Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

A comparative study of the effect of aromatherapy with geranium essential oil and foot reflexology on fatigue and daily life activities of hemodialysis patients

Protocol summary

Study aim
Comparison of the effect of aromatherapy with geranium essential oil and foot reflexology on fatigue and daily activities of hemodialysis patients

Design
A clinical trial with an aromatherapy group with geranium essential oil, foot reflexology group and control group (parallel groups) will not be blinded, randomized using random allocation software on 90 patients.

Settings and conduct
This research is a randomized clinical trial study that will be conducted on hemodialysis patients . The sample population of this study will be 90 patients hospitalized in the hemodialysis department of Ganjovian Hospital in 2023.

Participants/Inclusion and exclusion criteria
Patients hospitalized in hemodialysis ward who have been hospitalized for more than 3 months and complain of fatigue

Intervention groups
Patients in the control group will not receive any intervention recommendations and will only be asked to answer the questionnaire questions. For the aromatherapy intervention group, geranium extract is used. In the first hour of hemodialysis, 10 drops of geranium extract will be poured into the eye pad by a researcher, then the researcher attaches the soaked cotton pad to the patients' collar. For the reflexology intervention group, each person will receive massages of approximately 20 minutes by a trained researcher who will be present during all 3 sessions of hemodialysis treatment for 5 weeks. All interventions are performed one hour after the start of the dialysis session

Main outcome variables
Changes in patient fatigue; changes in patients' daily activities

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150704023044N4**
Registration date: **2023-02-19, 1401/11/30**
Registration timing: **prospective**

Last update: **2023-02-19, 1401/11/30**
Update count: **0**

Registration date
2023-02-19, 1401/11/30

Registrant information

Name
Leila Kalani

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
2023-05-20, 1402/02/30

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of aromatherapy with geranium essential oil and foot reflexology on fatigue and daily life activities of hemodialysis patients

Public title
Investigation of aromatherapy and foot reflexology on fatigue and daily life activities of hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
1. Patients between the ages of 18 and 60 who have been diagnosed with chronic renal failure by a kidney specialist, hemodialysis patients who have been treated with hemodialysis for at least 3 months and undergo hemodialysis in one of these mentioned centers. 2. Patients who complain of fatigue and with a visual scale of fatigue intensity, have a fatigue score equal to or greater than 5. 3. Patients who have a hemoglobin level of more than 9 g/dL and a hematocrit of more than 30% 4. Patients who do not have wounds or fractures in the points. be in a condition to be able to participate in the research and answer the questionnaire. 5. The patient has not used any other complementary medicine treatment in the last three months. 6. Not using sedatives in the last 4 hours. 7. Not having burn disorders Skin diseases on the feet and infectious wounds 8. Having a healthy sense of smell. 9. Not having an allergy to the studied extract

Exclusion criteria:
1. Patients who have one or both legs cut off. 2.The patient has not had any acute psychiatric problems in the past 6 months. 3.Patients with chronic heart failure stage 3 and 4 according to ACC / AHA criteria 4.Patients treated with steroids Type 1 and type 2 diabetic patients with diabetic neuropathy. 5.Patients with disabilities Pregnant patients 6.Patients with systemic lupus erythematosus Patients with rheumatoid arthritis

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize the samples and also to balance the study groups, the allocation of patients to the 3 groups will be done by the block randomization method. C (control (without intervention)). Blocking will be done in six blocks and 15 blocks will be formed depending on the sample population. We predict all possible states of grouping, for example the first block will be AARRCC and the next block will be RCARAC for example, and the rest of the blocks will be defined as well. Due to the large number of blocks, block randomization software will be used Finally, the sample size will be the same in the groups, with 30 patients in the aromatherapy group, 30 in the reflexology group, and 30 in the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is a comparative study of two complementary medicine methods that has not been conducted in Iran on the daily activities of hemodialysis patients and we want to check the effect of two complementary medicine methods to see which one is more effective.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of dezful University of Medical Sciences

