Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of lavender aromatherapy and surface stroke back massage on the level of fatigue and sleep quality of hemodialysis patients

Protocol summary

Study aim
Comparison of Inhalation Aromatherapy with Lavender Scent and Back Surface Stroke Massage on Fatigue and Sleep Quality in Hemodialysis Patients

Design
Case study: Hemodialysis patients - A clinical trial study - available sampling and assignment method to patients randomly andd blocks with block size 6

Settings and conduct
Place: Shahid Beheshti Abadan How to do: At first, serum urea, creatinine, albumin, and hemoglobin tests of patients' blood are recorded according to the latest test in the case. In the next step, in the aroma group, the herbal fragrances will be healed for 12 sessions during the night after each hemodialysis session. In this way, two drops of pure lavender essential oil in a dropper are given to the patient and they are told that exactly before bedtime 2 drops of essential oil on a pre-prepared cotton ball, pinched and attached with a pin to his collar And then throws it in the morning. The second intervention is a superficial impact massage that is performed in the Massage Therapy intervention group in which patients undergo 12 sessions of 10 minutes overnight after 2 hours of onset of hemodialysis at night by a researcher who has been trained and certified. It will be under massage In the third group, the control group, there is no intervention and patients receive routine daily care.

Participants/Inclusion and exclusion criteria
Patients under hemodialysis for at least 6 months,Aged 18 years and older. Perform 3 hemodialysis sessions per week and each session 4 hours/patient expire

Intervention groups
Aromatherapy Massage therapy Control

Main outcome variables
fatigue; sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181119041702N1**
Registration date: **2018-12-28, 1397/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-28, 1397/10/07**
Update count: **0**

Registration date
2018-12-28, 1397/10/07

Registrant information

Name
zeinab raiesifar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 5336 2608

Email address
raiesifar.z@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-01, 1397/09/10

Expected recruitment end date
2019-01-30, 1397/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of lavender aromatherapy and surface stroke back massage on the level of fatigue and sleep quality of hemodialysis patients

Public title
Comparison of the effect of aromatherapy and surface stroke back massage on the level of fatigue and sleep quality of patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients under hemodialysis for at least 6 months -able to communicate willingness to participate in the study aged 18 years-and-up 3 hemodialysis sessions per week and 4 hours each session non using of other complementary therapies Lack of sensitivity to aromatherapy
Exclusion criteria:
Age under 18 years Unwillingness to participate in research

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
- Assignment of intervention randomly and random block method with block size 6 -The unit of randomization of individuals -Randomization by a statistics specialist using the table of random permutations - In this study, depending on the nature of the interventions, there is no blinding condition for patients and researchers.

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
The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Nursing Blvd -Negin Irvand 25
City
Abadan
Province
Khouzestan
Postal code
6975116955

Approval date
2018-11-17, 1397/08/26

Ethics committee reference number
IR.AJUMS.REC.1397.620

Health conditions studied

1

Description of health condition studied
dialisis

ICD-10 code
Y84.1

ICD-10 code description
Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
The quality of sleep in patients with dialysis

Timepoint
Sleep quality measurement before intervention and 1 and 2 months after intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
the level of fatigue in dialysis patients

Timepoint
Fatigue measurement before intervention and 11 times during intervention and 1 and 2 months after intervention

Method of measurement
NRS numerical checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aromatherapy group:After each dialysis session, in a dialis unit of two drops, Two drops of lavender is given to the patient in a syringe to take home, and precisely before bed, the essential oil is

poured on a cotton and connected to a pocket with a pin, and it blinks in the morning, and at the next session of the dialysibimar, the effect This intervention is measured using relevant questionnaires, and this process continues for up to 12 sessions.

Category
Treatment - Other

2

Description
Intervention group: Massage Therapy Group:In this group, 12 sessions of back stroke massage in the dialysis unit are performed for patients, and then in the next session of dialysis, the effect of this intervention is measured using relevant questionnaires.

Category
Treatment - Other

3

Description
Control group: The control group does not receive any intervention

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Abadan Shahid Beheshti Hospital

Full name of responsible person
Shahram Baraz

Street address
No.25, Valie Asr Blvd., Abadan Town

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raiesifar.z@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Majid Karandish

Street address
Golestan Blvd, Ahvaz Town

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6135715794

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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
Ahvaz University of Medical Sciences

Proportion provided by this source
40

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
Ahvaz University of Medical Sciences

Full name of responsible person
Shahram Baraz

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position

Associate professor

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Person responsible for updating data

Contact

Name of organization / entity

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Zeinab Raiesifar

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Msc Stusent

Latest degree

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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

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

Yes - There is 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

Only part of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

The data from this research will only be available to researchers working in academia and academia

Under which criteria data/document could be used

The data is indexed on the site and accessible via personal email

From where data/document is obtainable

To site or email, the person who registered the information

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

Approximately after 6 months from the publication of the article, data is available to the responsible author via the site or email

Comments