Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of aromatherapy with passiflora oil on sleep quality and life balance of patients undergoing hemodialysis

Protocol summary

Study aim
Determining the effect of aromatherapy with passiflora oil on sleep quality and life balance of patients undergoing hemodialysis in the hemodialysis department of Shahid Modares kashmar, Valiasr Bardskan and Khatam al Anbia Khalilabad in 2023

Design
A clinical trial with a control group, with parallel groups, three blinded, randomized, on 72 patients, randomization will be done using the block randomization method, with the help of Random Allocation software.

Settings and conduct
Patients suffering from chronic kidney failure, undergoing hemodialysis in the dialysis centers of Shahid Modares, Kashmir, Vali Asr Bardskan, and Khatam Al Anbia, Khalilabad, who suffer from sleep disorders, are assigned to two intervention and control groups by block randomization method. . In this study, the researcher, patients, and data safety and monitoring committee will be blinded

Participants/Inclusion and exclusion criteria
Conscious patients with aged 17 to 80 years, with a history of at least 6 months of hemodialysis twice a week and three hours each time, with a sleep score of 5 and above 5 of the Pittsburg questionnaire, who don't have smell disorders, severe mental disorders, and the use of drugs or sedatives, breathing problems known as asthma, history of allergy to medicinal plants, skin sensitivity following the test of amaranth oil on the front part of the patient's forearm

Intervention groups
For six weeks, the intervention group put two pieces of cotton soaked in 7 drops of passiflora oil each night on both sides of their pillow before sleeping, inside a cellophane container designed by the researcher. They have to put it away and throw out next morning. The same procedure will be performed in the control group and a placebo (sweet almond oil) will be used instead of passiflora oil

Main outcome variables
Sleep quality, life balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221212056801N1**
Registration date: **2023-01-09, 1401/10/19**
Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**
Update count: **0**

Registration date
2023-01-09, 1401/10/19

Registrant information

Name
Marzieh Dolatshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5772 3106

Email address
dolatshahi1784@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-27, 1401/11/07

Expected recruitment end date
2023-03-10, 1401/12/19

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of aromatherapy with passiflora oil on sleep quality and life balance of patients undergoing hemodialysis

Public title

Investigating the effect of aromatherapy with passiflora oil on sleep quality and life balance of patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

complete awareness Age between 19-70 years A history of at least 6 months of hemodialysis dialysis twice a week for three hours each time Having a Sleep Quality score of 5 and above 5 of the above 5 based on the Pittsburgh questionnaire

Exclusion criteria:

Presence of smell disorder Severe mental disorder and the use of drugs or sedatives respiratory disorder such as asthma History of allergy to herbal medicine skin sensitivity following the test of passiflora oil on the front part of the patient's forearm

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In each treatment center, patients will be allocated to intervention and control groups by permuted block randomization. For this, we are about to have 12 blocks of 6 members. According to the number of patients in each of the centers (70 patients in Kashmar, 28 patients in Bardaskan and 21 patients in Khalilabad), 3 blocks will be allocated in Bardaskan center, 3 blocks in Khalilabad center, and 6 blocks in Kashmar center. Random Allocation software will be used for determination of random blocks. In order to hide the random allocation, we will use opaque sealed envelopes with a random sequence. In this method, which is abbreviated as the SNOSE method, after creating a random sequence with the help of software, a number of envelopes will be prepared based on the sample size, each of the created random sequences will be recorded on cards and placed inside the envelopes. Then the envelopes are numbered in the same order as the created sequence. Then, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the group assigned to the patient will be determined.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding purposes, random allocation will be done by one of the investigators, then the study will be performed by another investigator. In this way, the researcher who provides the oils to the patients is not aware of the type of oil and patients will not be informed about the type of oil either. Patients will receive identical packages. Finally, the data will be prepared for analysis. At the time of analysis, the researcher will not be aware of the patient grouping. In this case, the study is three-way blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research Ethics committee of Sabzevar University of Medical Sciences

Street address

Blvd. Shohada Nuclear, Sabzevar University of Medical Sciences campus

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112 - 3 صندوق

Approval date

2023-01-01, 1401/10/11

Ethics committee reference number

IR.MEDSAB.REC.1401.085

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

N18.4

ICD-10 code description

Chronic kidney disease, stage 4 (severe)

