

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of Damask rose extract on sleep quality and fatigue in hemodialysis patients: a semi experimental study

Protocol summary

Study aim

The aim of this study is to evaluate the effect of Damask rose extract on sleep quality and fatigue in hemodialysis patients.

Design

Among the available participants who are suitable considering to our inclusion criteria, will be divided into 2 groups: Intervention and control group. The Sample size will be 74 patients. Blind will not be done in this study.

Settings and conduct

The patients will be trained to provide three drops of Damask rose extract for one month, every night before bedtime, on cotton and attach them with a pin to their collar and take them off of their clothes after waking up. There will be no intervention for the control group. questionnaire will be handed to both groups before the intervention and one month after it. The place of study would be in Imam Reza hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 18 to 65 year hemodialysis history for at least 6 months Performing hemodialysis at least three sessions a week Exit criteria: Suffering from diseases that are Olfactory disorder, Psychological problems that require to take medication, sleep disorder diseases (other than ESRD) No alignment for performing aroma therapy more than three times a week

Intervention groups

intervention: The patients will be provided three drops of Damask rose extract for one month, every night before bedtime, on cottons and attach them with a pin to their collar. control: Without intervention

Main outcome variables

sleep quality and fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110629006918N28**

Registration date: **2019-01-28, 1397/11/08**

Registration timing: **retrospective**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

Alehe Seyedrasooli

Name of organization / entity

Faculty of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Damask rose extract on sleep quality and fatigue in hemodialysis patients: a semi experimental study

Public title

The effect of Damask rose extract on sleep quality and fatigue

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having the minimum age of 18 and maximum of 65
Having a hemodialysis history for at least 6 months
Performing hemodialysis at least three sessions a week
Patient's willing to participating in the study

Exclusion criteria:

Suffering from diseases that are Olfactory disorder, Psychological problems that require to take medication, sleep disorder diseases (other than hemodialysis or ESRD) No alignment for performing aroma therapy more than three times a week history of allergy to Damask Rose extract

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the eligible patients will be selected through convenience sampling technique and then randomized equally into the intervention (aroma therapy) and control groups, using randomized block design in two blocks of sizes 2 and 4 by a person blinded to the sampling. The interventions will be sealed in serially numbered opaque envelopes and the Datinf Randlist will be used to randomize the participants in the intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Shariety South St, Faculty of Nursing & Midwifery, Tabrize, Iran

City

Tabriz

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East Azarbaijan

Postal code

5138947977

Approval date

2018-07-31, 1397/05/09

Ethics committee reference number

IR .TBZMED .REC.1397.354

Health conditions studied**1****Description of health condition studied**

fatigue

ICD-10 code

G93.3

ICD-10 code description

Postviral fatigue syndrome

2**Description of health condition studied**

sleep quality

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes**1****Description**

sleep quality

Timepoint

Sleep quality measurement will be done at the beginning of the study and one month after the intervention begins.

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

2**Description**

Fatigue

Timepoint

Fatigue severity measurement will be done at the beginning of the study and one month after the intervention begins.

Method of measurement

FSS (Fatigue Severity Scale)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: The intervention group will be trained to provide three drops of Damask rose extract (made by Kashan Barij Essence Pharmaceutical company), for one month, every night before bedtime, on prepared cottons and attach them with a pin to their collar and take them off of their clothes the next morning, after waking up.

Category

Prevention

2

Description

Control group: It would not be done any intervention in this group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Bahar Elahi

Street address

Gulgasht St, Imam Reza hospital, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Bahar Elahi

Position

MSN

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

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable