (S) Hospital in Khomein were randomly assigned to control, aromatherapy, and VR groups. The statistician responsible for data analysis will be blinded. Aromatherapy Group: Patients apply 2 drops of lavender essential oil on a cotton ball before bedtime and take 10 deep breaths. VR Group: Soothing nature videos play for 15 minutes before sleep. Control Group: No intervention is performed.Patients complete the Pittsburgh Sleep Quality Index (PSQI) questionnaire before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18+, informed consent, willingness to participate, diagnosed with type 2 diabetes by an endocrinologist, and a PSQI score of 5+. Exclusion Criteria: Sensitivity to lavender, asthma, migraines, headaches, using sleeping pills/antidepressants, olfactory/visual impairments, respiratory diseases, and using complementary medicine in the past month.

Intervention groups

Aromatherapy Group: Each night, 2 drops of lavender essential oil are placed on a cotton ball before sleep. Patients take 10 deep breaths, and the cotton ball is attached to their shirt until morning. This is repeated for three consecutive nights. Virtual Reality (VR) Group: High-quality soothing nature videos are played for 15 minutes before sleep. Control Group:No intervention is performed.

Main outcome variables

The sleep quality score in the Pittsburgh Sleep Quality Index (PSQI).

General information

Reason for update

Acronym

Virtual Reality (VR)

IRCT registration information

IRCT registration number: **IRCT20241125063850N1**
Registration date: **2025-04-18, 1404/01/29**
Registration timing: **prospective**

Last update: **2025-04-18, 1404/01/29**
Update count: **0**

Registration date

2025-04-18, 1404/01/29

Registrant information

Name

Melika Jafari Dehnayebi

Name of organization / entity

Khomein University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Lavender Aromatherapy with Virtual Reality on the Quality of Sleep in Type 2 Diabetic Patients

Public title

The Effect of Lavender Aromatherapy and Virtual Reality on the Sleep Quality of Patients with Type 2 Diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years or older Informed consent and willingness to participate in the research A confirmed diagnosis of type 2 diabetes by an endocrinologist Having a score of 5 or higher on the Pittsburgh Sleep Quality Index (PSQI)

Exclusion criteria:

Sensitivity to the scent of lavender Having conditions such as asthma, migraines, and headaches Impairments in the sense of smell or vision, or having respiratory diseases Use of complementary medicine in the past month

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

1. Method of Randomization: - Simple randomization using a random number table will be employed. 2. Unit of Randomization: - Individual-based randomization will be applied, meaning each diabetic patient will be independently assigned to a group. 3. Randomization Tools: - A random number table will be used to generate the sequence. - Sealed, opaque envelopes will be prepared to conceal group assignments, ensuring they remain undisclosed until the intervention begins. 4. Procedure for Generating Random Sequence: - The sequence will be generated using statistical software such as SPSS, ensuring both randomness and reproducibility. - The generated sequence will be securely stored and used exclusively by an independent team member responsible for allocation. 5. Allocation Concealment: - Allocation concealment will be achieved through sealed, opaque envelopes prepared in advance. These envelopes will be carefully shuffled and sequentially numbered. Each participant will select an envelope upon enrollment, and their group assignment will be determined accordingly, eliminating bias. - The individual responsible for recruiting and enrolling participants will have no involvement in the allocation process, ensuring no potential bias occurs.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, only the statistician, who will be responsible for data analysis and final conclusions, will be blinded. This means they will be unaware of the group assignment related to the questionnaire data and will not know whether the data belong to the aromatherapy group, the VR group, or the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Khomein University of Medical Sciences

Street address

Quds Avenue

City

khomein

Province

Markazi

Postal code

3881743364

Approval date

2025-03-04, 1403/12/14

Ethics committee reference number

IR.KHOMEIN.REC.1404.004

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11.6

ICD-10 code description

Type 2 diabetes mellitus with other specified complications

Primary outcomes

1

Description

The sleep quality score in the Pittsburgh Sleep Quality Index (PSQI)

Timepoint

Measurement of sleep quality using a questionnaire at the beginning of the intervention (before the start of the intervention) and three days after the initiation of lavender aromatherapy or VR intervention.

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

The aromatherapy intervention group with lavender essential oil: In this group, each patient will apply 2 drops of lavender essential oil (in this study, the essential oil is obtained from the Gia Kala company, which holds production licenses from the Food and Drug Administration, Ministry of Industry, and certifications including ISO 14001, 22000, and HACCP. The lavender essential oil is produced using completely standard and organic raw materials. The analysis method is HPLC, the production process is 100% hygienic and antimicrobial, and the extraction is carried out with scientific and knowledge-based methods using an ethanol-water solvent) onto a piece of cotton every night before sleep. The cotton is then placed in front of the patient's nose, where they will perform 10 deep breaths. The cotton will be pinned to the patient's shirt and will remain attached until 8 a.m. the following morning. This intervention will be carried out for three consecutive nights.

Category

Rehabilitation

2

Description

Intervention group VR: In the VR group, a video featuring high-quality calming images of nature will be played for the patient for 15 minutes before sleep.

Category

Rehabilitation

3

Description

Control group: In the control group, no intervention will be performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zahra Hospital

Full name of responsible person

Melika Jafari Dehnayebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Khomein Faculty 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

Khomein Faculty of Medical Sciences

Full name of responsible person

Melika Jafari Dehnayebi

Position

Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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