

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of back slow stroke massage on sleep quality and perceived wellbeing in dialysis patients in Khoy shahidmadani hospital 2023

Protocol summary

Sleep quality and perceived well-being score

Study aim

Determining the effect of slow stroke back massage method on sleep quality and perception of well-being of dialysis patients

Design

The present study is a clinical trial type with control and intervention groups, unblinded, random allocation using numbered cards. The sample size was calculated as 41 people (82 people in total) in each group.

Settings and conduct

Patients will be massaged from 3 to 7 pm in one of the rooms of the dialysis department where there is no disease. In the intervention group, the researcher will massage each patient three times a week for ten minutes with slow, gentle and rhythmic movements of the palms on the patient's back with a uniform speed of about 60 movements per minute and this work will continue for four weeks. .

Participants/Inclusion and exclusion criteria

Inclusion conditions 1. Age more than 18 years and less than 70 years 2. Obtaining a score of 5 and above from the Pittsburgh Sleep Quality Questionnaire 3. Patients who have at least 3 months history of dialysis, at least twice a week and for at least two hours. Exclusion conditions 1. Suffering from heart, respiratory, liver, cancer or mental disorders such as depression 2. History of surgery and wound in the back and abdomen in the last 6 months 3. Using all kinds of complementary medicine methods during the previous three months 4. Personal use of sleeping pills, benzodiazepines, sedatives and narcotics by the patient 5. Failure to follow up to participate in massage therapy sessions

Intervention groups

In the intervention group, massage was done each three times a week for ten minutes with slow on the patient's back, about 60 movements per minute for four weeks. The control group will receive routine care during four weeks.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231122060139N1**

Registration date: **2023-12-18, 1402/09/27**

Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**

Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

Masumeh Akbarbegloo

Name of organization / entity

Khoy University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3625 5777

Email address

m_akbarbegloo@khoyums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-06, 1402/10/16

Expected recruitment end date

2024-04-04, 1403/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of back slow stroke massage on sleep quality and perceived wellbeing in dialysis patients in Khoy shahidmadani hospital 2023

Public title

The effect of back slow stroke massage on sleep quality and perceived wellbeing in dialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Male and female hemodialysis patients who have medical records in Shahid Madani Khoy Hospital.2. Having the ability to communicate3. Age more than 18 years and less than 70 years4. Obtaining a score of 5 and above from the Pittsburgh Sleep Quality Questionnaire5. Patients who have a history of dialysis for at least 3 months, at least twice a week and for at least two hours.

Exclusion criteria:**Age**

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

After the selection of eligible people through available sampling, the patients will be randomly allocated into two intervention and control groups. The random allocation method will be such that the names of eligible hemodialysis patients in Shahid Madani Khoy Hospital are written on a number of cards selected by the researcher as the control group and the same number of cards for the intervention group; Then, by merging the cards together, one issued card is recorded and its allocation is recorded, and that card is returned to the group of other cards after being issued. Then the cards are merged again and another card is removed. This process continues until reaching a random sequence according to the sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee in research of Khoy University of Medical Sciences

Street address

No. 35, Shahid Modarres Ave., Emam Blvd., Khoy Town

City

Khoy

Province

West Azarbaijan

Postal code

5816753464

Approval date

2023-09-18, 1402/06/27

Ethics committee reference number

IR.KHOY.REC.1402.039

Health conditions studied**1****Description of health condition studied**

slow stroke back massage

ICD-10 code

Z50.9

ICD-10 code description

Care involving use of rehabilitation procedure, unspecified

Primary outcomes**1****Description**

Sleep quality score in the Pittsburgh Questionnaire

Timepoint

Before, two weeks and one month after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes**1****Description**

The wellness perception score in the Adams perceived wellness survey

Timepoint

Before, two weeks and one month after the intervention

Method of measurement

Adams perceived wellness survey

Intervention groups

1

Description

Intervention group: In the test group, each patient will be massaged three times a week for ten minutes with slow, gentle and balanced movements of the palms on the patient's back with a uniform speed of about 60 movements per minute and this work will continue for four weeks.

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 of Shahid Madani Hospital in Khoy city

Full name of responsible person

Masumeh Akbarbegloo

Street address

No. 35, Shahid Modarres Ave., Emam Blvd., Khoy Town

City

Khoy

Province

West Azarbaijan

Postal code

5813974699

Phone

+98 44 3622 1672

Email

m_Akbarbegloo@khoyums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoy University of Medical Sciences

Full name of responsible person

Hosein Motarefy

Street address

Valiasr Ave., Khoy Town., Khoy University of Medical Sciences

City

Khoy

Province

West Azarbaijan

Postal code

5816753464

Phone

+98 44 3625 5777

Email

motarefy_h@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoy 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

Khoy University of Medical Sciences

Full name of responsible person

Masumeh Akbarbegloo

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No. 35, Shahid Modarres Ave., Emam Blvd., Khoy Town

City

Khoy

Province

West Azarbaijan

Postal code

5813974699

Phone

+98 44 3622 1672

Email

m_Akbarbegloo@khoyums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoy University of Medical Sciences

Full name of responsible person

Masumeh Akbarbegloo

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No. 35, Shahid Modarres Ave., Emam Blvd., Khoy
Town

City

Khoy

Province

West Azarbaijan

Postal code

5813974699

Phone

+98 44 3622 1672

Email

m_Akbarbegloo@khoyums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Khoy University of Medical Sciences

Full name of responsible person

Masumeh Akbarbegloo

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No. 35, Shahid Modarres Ave., Emam Blvd., Khoy
Town

City

Khoy

Province

West Azarbaijan

Postal code

5813974699

Phone

+98 44 3622 1672

Email

m_Akbarbegloo@khoyums.ac.ir

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