Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Lavender Aromatherapy on Aggression and Quality of Life in Patients with Schizophrenia

Protocol summary

Study aim
Investigating the effect of lavender aromatherapy on aggression and quality of life in patients with schizophrenia

Design
A Randomized Crossover Clinical Trial

Settings and conduct
The present study will be performed in the Ghaem Psychiatric Center in Shahroud county. In the intervention group, a lavender essential oil with a concentration of 1.5% for participants every night for 30 nights, before going to bed, three Pour a drop of essential oil on a piece of cotton and place it under the outer cover of the pillow. For the control group, sunflower oil will be used instead of lavender in the same way. The data collector, intervener and statistical analyst will not be aware of the contents of the containers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Be at least 15 years old, History of at least one month of hospitalization, Definitive diagnosis of schizophrenia by a psychiatrist, No cognitive impairment Exclusion criteria: Occurrence of stressful events one month before the study Drug addiction, Having an acute psychiatric condition that disrupts communication, Escape, death or transfer of the patient to other centers, Allergies to plants and their extracts, Perceptual disorders related to the sense of smell

Intervention groups
In the intervention group, lavender essential oil (from Stoechas species prepared by distillation method with a concentration of 1.5%, prepared by Barijessence Pharmaceutical co. Kashan) for participants every night for 30 nights, before going to bed, three Pour a drop of essential oil on a piece of cotton and place it under the outer cover of the pillow. For the control group, sunflower oil will be used instead of lavender in the same way.

Main outcome variables
Aggression and Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180728040617N5**
Registration date: **2023-03-27, 1402/01/07**
Registration timing: **prospective**

Last update: **2023-03-27, 1402/01/07**
Update count: **0**

Registration date
2023-03-27, 1402/01/07

Registrant information
Name
Seyedmohammad Mirhosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 23 3239 3811
Email address
mirhoseinim@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Lavender Aromatherapy on Aggression and Quality of Life in Patients with Schizophrenia

Public title
The Effect of Lavender Aromatherapy on Aggression and Quality of Life in Patients with Schizophrenia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
History of at least one month of hospitalization Definitive diagnosis of schizophrenia by a psychiatrist No cognitive impairment Be at least 15 years old
Exclusion criteria:
Occurrence of stressful events one month before the study Drug addiction Having an acute psychiatric condition that disrupts communication Escape, death or transfer of the patient to other centers Allergies to plants and their extracts Perceptual disorders related to the sense of smell
Age
From **15 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into intervention and control groups by random block allocation using quadruple blocks created by SPSS software version 22. According to the sample size of 74 in the present study, 19 quadruple blocks will be considered. Each patient will be randomly assigned to Group A (intervention) or B (control group) in the order determined by the software. Individuals are assigned to the target group in order of their entry into the study and randomly through randomized blocks.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Basij Blvd.
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2023-02-06, 1401/11/17
Ethics committee reference number
IR.SEMUMS.REC.1401.299

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Aggression
Timepoint
At the beginning of the study (before the intervention), one day and one week after the intervention
Method of measurement
Buss & Perry aggression questionnaire

2

Description
Quality of life
Timepoint
At the beginning of the study (before the intervention), one day and one week after the intervention
Method of measurement
Schizophrenia Quality of Life Scale (SQLS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The lavender essential oil (from Stoechas species prepared by distillation method with a concentration of 1.5%, prepared by Barijessence Pharmaceutical co. Kashan) for participants every night for 30 nights, before going to bed, three Pour a drop of essential oil on a piece of cotton and place it under the

outer cover of the pillow.

Category

Rehabilitation

2

Description

Control group: Sunflower oil for participants will be poured three drops of it on a piece of cotton every night for 30 nights before going to bed and put a pillow under the outer cover.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Rehabilitation Center for Chronic Psychiatric Patients

Full name of responsible person

Seyedmohammad Mirhosseini

Street address

Shahid motahari St.

City

Shahroud

Province

Semnan

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3617645133

Phone

+98 23 3233 6043

Email

smohammadmh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Majid Mir Mohammadkhani

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3514799442

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majidmir@semums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Shahroud University of Medical Sciences

Full name of responsible person

Seyedmohammad Mirhosseini

Position

Instructor of Psychiatric Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

7th Tir Sq, Shahroud University of Medical Sciences, Shahroud, Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Seyedmohammad Mirhosseini

Position

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some of the patients' demographic information can be shared after unidentifying individuals. All quality of life and aggression assessment information can be shared with unidentified individuals.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Project partners

Under which criteria data/document could be used

People who do similar research

From where data/document is obtainable

It will be done by email with the person in charge of the project.

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

Data is made available to individuals via email.

Comments