Street address
student squer,Azadegan Blvd

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Dezful

Province
Khouzestan

Postal code
6461665145

Approval date
2019-10-28, 1398/08/06

Ethics committee reference number
IR.DUMS.REC.1398.033

Health conditions studied

1

Description of health condition studied
FATIGUE

ICD-10 code

ICD-10 code description

2

Description of health condition studied
ADL

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Visual fatigue severity score: Each item is graded from zero to 10, with a score of zero (no fatigue), a score of 3-1 = mild fatigue, 6-4 = moderate fatigue, and 10-7 = severe fatigue, and this scale Before entering the study, patients are given and if they have a score of 5 on this visual scale, they enter the study and the Piper fatigue scale is used for all people who entered the study. Piper fatigue scale: has 27 items and 4 After mental fatigue, which includes behavioral, emotional, sensory, and cognitive dimensions. The behavioral dimension that has 6 items and the question 7-2, the emotional dimension has 5 items and the question 12-8, the sensory dimension has 5 items and the question 17-13 and the cognitive dimension that has 6 items and the question 23-18 scale It will review and calculate a total of 22 items of the overall scale score, 5 additional items that include numbers 1 and 24 to 27 will not be used to calculate the subs scale score and the overall fatigue scale score, and will be used to evaluate descriptive data. Each item is graded from zero to 10, with a score of zero (no fatigue), a score of 3-1 = mild fatigue, 6-4 = moderate fatigue, and 10-7 = severe fatigue. This scale will be given to all patients once before the start of the intervention and one week after the end of the 5 WEEK to determine the severity of the fatigue.

Timepoint

The results will be measured at the beginning of the study and the fifth weekend

Method of measurement

Piper Fatigue Questionnaire :It has 27 items and 4 after mental exhaustion including behavioral, emotional, sensory, and cognitive aspects. Behavioral dimension with 6 items and Question 7-2, Emotional dimension with 5 items and Question 12-8, Sensory dimension with 5 items and Question 17-13 and Cognitive dimension which measures 6 items and Question 18-23 It will evaluate and calculate the total of 22 items of the overall scale score, 5 additional items including 1 and 24 to 27 not used to calculate the subscale score and overall fatigue scale score and will be used in the evaluation of descriptive data. Each item ranged from zero to 10, with a score of zero (no fatigue), a score of 1-3 = mild fatigue, 4-6 = moderate fatigue, and = 7-10 = severe fatigue. This scale will be administered to all patients once before the intervention and 5 week after the intervention to determine the severity of fatigue. The overall fatigue severity score will be evaluated as high codes.Visual Fatigue Severity Scale used to screen samples for inclusion in the study. If a patient has a fatigue severity score of 5 or higher, he or she will be enrolled in the study and scored on a visual scale of 0 to 10, which will eventually result in fatigue (0), low fatigue (1-3), moderate fatigue (0). 4-6) and severe fatigue (7-10) are interpreted

2

Description

Daily Living Activity Score: Has 4 domains (mobility, kitchen activities, home activities, and leisure activities)

