Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of acupressure on sleep quality and anxiety in hemodialysis patients

Protocol summary

Summary

This controlled clinical trial and double blind study will conduct to determine the effectiveness of acupressure on sleep quality and anxiety in hemodialysis patients. 75 hemodialysis patients will select from Bushehr hospitals via convenience sampling, then the subjects will allocate into three groups (intervention, placebo and control group) by using stratified random allocation. At least six mounts history of hemodialysis and greater than five score in Pittsburgh Sleep Quality Index, ages from 18 to 65 years, are necessary for including to the study. Subjects in intervention group will receive acupressure in true acupoint (hand Shenmen, PC6 and Yintang points) three times a week for one month, placebo group will experience massage in pseudo points with about 1 to 1.5 cm distance near to the true points (hand Shenmen acupoints) and no intervention will do in control group. Intervention will be take place in hemodialysis unit by two trained practitioners. Pretest and posttest for measurement of sleep and anxiety will do by using Pittsburgh Sleep Quality Index, Sleep Log and Spielberger State Trait Anxiety Inventory (STAI).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061717237N3**
Registration date: **2014-09-17, 1393/06/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

Name

Mahnaz Modanloo

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Golestan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure on sleep quality and anxiety in hemodialysis patients

Public title

The effect of Acupressure on sleep quality and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age from 18 to 65 years; at least 6 months history of hemodialysis; three times hemodialysis in a week and four hours for each session; five or greater score in Pittsburgh Sleep Quality Index; having complete alertness, hearing and speech ability; having the ability to read and write; not having developing a psychiatric disorders which lead to consumption of psychiatric

drugs; cancer; lupus erythematosus; dermatological disease; advanced heart failure; stroke;amputation; sore, infection or fistula in acupoints; Carpal Tunnel Syndrome (CTS). Exclusion criteria: Patient hospitalization in intensive care unit, consumption of psychiatric drugs and distortion in mental status, death during intervention; the incidence of severe stressful event such as the death of someone close; not wanting to continue participation; travel; surgery and transplants lead to exclusion of subjects from the study.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization strategies: Considering sleep quality level, patients were allocated to three matched intervention, placebo and control groups. Allocation will be achieved using stratified random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee

Street address
Deputy of Research and Technology, Golestan University of Medical Sciences (Falsafi Complex), Hirkan Boulevard, Gorgan

City
Gorgan

Postal code
4934174515

Approval date
2014-06-08, 1393/03/18

Ethics committee reference number
562089303181

Health conditions studied

1

Description of health condition studied
Chronic Renal failure

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5 (on dialysis)

Primary outcomes

1

Description
Quality of sleep

Timepoint
Before intervention and a week after four weeks intervention

Method of measurement
Pittsburgh Sleep Quality Index and Sleep Log

Secondary outcomes

1

Description
Anxiety

Timepoint
Before intervention and a week after four weeks intervention

Method of measurement
State Trait Anxiety Inventory (STAI)

Intervention groups

1

Description
Intervention group: Acupressure will be done on true acupoints (hand Shenmen, PC6 and Yintang) by using 3 to 4 kg pressure, with the practitioners' thumb in a period of two revolutions per second.The intervention will conduct three times a week for a month.

Category
Other

2

Description
Placebo group: Massage will done in pseudo points with about 1 to 1.5 cm distance near to the true acupoints three times a week for a month.

Category
Other

3

Description
Control group: Without any intervention. During the study, If any intervention is required to modifying

patients' anxiety and sleep disturbance, they will be excluded from study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Abuzar Mehbudi

Street address

Hemodialysis Ward, 17 Shahrivar Hospital, Shahid Chamran Street, Borazjan

City

Borazjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology Deputy of Golestan University of Medical Sciences

Full name of responsible person

Masood Khoshnia

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Deputy of Research and Technology, Golestan University of Medical Sciences (Falsafi Complex), Hirkan Boulevard, Gorgan

City

Gorgan

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology Deputy of Golestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Abuzar Mehbudi

Position

MS Student of Critical Nursing Care

Other areas of specialty/work

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Position

PhD

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty