

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 and 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

Khuzestan

## 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

dialysis

#### 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 dialysis, 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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**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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info@ajums.ac.ir

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

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Ahvaz University of Medical Sciences

**Full name of responsible person**

Zeinab Raiesifar

**Position**

Msc Stusent

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Email**

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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**