

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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****Street address**

Urmia, Resalat Bolvard, Quareter Emergency

**City**

Khoy

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+98 44 3635 5051

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behnam.abdollahpoor@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Urmia Medical Sciences University

**Full name of responsible person**

Shamsadin Shams

**Position**

Master of Science

**Other areas of specialty/work****Street address**

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+98 44 3223 4897

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shamsadin1@yahoo.com

**Web page address****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****City****Postal code**

5817648557

**Phone**

+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*