Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of efflorescence massage and diluted vinegar solution on sleep quality in hemodialysis patients

Protocol summary

Study aim

Determining the effect of Eflorage massage plus 0.3% diluted vinegar solution on the sleep quality of hemodialysis patients.

Design

This experimental study is a blind randomized controlled trial with two parallel groups. The sample size will be 80 people. The research sample is selected using a random number table and randomly allocated with a lottery envelope. For female patients, the intervention will be done by a woman, and for male doctors, the intervention will be done by a man. The training course of massage technique and certification will be obtained.

Settings and conduct

Academic hemodialysis centers of Bandar Abbas will be the research environment. Blinding of the evaluator, using the code assigned to the patients, performs the evaluation and leaves the ward. Patients of the control group receive the standard and common care of the ward and leave the ward. Patients in the intervention group are directed to a special room to receive the intervention. The statistical analyst will also perform analyzes using the registered codes of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Voluntary; over 18 years of age; have an itch score above 3. Exclusion criteria: Mental and cognitive disorders; having a recent stressful event; drug use; having any wound or pain or skin sensitivity.

Intervention groups

Intervention group: back massage is done for about 6 minutes, front leg massage for 4 minutes and back of leg (back of leg and thighs) for 4 minutes. Lubricant gel will be used. Control group: samples of the control group receive routine and standard care of the department.

Main outcome variables

Sleep disturbance score, sleep duration, waking up, total sleep disturbance score of hemodialysis patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230611058450N1**
Registration date: **2023-09-18, 1402/06/27**
Registration timing: **retrospective**

Last update: **2023-09-18, 1402/06/27**
Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name
HADI YOUSEFI
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of efflorescence massage and diluted vinegar solution on sleep quality in hemodialysis patients

Public title

Investigating the effect of exfoliation massage and diluted vinegar solution on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should voluntarily participate in the research Patients who are treated with hemodialysis for more than three months Patients who undergo hemodialysis treatment three times a week Patients who have an itch score above 3 Patients should be over 18 years old

Exclusion criteria:

Have any wound, pain and skin discomfort or any other skin problem other than uremic itching Phosphorus serum level should be more than 6 mg/dl and parathormone serum level should be more than 600 pg/ml. have skin sensitivity to vinegar solution or are candidates for kidney transplant Suffering from mental and cognitive disorders or banning massage due to embolism, DVT, fracture, dislocation, physical damage to the limbs and spine. The occurrence of an unfortunate and stressful accident in the last 2 months or the use of drugs Patients who are hemodialyzed with a solution other than bicarbonate and non-Polysulfone filters

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population of this research consists of all patients referred to the hemodialysis department (170 people). The names of all patients are registered in the hemodialysis appointment schedule (hours/days/weeks/months) and can be accessed. All patients are coded (01 to 170), then using the random numbers table and moving in the first column from right to left and from top to bottom according to the determined sample size (up to 80 people), the research sample will be selected. If the selected patient does not want to participate in the study, the sample selection process will continue from the end point of the sample selection in the table until the completion of the research sample. Necessary information is provided to selected patients. After obtaining consent and agreement to participate in the study, random allocation of samples will be done using the envelope lottery method in the intervention group (40 people) and the control group (40 people).

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of blinding, each patient and each group is assigned a code, and the evaluator uses the code assigned to the patients (without knowing whether the patient is in the intervention or control group) when the patients come for the fourth appointment (the number of times of routine hemodialysis It is recorded in the patients' files in the hemodialysis department) considering the general condition of the patients before hemodialysis or during the first hour of hemodialysis, the evaluator completes the research tools, scales and data collection, then leaves the department and There will be no further contact with patients. The fourth hemodialysis of the patients is also done within 3 to 4 hours (routine of the department). At the end, the patients are separated from the machine and receive the standard and common care of the department. Control group patients leave the ward. Patients in the intervention group are directed to a special room to receive exfoliation massage and vinegar solution (about 15 minutes) and then leave the ward. This process will be repeated after every three hemodialysis sessions until the end of the 12th hemodialysis session. It is necessary to explain that patients have 2 or 3 appointments per week at specific hours, depending on their physical conditions and so-called tolerance. The statistical analyst will also perform analyzes using the registered codes of the groups (without knowing whether the patient is in the intervention or control group).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Chamran Blvd., Hormozgan University of Medical Sciences and Health Services. Bandar Abbas, Iran.

