

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 months 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

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Mahnaz Modanloo

**Name of organization / entity**

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Iran (Islamic Republic of)

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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 be 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**

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**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

**Street address**

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**

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**Full name of responsible person**

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MS Student of Critical Nursing Care

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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*