

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

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

Protocol summary

Fatigue and sleep disorders in hemodialysis patients.

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

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

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3373 8331

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.

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3373 8331

Email

Alirezamomeni136@gmail.com

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

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

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3373 8331

Email

Alirezamomeni136@gmail.com

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
Street address
School of Nursing and Midwifery, Ahvaz Jundishapur
University City, Golestan Road.
City
Ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
+98 61 3373 8331
Email
Shariati-a@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Alireza Momeni
Position
Master Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Ahvaz Jundishapur
University City, Golestan Road.
City
Ahvaz
Province
Khouzestan
Postal code

15794 - 61357
Phone
+98 61 3373 8331
Email
Alirezamomeni136@gmail.com

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