Timepoint

The results will be measured at the beginning of the study and the fifth weekend

Method of measurement

Nottingham Daily Activity Survey Questionnaire: It is a standard and valid questionnaire in this field and has been used in numerous studies. This questionnaire has 20 questions and 4 domains (mobility, kitchen activities, home activities and leisure activities). And the patient can choose from a 4-point Likert scale depending on their activity status. Patients could score between 0 and 60 on this questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: reflexology--This research has been approved by the ethics committee of Dezful University of Medical Sciences with the code IR.DUMS.REC.1398.033. After obtaining the approval of the ethics committee, the researcher obtained a letter of introduction from the university and the hospital administrators. Selects data and people eligible to study using the input and non-input criteria. . In order to observe ethical considerations, the researcher introduces himself to the patient and gives sufficient and clear explanations to the patients and their companions about the objectives and method of research face to face and a written written consent is obtained from them.After selecting the samples in an easy and accessible way, the researcher first records the demographic information of the patients and then provides the necessary explanations and training on determining the severity of fatigue using the VISUAL ANALOG SCALE FATIGUE questionnaire. Patients are then asked to mark the severity of their fatigue based on the VAS questionnaire before the intervention begins, and patients with a fatigue score higher than 5 enter the study.In order to randomize the samples and also to balance the studied groups, the allocation of patients in 3 groups will be done by block research by the researcher. The researcher in this method each patient in one of 3 groups A (armotherapy) or R (reflexology) or C (control) will set. The blocking will be done in the form of six blocks and 15 blocks will be formed according to the number of sample communities. In all cases, we can predict the order of the groups, for example, the first block will be AARRCC, the next block will be RCARAC, for example, and the rest of the blocks will be defined in the same way. Due to the large number of blocks, block randomization software will be used, and then 15 blocks will be selected randomly and with the help of a table of random numbers. Individuals will also be randomly selected and placed in blocks. Finally, the sample size will be the same in the groups and 30 patients will be in the aromatherapy group, 30 patients in the reflexology

group and 30 patients in the control group. To prevent the effect of aromatherapy method on reflexology and control group, it was tried to place patients of 3 groups in 3 different times to remove all effective variables. Before the intervention, the researcher completes the Piper fatigue questionnaire and the daily activities of Nottingham life by asking the patient. How to do reflex massage is done only in the hospital and by researchers. Researchers have passed theoretical and practical training in reflexology under the auspices of the Iranian Acupuncture Association and received the relevant certificate. Reflexology intervention is performed by two male and female researchers.Stages of Reflexology Intervention: After half an hour from the start of dialysis, the patient is placed in an open position and a pillow is placed under the patient's head so that the patient's head rises 15 to 30 degrees and the patient's face can be controlled to control reactions. Be observed. During the massage, the intruder removes his watch, ring, ring and bracelet, shortens his nails, and washes his hands with soap and water. The foot massage is performed by researchers for 3 sessions per week for 20 minutes and for 5 weeks.The steps of reflexive massage of the soles of both feet: include heating the intervention site for 3 minutes and then initiating 15 general reflexology steps as follows.1. One minute of pulsating pressure on the kidney point12 and 3. At least 10 sweeping movements with two thumbs on the arch of the sole of the foot (between the heel and the toe)4. A minute of pulsating pressure at the point of sex (in the middle of the heel) and then a minute of rotation.5. One minute of rotational pressure on the protrusion of the big toe (pituitary point)6. Three stages of rotational massage and stretching of the toes (Sinus area)7 and 8. At least 10 sweeping movements with two thumbs between the heel and the chest (longer and more late than steps 2 and 3)9. At least 10 times one-way and two-way sweeping movements in the chest part of the foot (Lung area)10. At least 10 times cascading movement with three fingers on the foot (Brest area)11 and 12. At least 10 times sweeping with four fingers between the heel and toes on both the inside and outside of the foot.13 and 14. One minute of rotating massage on both sides of the inner and outer ankles15. A minute of reciprocating massage on the ankle joint (Fallopian tube area) and finally again a minute of pulsating pressure on the kidney point1. These steps are the same for both legs, but for the left foot, in addition to general reflexology intervention, 6 specialized reflexology steps are performed. The steps are as follows:1. At least 10 times one-way Walking movement across the chest2. One minute of pulsating pressure on the heart point3. One minute of pulsating pressure on the kidney point14. One minute of pulsating pressure on the hypogastric point5. One minute of rotational pressure on the protrusion of the big toe (pituitary point)6. At least 10 times walking between the toes to the inside of the foot (Coccyx Sacrum, Lumbar spune, Thoracic spine, Cervical spine).After the end of fifth weeks, the Piper fatigue questionnaire and the daily life activities of Nottingham are completed by the patients, and the data are collected by the researcher and entered into SPSS software for statistical calculation.

