

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study of the effect of hot stone massage therapy on hemodialysis patients sleep quality level in Urmia Taleghani therapeutic-educational center in 2015

Protocol summary

Summary

Purpose or goals: the effect of massage with hot stones on sleep quality in patients undergoing hemodialysis training center - Taleghani Hospital in 1394 - 1393 as a quasi-experimental study will be carried out this research. Inclusion criteria: patient be male; in the case of hemodialysis hospital research at least six months ; willingness to participate in the study; contributing to the lack of any known disease ; sleep disorders (respiratory diseases, cancer) except for kidney failure; to full consciousness; hearing ability ; speech acceptable for answering the questions; the absence of confirmed previous psychiatric disorders; lack of addiction to drugs and alcohol. Exclusion criteria: the death of the patient; the patient continued lack of cooperation; lack of patient refer to the hospital. 60 samples were determined and were divided into intervention and control groups. Before the start of the first session, the sleep quality of patients in both groups was measured using the Pittsburgh Sleep Quality Index. "The patients in the intervention group after the completion of hemodialysis, massage with hot stones will be in the afternoon. To protect the privacy of patients will use a folding screen. The basalt stones heated in heater to 120-130 degrees Fahrenheit and then the patient lying prone position for 10 minutes in hot stones are placed over the main chakras of the patient. The massage is done for 20 minutes. Lower back and neck massage started continues. Massage therapy three days a week for four weeks, totaling 12 sessions of hemodialysis done after the end of the day after the end of the last session, patients will sleep quality questionnaire to fill out". "For patients in the control group, in the first sleep quality questionnaire completed by patients. Also, after a month without any interference, will also try to fill out the questionnaire". Outcome: sleep quality hemodialysis patients after the use of massage with hot stones treatment will be different between the

two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042922009N1**

Registration date: **2015-06-25, 1394/04/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-25, 1394/04/04

Registrant information

Name

Behnam Abdollahpoor

Name of organization / entity

Urmia Medical Sciences University

Country

Iran (Islamic Republic of)

Phone

+98 44 3635 5051

Email address

abdollahpoor.b@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia Medical Sciences University

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-07-01, 1394/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effect of hot stone massage therapy on hemodialysis patients sleep quality level in Urmia Taleghani therapeutic-educational center in 2015

Public title
The effect of hot stone massage therapy on hemodialysis patients sleep quality level

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: patient be male; in the case of hemodialysis hospital research; willingness to participate in the study; contributing to hemodialysis for at least six months; lack of any known disease affect sleep disorders (respiratory diseases, cancer) except kidney failure; to full consciousness; hearing ability and speech acceptable for answering the questions; the absence of confirmed previous psychiatric disorders; lack of addiction to drugs and alcohol. Exclusion criteria: the death of the patient; the patient continued lack of cooperation; lack of recurrent patient to the hospital

Age
From **15 years** old to **100 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
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 urmia Medical Sciences University

Street address

Urmia, Resalat bolvard, Quarter emergency

City
urmia

Postal code

Approval date
2015-04-07, 1394/01/18

Ethics committee reference number
umsu.rec.1394.17

Health conditions studied

1

Description of health condition studied

hemodialysis

ICD-10 code

Z49.0

ICD-10 code description

Preparatory care for dialysis

Primary outcomes

1

Description

sleep quality

Timepoint

Before the start of the first session, the day after the last session

Method of measurement

Pittsburgh Sleep Quality

Secondary outcomes

1

Description

sleep disorders

Timepoint

Before the start of the first session, the day after the last session

Method of measurement

Pittsburgh Sleep Quality

Intervention groups

1

Description

60 samples were determined and were divided into intervention and control groups. Before the start of the first session, the sleep quality of patients in both groups was measured using the Pittsburgh Sleep Quality Index. "The patients in the intervention group after the completion of hemodialysis, massage with hot stones will be in the afternoon. To protect the privacy of patients will use a folding screen. The basalt stones heated in heater to 120-130 degrees Fahrenheit and then the patient lying prone position for 10 minutes in hot stones are placed over the main chakras of the patient. The massage is done for 20 minutes. Lower back and neck massage started continues. Massage therapy three days

a week for four weeks, totaling 12 sessions of hemodialysis done after the end of the day after the end of the last session, patients will sleep quality questionnaire to fill out".

Category

Other

2

Description

"For patients in the control group, in the first sleep quality questionnaire completed by patients. Also, after a month without any interference, will also try to fill out the questionnaire".

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Taleghani Hospital

Full name of responsible person

Behnam Abdollahpoor

Street address

Urmia, Kashani Avenue

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, urmia medical sciences university

Full name of responsible person

Dr Iraj Mohebbi

Street address

Urmia, Resalat Mission, Quarter Emergency

City

Urmia

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, urmia medical sciences university

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

Urmia Medical Sciences University

Full name of responsible person

Behnam Abdollahpoor

Position

Graduate Student

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Behnam Abdollahpoor

Position

Graduate Student

Other areas of specialty/work

Street address

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5817648557

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+98 44 3635 5051

Fax

Email

Web page address

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