Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison of the Effect of foot reflexology massage and acupressure in hand Shen Men point on the quality of sleep in Patients Undergoing hemodialysis

Protocol summary

Study aim

A comparison of the Effect of foot reflexology massage and acupressure in hand Shen Men point on the quality of Sleep in Patients undergoing hemodialysis.

Design

90 patients on hemodialysis therapy who are eligible for research are selected from kidney care dialysis centers. Then, the patients are randomly divided into three groups: reflexology massage, acupressure and control, and each patient receives a specific number.

Settings and conduct

1 hour after starting dialysis 3 days a week for 4 weeks,10 minutes pressure in hand Shen Men point (acupressure) and foot thump pineal gland (reflexology massage) are performed in the dialysis center while the patient is in supine position and takes five deep breaths,s but the control group receives no treatment.

Participants/Inclusion and exclusion criteria

A 6-month history of dialysis, a total score of "5" or more in The Pittsburgh Sleep Quality Index, enjoying full awareness, lack of mental disorders and a history of illnesses that affect on sleep , no alternative and complementary therapies, no drug abuse؛ unwillingness to cooperate, traveling, death, presence of a traumatic stress or transitioning to intensive care unit in order to have an organ transplantation procedure.

Intervention groups

90 patients on dialysis are divided into intervention and control groups for comparing the effect of therapies on their sleep quality, . There is no treatment in control group except for daily care. In acupressure in hand Shen Men point group each wrist is pressured by the thump for 5 minutes (both wrists are pressured for 10 minutes) continuously in a rotational manner (2 rotations per second) and in foot thump Pineal gland reflexology massage group each foot is massaged slowly and in a regular rhythm for 5 minutes.

Main outcome variables

Due to its simplicity and safeness, and also the prevalence of sleep disorders, this method is a preferred one for sleep quality improvement.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171220037980N1**
Registration date: **2018-01-25, 1396/11/05**
Registration timing: **retrospective**

Last update: **2018-01-25, 1396/11/05**
Update count: **0**

Registration date

2018-01-25, 1396/11/05

Registrant information

Name

Masoumeh Emamverdi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the Effect of foot reflexology massage and acupressure in hand Shen Men point on the quality of sleep in Patients Undergoing hemodialysis

Public title

"A comparison of the Effect of foot reflexology massage and Acupressure in hand Shen Men point on the quality of sleep"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having dialysis treatment for at least 6 months and having a medical record in the referral centers Having a total score of "5" or more in Pittsburgh Sleep Quality Index Enjoying full consciousness and having the ability of hearing and speaking Lacking mental disorders and not using daily neurological drugs Lacking a history of diseases that affect on sleep including cancer, skin disease, advanced heart failure, insulin- dependent diabetes and brain attack Lacking limbs amputation at the site of intervention or presence of acute infections and coagulation disorders Non-use of other alternative and complimentary therapies People who have at least the ability to read and write No drug abuse

Exclusion criteria:

Unwillingness to continue cooperation during the study period Transitioning to intensive care unit in order to have an organ transplantation procedure Patient death Travelling Presence of a traumatic stress that results in sleep disorder Use of any hypnotic medicines that affect on sleep during the study period

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first step according to a convenience target based sampling method In terms of entry criteria then by a simple random sampling (choosing randomly from the list of the patients), the patients are divided into three equal groups including reflexology, acupressure and control groups.

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 Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences , Asian Road, Gonabad , Khorassan Razavi.

City

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Province

Razavi Khorasan

Postal code

9691793718

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

IR.GMU.REC.1396.65

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of people whose total score of "5" or more in the Pittsburgh Sleep Quality Index.

Timepoint

The sleep quality will be measured at the beginning of the study (before intervention) and middle of intervention (completion of 2 weeks) and at the end of intervention (completion of 4 weeks).

Method of measurement

Pittsburgh Sleep Quality Index Questionnaire .

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Intervention in the acupressure group will be performed 1 hour after the start of dialysis,,3 days a week and for a period of 4 weeks. First, the patient lies in a supine position and takes 5 deep breaths then acupressure in hand Shen Men point of each wrist crease is pressured by a finger by a level of 3-4 kg continuously for 5 minutes 2 rotations per second.
Category
Lifestyle

2

Description
Second intervention group: Intervention in the reflexology massage group will be performed 1 hour after the start of dialysis, 3 days a week, for 4 weeks. First, the patient lies in a supine position and take 5 deep breaths, then the foot thump pineal gland, will be massaged for 5 minutes with a slow and regular rhythm and in a depth which is tolerable for the patient.
Category
Lifestyle

3

Description
Control group: There will be no intervention except for daily care,.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
dialysis Center of Moheban
Full name of responsible person
Hoshang Arian
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between Ghaffari and Reza, Besat Boulevard, Ahmad Abad
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2

Recruitment center
Name of recruitment center
dialysis Center of Shafa Toos
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
Gonabad University of Medical Sciences

Full name of responsible person
Masoumeh Emamverdi
Position
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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
Not applicable
Data Dictionary
Not applicable