Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of acupressure on anxiety, fatigue and blood pressure in patients undergoing hemodialysis

Protocol summary

Study aim
The effect of acupressure on anxiety, fatigue and blood pressure in patients undergoing hemodialysis

Design
In this study, it is a randomized controlled clinical trial with a before-and-after design, among the patients undergoing hemodialysis who meet the inclusion criteria, 105 people will be selected by random permutation blocks and will be divided into three acupressure groups. 35 people), sham (35 people) and control (35 people) points will be placed.

Settings and conduct
The location of the study is the 9-day Torbet Heydarieh hospital and the dialysis clinic of the city. The Spielberger anxiety and fatigue questionnaire is filled before and after the intervention, then it is filled again one month after the intervention. The blood pressure of the patients is also recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria : - At least 18 years old - Dialysis treatment for at least 6 months - Perform dialysis at least 2 times a week and each time for 3-4 hours - Absence of contraindications to acupressure - Listening and speaking ability - Not taking sedatives such as benzodiazepines - Willingness to cooperate in the study Exit criteria - Performing kidney transplant or peritoneal dialysis during research - Suffering from hemodynamic complications in most dialysis sessions - Unwillingness to continue cooperation in the study

Intervention groups
Acupressure group massage is performed at the specified points at the beginning of dialysis that does not interfere with the patient's dialysis. Sham points group will receive acupressure on false points where applying pressure has no soothing effect. The control group will not have any intervention on the patients.

Main outcome variables
Reducing patients' anxiety, reducing fatigue and controlling blood pressure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221223056899N1**
Registration date: **2022-12-28, 1401/10/07**
Registration timing: **prospective**

Last update: **2022-12-28, 1401/10/07**
Update count: **0**

Registration date
2022-12-28, 1401/10/07

Registrant information
Name
toktam soleimani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5223 9677
Email address
soleimanitoktam1374@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-20, 1401/12/01
Expected recruitment end date
2023-03-21, 1402/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of acupressure on anxiety, fatigue and blood pressure in patients undergoing hemodialysis

Public title

The effect of acupressure on anxiety, fatigue and blood pressure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Dialysis at least 2 times a week and each time for 3-4 hours Dialysis treatment for at least 6 months willingness to cooperate in the study no use of sedatives such as benzodiazepines Hearing ability and speech No limb amputation or wound at the place of massage No contraindications to acupressure Age at least 18 years

Exclusion criteria:

Hospitalization of the patient during intervention Suffering from hemodynamic complications in most dialysis sessions The occurrence of a severe stressful event, such as the death of a first-degree relative Travel or death of the patient Unwillingness to continue cooperation in the study Performing kidney transplant or peritoneal dialysis during research

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

All sample people are divided into three equal groups by simple random method. First, 105 cards (the same as the sample size) will be prepared. Then, one of the letters A, B or C will be written on each card. These cards will be placed inside a box so that nobody can see the cards inside the box. After the researcher shuffles the cards, the patients are asked to randomly pick a card from the box (the selected cards are not returned to the box after selection). In this way, people are placed in three groups of 35 people A, B and C. In this way, three cards are prepared and one of the numbers 1, 2 and 3 will be written on each card. Number 1, 2 and 3 will belong to intervention, sham and control respectively. These cards are placed in a box and after mixing, the researcher will randomly select one card for each group (the selected cards will not return to the box after selection).

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients are divided into three intervention groups, sham points and control. The patients of the intervention group receive acupressure in real points and sham acupressure spheres in false points. The patients do not know the exact location of the points. In this study, the researcher's help in completing All questionnaires will be used for blinding and to prevent bias in the results. In this way, the researcher's help will be unaware of the groupings and the type of interventions that are carried out in each group and by each person.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

No.24,Ghaem29/1 Ave

City

Torbat-Heydariyeh

Province

Razavi Khorasan

Postal code

9518656667

Approval date

2022-03-09, 1400/12/18

Ethics committee reference number

IR.BUMS.REC.1400.443

Health conditions studied

1

Description of health condition studied

Renal failure

ICD-10 code

N17-N19

ICD-10 code description

Primary outcomes

1

Description

Reducing the level of anxiety

Timepoint

Before the start of the intervention, after the end of the intervention and one month after the end of the intervention

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

1

Description
Reducing the fatigue level of hemodialysis patients
Timepoint
Before and after the intervention
Method of measurement
Paper fatigue questionnaire

Intervention groups

1

Description
The patients of acupressure group are massaged at PC6 or Nei Guan points, GV 20 and ST36 (both legs) in total (9 points) by the thumb pulp of the therapist's hand and at the beginning of dialysis, which does not interfere with the patient's dialysis. The pressure level is 3 to 4 kg for 10 minutes. It will be done three times a week for 4 weeks. Follow-up is also done in the dialysis sessions, which the patient is definitely present.
Category
Treatment - Other

2

Description
Control group: Sham points group patients will receive acupressure on false points where applying pressure does not have any soothing effect, in the form of massage on two SP9 points that are inside the leg at the junction of the tibial shaft and the tibial condyle in a depression (to instead of ST36) and point CV24, which is exactly between the chin and lower lip on the front midline of the body in the middle of the distance between lip and chin (instead of GV20) and point SP6 (instead of LV3) and point KI27 (instead of GB 20) and point TW 6 (instead of PC6) will be performed by the therapist's thumb pulp with a pressure of 3 to 4 kg for 10 minutes three times a week for 4 weeks.
Category
Treatment - Other

3

Description
Control group: In the control group, no intervention will be performed on the patients.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
9th Day Hospital and Dialysis Clinic
Full name of responsible person
Toktam Soleimani
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No.24,Ghaem29/1Ave
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Email
soleimanitoktam1374@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Ahmad Nasiri
Street address
Ghafari Ave.Birjand University of Medical Sciences, Faculty of Nursing and Midwifery
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Province
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9717853577
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nasiri2006@bums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Toktam Soleimani
Position
Nurse
Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

1400

To whom data/document is available

Toktam Soleimani

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

Toktam Soleimani

What processes are involved for a request to access data/document

Through email, which takes a month.

Comments