Category

Rehabilitation

2

Description

Intervention group: Intervention group: Arimatorapy-This research has been approved by the ethics committee of Dezful University of Medical Sciences with the code IR.DUMS.REC.1398.033. After obtaining the approval of the ethics committee, the researcher obtained a letter of introduction from the university and the hospital administrators. Selects data and people eligible to study using the input and non-input criteria. . In order to observe ethical considerations, the researcher introduces himself to the patient and gives sufficient and clear explanations to the patients and their companions about the objectives and method of research face to face and a written written consent is obtained from them.After selecting the samples in an easy and accessible way, the researcher first records the demographic information of the patients and then provides the necessary explanations and training on determining the severity of fatigue using the VISUAL ANALOG SCALE FATIGUE questionnaire. Patients are then asked to mark the severity of their fatigue based on the VAS questionnaire before the intervention begins, and patients with a fatigue score higher than 5 enter the study.In order to randomize the samples and also to balance the studied groups, the allocation of patients in 3 groups will be done by block research by the researcher. The researcher in this method each patient in one of 3 groups A (armotherapy) or R (reflexology) or C (control) will set. The blocking will be done in the form of six blocks and 15 blocks will be formed according to the number of sample communities. In all cases, we can predict the order of the groups, for example, the first block will be AARRCC, the next block will be RCARAC, for example, and the rest of the blocks will be defined in the same way. Due to the large number of blocks, block randomization software will be used, and then 15 blocks will be selected randomly and with the help of a table of random numbers. Individuals will also be randomly selected and placed in blocks. Finally, the sample size will be the same in the groups and 30 patients will be in the aromatherapy group, 30 patients in the reflexology group and 30 patients in the control group. To prevent the effect of aromatherapy method on reflexology and control group, it was tried to place patients of 3 groups in 3 different times to remove all effective variables. Before the intervention, the researcher completes the Piper fatigue questionnaire and the daily activities of Nottingham life by asking the patient. How to do reflex massage is done only in the hospital and by researchers. Researchers have passed theoretical and practical training in reflexology under the auspices of the Iranian Acupuncture Association and received the relevant certificate. Reflexology intervention is performed by two male and female researchers.Geranium essential oil from the scent of aromatic geranium or tea perfume with the scientific name of pelargonium gaveolenns from the geraniaceae family with 2% error in sesame oil, its essential oil contains citronellol, geraniol and neroli.

Produced by Pharmacogenesis at Shahid Beheshti University of TehranBefore starting to work with geranium extract, first a sensitivity test is performed on patients by placing a drop of the extract on the skin of the anterior part of the forearm and checking it until 24 hours later, and in case of itching, redness, rash and cough and sneezing. , The patient leaves the study. First, in the first half hour of hemodialysis, 5 drops of geranium extract are poured on a cotton pad by the researcher with a dropper, and then the researcher attaches the impregnated cotton to the patients' collars and asks them to breathe normally. Before the intervention, the questionnaire is given and completed by aromatherapy patients at the end of week 5.

Category

Rehabilitation

3

Description

Control group: Control group:Only routine care is provided. The questionnaire is given and completed by aromatherapy patients before the intervention, at the end of week 5. At the end of the intervention, the control group and their families will be trained in reflexology and aromatherapy to perform at home, and nurses in the wards will be trained to perform interventions for patients

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ganjavian Dezful Hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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

Dezfoul 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

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Full name of responsible person

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Position

instructor-faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
after completing the project, the project will enter the statistical analysis stage and after reviewing the results for publication of the final paper results will be written and sent to the journal

When the data will become available and for how long
The access period begins when the article is indexed in the database

To whom data/document is available
all people

Under which criteria data/document could be used
All information will be provided for use by researchers in the field on condition of citation

From where data/document is obtainable
The requested information will be provided via email to leilakalani@yahoo.com

What processes are involved for a request to access data/document
Upon submission of the request via email to the responsible officer, the applicant will be given a maximum of3 days

Comments