Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Reflexology and Acupressure on Fatigue and its Consequences in Hemodialysis Patients in the Healthcare Centers of Hormozgan University of Medical Sciences, Bandar Abbas, 1402 – 1403

Protocol summary

Study aim
The Effect of Reflexology and Acupressure on Fatigue and its Consequences in Hemodialysis Patients.

Design
Clinical trial with two intervention groups and one control group, with parallel groups, one blind strain, randomized with random sequence generation software and hidden with sequentially numbered, sealed, opaque envelopes, on 96 patients.

Settings and conduct
Location: Hemodialysis centers in Bandar Abbas. Methodology: Convenience sampling, allocating samples into three groups: reflexology, acupressure and control with random sample allocation software. Data collection with demographic information questionnaires, Visual Fatigue Scale, Piper Fatigue Scale and Hospital Anxiety and Depression Scale. Blinding: 1. Outcome evaluator: Evaluations in the waiting room before and after intervention, coding and uploading to the statistical software. 2. Data analyst: Data analysis

Participants/Inclusion and exclusion criteria
Inclusion criteria: At least 18 years old, at least 3 months of hemodialysis experience, undergoing hemodialysis three times a week, having full consciousness and the ability to listen and speak Non-entry criteria: unwillingness to participate in the research, severe mental disorder and use of sedatives, occurrence of stressful events such as the death of first-degree relatives, divorce and conflicts in legal issues in the last six months, suffering from chronic diseases and debilitating diseases. (cancer, chronic respiratory failure, heart failure, rheumatoid arthritis, systemic lupus erythematosus), having amputations, wounds, swelling, burns and fractures at the intervention site.

Intervention groups
In the control group, the usual care of the hemodialysis department, in the reflexology group, foot reflexology massage and in the acupressure group, acupressure will be performed.

Main outcome variables
Reducing physical and mental fatigue, anxiety and depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240602061989N1**
Registration date: **2024-06-21, 1403/04/01**
Registration timing: **prospective**

Last update: **2024-06-21, 1403/04/01**
Update count: **0**

Registration date
2024-06-21, 1403/04/01

Registrant information

Name
Zahra Bakhshizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3361 6281

Email address
zahra.bakhshizade94@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-05, 1403/04/15

Expected recruitment end date
2024-07-20, 1403/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Reflexology and Acupressure on Fatigue and its Consequences in Hemodialysis Patients in the Healthcare Centers of Hormozgan University of Medical Sciences, Bandar Abbas, 1402 – 1403

Public title
The Effect of Reflexology and Acupressure on Fatigue and its Consequences in Hemodialysis Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
At least 18 years old At least 3 months history of hemodialysis Perform hemodialysis three times per week Having full consciousness and the ability to listen and speak
Exclusion criteria:
Unwillingness to participate in the study Severe mental disorder and the use of sedatives Occurrence of stressful events such as death of first-degree relatives, divorce and conflict in legal issues in the last six months Suffering from chronic and debilitating diseases (cancer, chronic respiratory failure, heart failure, rheumatoid arthritis, systemic lupus erythematosus) Having amputations, wounds, swelling, burns, and fractures at the intervention site
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization will be done using random sequence generation software. The randomization unit is individual, and sequentially numbered, sealed, opaque envelopes will be used for concealment.
Blinding (investigator's opinion)
Single blinded
Blinding description
One person as an outcome evaluator, without knowing the allocation of patients in groups, will perform all the evaluations in the waiting room before and after hemodialysis and immediately leave the hemodialysis department after doing it. He will not face patients during hemodialysis during intervention or non-intervention. In the continuation of blinding, he codes the data of the evaluation sheet and uploads it to the statistical software. The data analyst will also analyze the data without knowing the allocation of patients in the groups.
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
Hormozgan University of Medical Sciences, Faculty of Nursing and MidwiferyShahid Chamran Blvd., Bandar Abbas.
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2024-05-27, 1403/03/07
Ethics committee reference number
IR.HUMS.REC.1403.080

Health conditions studied

1

Description of health condition studied
Fatigue, anxiety and depression in hemodialysis patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fatigue score of hemodialysis patients
Timepoint
At the beginning of the study (before the start of the intervention), one hour after the start of each hemodialysis session, at the end of each hemodialysis session
Method of measurement
Visual Fatiue Scale

2

Description
Fatigue score of hemodialysis patients
Timepoint
At the beginning of the study (before the start of the intervention), at the end of sessions 3, 6, 9 and 12 of the intervention
Method of measurement
Piper Fatigue Scale

Secondary outcomes

1

Description
The anxiety score of hemodialysis patients
Timepoint
At the beginning of the study (before the start of the intervention), at the end of sessions 3, 6, 9 and 12 of the intervention
Method of measurement
Hospital Anxiety and Depression Scale

2

Description
The depression score of hemodialysis patients
Timepoint
At the beginning of the study (before the start of the intervention), at the end of sessions 3, 6, 9 and 12 of the intervention
Method of measurement
Hospital Anxiety and Depression Scale

Intervention groups

1

Description
Intervention group: Intervention group: Reflexology group: in this group, in addition to the usual care in the hemodialysis department, foot reflexology massage is performed. After one hour of the start of hemodialysis, the researcher holds the heel of the patient's left foot with his left hand at the room temperature and bends and straightens it from the wrist by pressing on the sole of the foot, then with the thumb of the right hand (thumb pulp) on The solar plexus point (right below the sole of the foot at the junction of the anterior 1 / 3 and the posterior 2 / 3 of the sole in the midline) will apply direct pressure for 4 minutes, in a circular manner at the rate of 3 - 4 kg. Released pressure for 2 minutes, applied again for 4 minutes. In the same way, the massage is repeated for the right foot. Three massage sessions will be performed per week, for four weeks (12 sessions).
Category
Rehabilitation

2

Description
Intervention group: Acupressure group: in this group, in addition to the usual care in the hemodialysis department, acupressure is performed. After one hourof the start of hemodialysis, the researcher determines three acupressure points (K1, ST36 and SP6) in each leg at the room temperature. When the sole of the foot is bent, the K1 point is located in the depression of the sole between the second and third toes and approximately 1 / 3 of the distance between the base of the second toe and the heel. The SP6 point is located four toes above the inner ankle, just behind the tibia. The ST36 point is located four fingers below the kneecap and on the outside of the tibia. The researcher applied pressure at each point with the thumb of the hand at a speed of two rotations per second for 3 minutes so that the patient felt vague pain, tingling and warmth in the point. At this moment, the acupuncture point is stimulated to induce "Chi". In the same way, acupressure is repeated for the right leg (9 minutes for each leg, 18 minutes in total).Three acupressure sessions will be performed per week, for four weeks (12 sessions).
Category
Rehabilitation

3

Description
Control group: Only the routine care of the hemodialysis department is performed.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Children educational, therapeutic and research center
Full name of responsible person
Zahra Bakhshizadeh
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hormozgan 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
Zahra Bakhshizadeh
Position
Student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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