Primary outcomes

1

Description
Sleep quality score in the Pittsburgh Questionnaire
Timepoint
Before the start of the study and 6 weeks after the start of aromatherapy with passiflora oil
Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
Life balance score in Matuska questionnaire
Timepoint
Before the start of the study and 6 weeks after the start of aromatherapy with passiflora oi
Method of measurement
Matuska's Life Balance Questionnaire

Secondary outcomes

1

Description
Sleep quality score in the Pittsburgh Questionnaire
Timepoint
Before the start of the study and 6 weeks after the start of aromatherapy with passiflora oil
Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
Life balance score in Matuska questionnaire
Timepoint
Before the start of the study and 6 weeks after the start of aromatherapy with passiflora oil
Method of measurement
Matuska's Life Balance Questionnaire

Intervention groups

1

Description
Intervention group: For six weeks, the intervention group is requested to put two pieces of cotton soaked in 7 drops of 30% concentrated passiflora oil each night on both sides of their pillow before sleeping, inside a cellophane container designed by the researcher. They have to put it away and throw out next morning
Category
Treatment - Other

2

Description
Control group: For six weeks, the Control group is requested to put two pieces of cotton soaked in 7 drops of sweet almond oil each night on both sides of their pillow before sleeping, inside a cellophane container designed by the researcher. They have to put it away and throw out next morning
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modares hospital
Full name of responsible person
Marzieh Dolatshahi
Street address
17 Shahrivar St
City
Kashmar
Province
Razavi Khorasan
Postal code
9678147585
Phone
+98 51 5522 7401
Email
kash.hcenter@mums.ac.ir

2

Recruitment center
Name of recruitment center
Vali Asr hospital
Full name of responsible person
Marzieh Dolatshahi
Street address
Ghaem St., Vali Asr Blvd.
City
Bardaskan
Province
Razavi Khorasan
Postal code
9681783158
Phone
+98 51 5542 2400
Email
Bardaskan.HC@mums.ac.ir

3

Recruitment center
Name of recruitment center
Khatam al-Anbia hospital
Full name of responsible person
Marzieh Dolatshahi
Street address
Khalilabad city, Kashmar road
City
Khalilabad
Province

Razavi Khorasan

Postal code
۹۶۷۷۱۱۵۵۶۵

Phone
+98 51 5772 8007

Email
ch_khalilabad@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Dr.Mojghan Ansari

Street address
Boulevard nuclear shohaday. Sabzevar University of Medical Sciences campus

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Phone
+98 51 4401 8330

Email
info@medsab.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
Marzieh Dolatshahi

Position
Critical care nursing master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 49,th6 Shahid Sadeghi Street

City
Kashmar

Province
Razavi Khorasan

Postal code
9671773453

Phone
+98 51 5772 3106

Email
dolatshahi1784@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Mojgan Ansari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Boulevard nuclear shohaday. Sabzevar University of Medical Sciences campus

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Phone
+98 51 4401 8300

Email
mojganansari01@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Marzieh Dolatshahi

Position
Critical care nursing master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 49,th6 Shahid Sadeghi Street

City
Kashmar

Province
Razavi Khorasan

Postal code
9671773453

Phone
+98 51 5772 3106
Email
dolatshahi1784@gmail.com

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
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

Title and more details about the data/document
Part of the research sample data after deid entification will be shared
When the data will become available and for how long
After collecting and analyzing the data, the results will be published in the form of an article became
To whom data/document is available
The results will be published for all researchers working in the class
Under which criteria data/document could be used
The results of this study can be used by all people who are in the field of treatment Caring for patients with chronic kidney failure and undergoing hemodialysis are being used.
From where data/document is obtainable
Applicants can contact Ms. Marzieh Dolatshahi at the address of Sabzevar University of Medical Sciences, Faculty of Nursing and Midwifery, refer to the student research committee unit
What processes are involved for a request to access data/document
Applicants can obtain documents after submitting an application to the student research committee and obtaining the necessary permits.
Comments