City

Bandar Abbas

Province

Hormozgan

Postal code

Postal code: 13885-7

Approval date

2023-05-10, 1402/02/20

Ethics committee reference number

IR.HUMS.REC.1402.036

Health conditions studied

1

Description of health condition studied
Dependence on renal dialysis
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
Sleep onset disorder
Timepoint
Before the intervention, the end of the third session of hemodialysis, the end of the sixth session of hemodialysis, the end of the ninth session of hemodialysis, the end of the twelfth session of hemodialysis
Method of measurement
Sleep disorder questionnaire by Mohammadi et al. (2008)

2

Description
Disruption of sleep continuity
Timepoint
Before the intervention, the end of the third session of hemodialysis, the end of the sixth session of hemodialysis, the end of the ninth session of hemodialysis, the end of the twelfth session of hemodialysis
Method of measurement
Sleep disorder questionnaire by Mohammadi et al. (2008)

3

Description
Trouble waking up
Timepoint
Before the intervention, the end of the third session of hemodialysis, the end of the sixth session of hemodialysis, the end of the ninth session of hemodialysis, the end of the twelfth session of hemodialysis
Method of measurement
Sleep disorder questionnaire by Mohammadi et al. (2008)

Secondary outcomes

1

Description
Total score of sleep disturbance
Timepoint
Before the intervention, the end of the third session of hemodialysis, the end of the sixth session of hemodialysis, the end of the ninth session of hemodialysis, the end of the twelfth session of hemodialysis
Method of measurement
Sleep disorder questionnaire by Mohammadi et al. (2008)

Intervention groups

1

Description
Intervention group: In addition to the routine and standard care of the intervention group, at the end of each hemodialysis session, the samples of the intervention group will receive exfoliation massage plus 0.3% diluted vinegar solution. The massage will be done on the back and legs (common areas of itching), which includes three back massages (full back massage, horizontal full back massage, sliding thumbs on the spine muscles) each step 15 times and a total of about 6 minutes and massage The front of the leg (legs and thighs) for 4 minutes, that is, two minutes for each leg, and the back of the leg (the back of the leg and thighs) for 4 minutes, that is, two minutes for each leg (20 repetitions for each) on the patient and in total It takes 14 minutes. During the massage, lubricant gel will be used as a media for a better massage effect and slippery position. The amount of gel used will be 30-60 cc according to the needs and according to the size of the people. In this study, 5% industrial white vinegar solution is used in the amount of 30 cc, which will reach 500 cc by adding the purified water of the dialysis section. This solution will be carefully prepared by the researcher using special measuring containers. 5% industrial white vinegar, a product of Asiashore Company, which after dilution reaches a concentration of 0.3%, then using a sponge (10 x 20 cm) soaked in diluted vinegar solution is massaged on the skin and on the areas. In the direction of the massage movement, it will be stretched twice in each area, once to maintain the pH of the skin and to ensure the removal of skin waste products. Two containers are used, one for washing the sponge and the other for soaking the sponge in vinegar solution.
Category
Rehabilitation

2

Description
Control group: Examples of the routine and standard care control group of the department, which include: training provided by personnel in the form of pamphlets or face-to-face and feedback-based, training provided by the resident doctor of the hemodialysis center, compliance with diets (low protein, low phosphorus diet), Skin care of the itchy areas for less irritation and using the right detergent, not scratching the skin, keeping it clean and maintaining skin hygiene. In this group, the drugs prescribed by the doctor are not stopped during the intervention. These drugs include antihistamines, gabapentin, and Renagel. The samples in both groups

are subjected to a skin test with a diluted vinegar solution before starting the intervention to ensure the absence of sensitivity.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Abdullah Gharibzadeh

Street address

No1; Shahid Chamran Boulevard, Bandar Abbas, Hormozgan, Iran

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2

Recruitment center

Name of recruitment center

Children 'hospital

Full name of responsible person

Amir Hasabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Vali Alipour

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hadi Yousefi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions will be available
Under which criteria data/document could be used
Meta analysis
From where data/document is obtainable
Hadi Yousefi by email
What processes are involved for a request to access data/document
Submit a request by email and receive a response within a week
Comments
at your service