Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of acupressure in acupuncture on fatigue and sleep disorders in hemodialysis.

Protocol summary

Study aim
Determining the effect of acupressure acupuncture points on fatigue and sleep disorders in hemodialysis patients in Ahvaz, 1398.

Design
Clinical trial with intervention and sham-control groups, with single, single-blind, randomized groups with Excel rand function on 40 patients.

Settings and conduct
This study is a single-blind randomized clinical trial (participant unaware of being in an intervention or sham-control group). Location of all teaching hospitals in Ahvaz. Patients are divided into two groups of intervention and sham-control by simple random sampling. One hour after the start of dialysis, three days a week for four weeks will be performed. The sham-control group will receive the intervention at 5 points of the 5-9HX spiral, which are far from the middle points of the ear.

Participants/Inclusion and exclusion criteria
Admission: Patients who have a score of 5 or more according to the Petersburg Questionnaire. Patients undergoing hemodialysis for at least 3 months. Able to communicate. Willingness to participate in the study. 2 to 4 hours per week and each session. Withdrawal: If the patient suffers from complications during dialysis during the intervention and needs immediate medical attention. Surgery, infection and bleeding during the research. Transfer to special wards for any reason. Failure to attend training sessions.

Intervention groups
The intervention group will perform acupressure on 5 points including TF4, AH6a, CO15, AT4 and CO18 at a pressure of 0.3 to 0.4 kg for 8 minutes with a rotating thumb for one hour one hour after the start of dialysis three days a week for four weeks. The sham-controllers receive the intervention at 5 different points of the 5-9HX spiral that are far from the middle points of the ear.

Main outcome variables
Fatigue and sleep disorders in hemodialysis patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201021049102N1**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**
Update count: **0**

Registration date
2022-01-01, 1400/10/11

Registrant information

Name
Alireza Momeni

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3292 7378

Email address
alirezamomeni136@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-02-04, 1400/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of acupressure in acupuncture on fatigue and sleep disorders in hemodialysis.

Public title
Effect of Auricular acupressure on fatigue and sleep disorders in Hemodialysis patients.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have a score of 5 or more according to the Petersburg Questionnaire. Perform 2 to 3 hemodialysis sessions per week And each session should be 2 to 4 hours. Patients undergoing hemodialysis for at least 3 months. Able to communicate. Willingness to participate in the study. Age 18 years and older. Perform 2 to 3 hemodialysis sessions per week And each session should be 2 to 4 hours.

Exclusion criteria:
If the patient has complications during dialysis during the intervention, he needs immediate medical attention. Surgery, infection and bleeding at the time of the study. Transfer to special departments for any reason. Failure to attend training sessions

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address
Esfand St., Golestan Blvd.

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2020-10-19, 1399/07/28

Ethics committee reference number
IR.AJUMS.REC.1399.568

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease ESRD

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
sleep disorders.

Timepoint
After 28 days of intervention.

Method of measurement
Petersborg Questionnaire

2

Description
fatigue.

Timepoint
After 28 days of intervention.

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group received ear acupressure by a nurse (who was evaluated for post-training qualification and approved by an acupuncturist) one hour after starting dialysis three days a week for four weeks on 5 points including TF4, AH6a , CO15, AT4 and CO18 in the form of pressure of 0.3 to 0.4 kg for 8 minutes with a rotating thumb clockwise. These points were selected based on the meridian theory of traditional Chinese medicine (TCM) and on-site clinical practice experience.

These points are anatomically connected to the ear branch of the vagus nerve. These points play an important role in sleep by regulating the autonomic nervous system, increasing parasympathetic activity, and decreasing sympathetic activity.

Category

Treatment - Other

2

Description

The sham-control group evaluated ear acupressure by a nurse (who was evaluated for post-training qualification and acupuncture approval) one hour after the start of dialysis three days a week for four weeks on five helical points (HX 5-9) will receive a pressure of 0.3 to 0.4 kg for 8 minutes with a rotating thumb clockwise. These points are clearly away from the inner ear area and lack evidence to manage insomnia.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeyni Hospital

Full name of responsible person

Alireza Momeni

Street address

School of Nursing and Midwifery, Ahvaz Jundishapur University City, Golestan Road.

City

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15794 - 61357

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Email

Alirezamomeni136@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdul Ali Shariati

Street address

School of Nursing and Midwifery, Ahvaz Jundishapur University City, Golestan Road.

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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

Faculty Grant

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

Ahvaz University of Medical Sciences

Full name of responsible person

Alireza Momeni

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdul Ali Shariati

Position

Faculty Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

Bachelor

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data that is related to the main outcome

When the data will become available and for how long

Access one 6 months after printing the results

To whom data/document is available

Only researchers working in academic centers

Under which criteria data/document could be used

Provided request to the responsible executor

From where data/document is obtainable

Executive Officer - Ahvaz Jundishapur School of Nursing

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

Will be reviewed and answered by the responsible executor

Comments