

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Aromatherapy with Bitter orange extract on Sleep quality in Patient with type 2 diabetic

Protocol summary

Summary

Objective: Determine the effect of aromatherapy with bitter orange extract on sleep quality in patients with type 2 diabetes. The study was parallel randomized clinical trial Inclusion criteria 1.Suffering from type 2 diabetes 2.Age between 30 to 65 years 3.No history of mental disease 4. No history of allergy and Asthma 5- Having sufficient strength of odor olfactory 6. Do not use sedative 7. No history of diabetic foot ulcers 8.Lack of experience stressful events during the 3 months ago 9.Lack of pregnancy, breast feeding and hot flushing 10- not having night work. Exclusion criteria 1. The unwillingness of patients to continue to cooperate 2- discharge from the hospital during the study 3. The incidence of symptoms such as shortness of breath and hives 4. stressful events during study. The sample size was calculated as 30 in each group. Richard champble sleep questionnaire before test was completed in both group.Researcher used 8 drop bitter orange extract 20% (Made in Hegrat company in Kashan) in consecutive three night in experimental group at 22 night and asked from patient to throw out it in the morning. recompleted questionnaire end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011520145N4**

Registration date: **2017-03-09, 1395/12/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-09, 1395/12/19

Registrant information

Name

Fatima Mohaddes Ardebili

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aromatherapy with Bitter orange extract on Sleep quality in Patient with type 2 diabetic

Public title

Effect of Aromatherapy on sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Suffering from type 2 diabetes according to medical records 2-Age between 30 to 65 years 3. No history of mental disorder 4. No history of respiratory allergies, asthma, allergic rhinitis and sensitivity to plant material according to patient express

5-Having sufficient strength of odor olfactory 6. Do not use sleeping pills, sedatives drugs, contraceptives and antimigraine drug 7. No history of diabetic foot ulcers due to its impact on sleep quality 8-Lack of experience stressful events during 3 months ago (such as divorce, death, marriage and etc) 9.Lake of pregnancy, breast feeding and hot flushing 10- Not having night worke
Exclusion criteria 1. The unwillingness of patients to continue to cooperate 2- discharge from the hospital during the study 3. The incidence of symptoms such as shortness of breath and hives 4. stressful events during study

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Medical wards were randomly divided into interventional and control groups. then for the homogenization of environmental conditions intervention and control environment changed every week.The one of two paper which was written the names of control and interventional was taken and each of medical wards placed in one of two group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Science

Street address

HEMMAT HIGH WAY NEXT TO THE MILLAD TOWER

City

TEHRAN

Postal code

1449614535

Approval date

2016-05-28, 1395/03/08

Ethics committee reference number

IR.IUMS.REC1395.9311686017

Health conditions studied

1

Description of health condition studied

DIABETES DISEASE

ICD-10 code

IV

ICD-10 code description

E10,E14

Primary outcomes

1

Description

sleep quality

Timepoint

Before the intervention and at the end of study.

Method of measurement

Richard Campbell Sleep Quality questionnaire

Secondary outcomes

1

Description

Do not have

Timepoint

Do not have

Method of measurement

Do not have

Intervention groups

1

Description

One intervention (experimental group) :8 Drop bitter orange extract 20% (Made in Hegrat Company in Kashan) at three consecutive night in inhaled.

Category

Other

2

Description

Two intervention (Control group): Receive routine care and performed no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu ali hospital

Full name of responsible person

Amir mohammad kazemifar

Street address

Cross road Bu ali, Qazvin

City

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2**Recruitment center****Name of recruitment center**

Velayat hospital

Full name of responsible person

Karami aliakbar

Street address

Taavon Square, 22 Boulevard, Minudar, Qazvin

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice Chancellor for Research and Technology Iran
University of Medical Sciences**Full name of responsible person**

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Medical Science, Hemmat Highway, Next to the Milad
Tower, Tehran**City**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice Chancellor for Research and Technology Iran
University of Medical Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty