

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Thai Massage on sleep quality and general health in hemodialysis patients

Protocol summary

Study aim

Determining the effect of Thai Massage on sleep quality and general health in hemodialysis patients

Design

In this randomized clinical trial, patients were randomly assigned to two groups of 40 individuals.

Settings and conduct

In the test group, the intervention is in the form of a Thai Massage, with each session lasting 60 minutes, before dialysis, three times a week for four consecutive weeks (12 sessions in total) will be held at Akhavan Hospital in Kashan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Tendency to collaborate and participate in the study - Giving informed written consent - The Pittsburgh Sleep Questionnaire score > 5 - Lack of amputation, fractures, infections, wounds and skin diseases in the limbs - Have three sessions of hemodialysis per week and 3-4 hours per session - Have at least three months of hemodialysis history - Full of consciousness - No history of alcohol and drug addiction. Exclusion Criteria: Lack of willingness to cooperate - Not attending two massage therapy sessions - Hospitalization and creating a physical or mental crisis during the research - Taking sedatives and sleeping pills

Intervention groups

In the test group, the intervention is in the form of a Thai Massage, with each session lasting 60 minutes, before dialysis, three times a week for four consecutive weeks (12 sessions in total). There will be no intervention in the control group for 4 weeks.

Main outcome variables

Sleep quality General health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111210008348N43**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Neda Mirbagher

Name of organization / entity

Kashan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

mirbagher_n@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Thai Massage on sleep quality and general health in hemodialysis patients

Public title

The effect of massage in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Tendency to collaborate and participate in the study
 Giving informed written consent The Pittsburgh Sleep Questionnaire score > 5
 Lack of amputation, fractures, infections, wounds and skin diseases in the limbs
 Have three sessions of hemodialysis per week and 3-4 hours per session
 Have at least three months of hemodialysis history
 Full of consciousness
 No history of alcohol and drug addiction
Exclusion criteria:
 Lack of willingness to cooperate
 Failure to attend two sessions of massage therapy
 Hospitalization and creating a physical or mental crisis during the research
 Taking sedatives and hypnotics

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of test and Control groups is done using quadratic random blocks method using software

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 Kashan University of Medical Sciences

Street address

Qutb Ravandi Boulevard. Kashan University of Medical Sciences.

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.008

Health conditions studied

1

Description of health condition studied

Thai Massage

ICD-10 code

Z50

ICD-10 code description

Care involving use of rehabilitation procedures

Primary outcomes

1

Description

Sleep quality score in the Pittsburgh Questionnaire

Timepoint

Before, after and one month after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

General Health Score in the Goldberg Questionnaire

Timepoint

Before, after and one month After intervention

Method of measurement

Goldberg General Health Questionnaire

Intervention groups

1

Description

Intervention group: In the test group, the intervention is in the form of Thai Massage, with each session lasting 60 minutes, before dialysis, three times a week for four consecutive weeks (12 sessions in total).

Category

Treatment - Other

2

Description

Control group: For the control group, the usual treatment measures (hemodialysis and drug therapy) will be performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis Center in Kashan Akhavan Hospital

Full name of responsible person

Neda Mirbagher

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

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salam_20012003@yahoo.co.uk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Neda Mirbagher

Position

Associate

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable