

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of Effleurage Massage on Intensity of physiological stress associated with the treatment in hemodialysis patients

Protocol summary

Summary

This study is a clinical trial on 41 patients undergoing hemodialysis. To evaluate the Effects of Effleurage Massage on Intensity of physiological stress associated with the treatment in hemodialysis patients. Inclusion criteria in this study were (A minimum of six months of dialysis, be able to communicate verbally and age above 18 years, no candidate for a kidney transplant and no history of physical stress (damage) and psychological (bereavement, grief, etc.) do not have a pacemaker, lack upper and lower limb amputation and even drugs are associated with mental. Then consent form to be filled. The patients will be randomly assigned to two groups. The questionnaire contains of demographic information and (HSS). The correlation coefficient is 97/6. The stress include (muscle cramps, fatigue, itching, joint stiffness, soreness caused by inserting the needle, nausea and diarrhea and constipation). Before the intervention of stress is recorded in both groups. Then For each experimental group, in addition to the initial meeting Two sessions will be held in private. Initially, the researcher training effleurage massage to care giver of patient. Three types of massage on the back, Two neck massage, four hand massage and four foot massage. In addition, individuals will be given booklets. Each training session is 30 minutes. Therapeutic massage is a total of 12 sessions (each session twenty minutes) And one hour before bedtime is planned. No intervention for patients in the control group. Complete and delivery the questionnaire (HSS) by two group patients during a 4-week. Exclusion criteria unwillingness to continue the experimental, use of drugs affecting mental illness, and hospitalization for any reason, surgery and infection in the study. Data were analyzed using SPSS software with Mann-Whitney, Chi-square, Friedman and sign test. The significance level was (0/05)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121520326N1**

Registration date: **2015-01-08, 1393/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-08, 1393/10/18

Registrant information

Name

Mahdieh Arian

Name of organization / entity

North Khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 6909

Email address

m.arian@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

North Khorasan University of Medical Sciences Assistance
Research of North Khorasan University of Medical
Sciences

Expected recruitment start date

2013-02-28, 1391/12/10

Expected recruitment end date

2013-05-17, 1392/02/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of Effleurage Massage on Intensity of physiological stress associated with the treatment in hemodialysis patients

Public title
Effects of Effleurage Massage on physiological stress in hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: at least six months of dialysis; ability to communicate verbally; age over 18 years old; not being candidate for a kidney transplant; no history of physical stress (damage) and psychological (bereavement, grief, etc.); not having pacemaker; no amputation in lower or upper extremities; not taking psychiatric treatment medications. Exclusion criteria: unwillingness to continue in the study; use of drugs affecting mental illness, admission in hospital for any reason; surgery and infection during the study

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **41**

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

North Khorasan University of Medical Sciences,
Bojnurd,Iran

Street address

Building of the Central of north khorasan univesity of
medical sciences

City

Bojnurd

Postal code

Approval date
2013-03-05, 1391/12/15

Ethics committee reference number
584/91/پ

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

physiological stress

Timepoint

each week for 4 weeks

Method of measurement

questionnaire Hemodialys is Stress Scale(HSS)

Secondary outcomes

1

Description

muscle cramps, fatigue, itching, joint stiffness, soreness caused by inserting the needle, nausea and diarrhea and constipation

Timepoint

each week for 4 weeks

Method of measurement

questionnaire Hemodialys is Stress Scale(HSS).

Intervention groups

1

Description

Inclusion criteria in this study were (A minimum of six months of dialysis, be able to communicate verbally and age above 18 years, no candidate for a kidney transplant and no history of physical stress (damage) and psychological (bereavement, grief, etc.) do not have a pacemaker, lack upper and lower limb amputation and even drugs are associated with mental . Then consent form to be filled. 20 cases of patients who have conditions of entry will be randomly selected. Then, in a briefing before the intervention demographic and (HSS) questionnaire will be completed. For each experimental group, in addition to the initial meetingTwo sessions will be held in private. Initially, the researcher training effleurage massage to care giver of patient.Three types of massage on the back ,Two neck massage, four hand

massage and four foot massage. In addition, individuals will be given booklets. Each training session is 30 minutes. Therapeutic massage is a total of 12 sessions (each session twenty minutes) And one hour before bedtime is planned. Complete and delivery the questionnaire (HSS) by patients during a 4-week . Exclusion criteria unwillingness to continue the experimental ,use of drugs affecting mental illness, and hospitalization for any reason, surgery and infection in the study

Category

Other

2

Description

Inclusion criteria in this study were (A minimum of six months of dialysis, be able to communicate verbally and age above 18 years, no candidate for a kidney transplant and no history of physical stress (damage) and psychological (bereavement, grief, etc.) do not have a pacemaker, lack upper and lower limb amputation and even drugs are associated with mental . Then consent form to be filled. 21 cases of patients who have conditions of entry will be randomly selected. Then, in a briefing before the intervention demographic and (HSS) questionnaire will be completed. No intervention for patients in the control group. Complete and delivery the questionnaire (HSS) by patients during a 4-week . Exclusion criteria unwillingness to continue the experimental ,use of drugs affecting mental illness, and hospitalization for any reason, surgery and infection in the study

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospitalin

Full name of responsible person

Street address

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

north khorasan univesity of medical sciences

Full name of responsible person

mahdi bakhshabadi

Street address

Building of the Central of north khorasan univesity of medical sciences, Dolat Bulvar, Bojnoord, north khorasan,Iran

City

bojnurd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

north khorasan univesity of medical sciences

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

North Khorasan University of Medical Sciences

Full name of responsible person

Mahdieh Arian

Position

Faculty member

Other areas of specialty/work

Street address

Building of the Central of north khorasan univesity of medical sciences, Dolat Bulvar, Bojnoord, north khorasan,Iran

City

Bojnurd

Postal code

Phone

+98 58 3226 9909

Fax

Email

m.arian@nkums.ac.ir; arianyem@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

North Khorasan University of Medical Sciences

Full name of responsible person

Mahdieh Arian

Position

Faculty member

Other areas of specialty/work

Street address

Building of the Central of north khorasan univesity of medical sciences, Dolat Bulvar, Bojnoord, north khorasan,Iran

City

Bojnord

Postal code

Phone

+98 58 3229 6909

Fax**Email**

m.arian@nkums.ac.ir; arianyem@gmail.com

Web page address**Phone**

+98 58 3229 6909

Fax**Email**

m.arian@nkums.ac.ir; arianyem@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

North Khorasan University of Medical Sciences

Full name of responsible person

Mahdieh Arian

Position

Faculty member

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

Building of the Central of north khorasan univesity of
medical sciences, Dolat Bulvar, Bojnoord, north
khorasan,Iran

City

Bojnurd

Postal code**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