

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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 university 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 Hemodialysis 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 Hemodialysis 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 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. 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, Bojnord, 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  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

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

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medical sciences, Dolat Bulvar, Bojnoord, north  
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**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*