

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The assessment of effect of the Emotional Freedom Technique on fatigue, anxiety and symptoms burden of patients under hemodialysis

#### Protocol summary

##### Study aim

Determining the effect of the Emotional Freedom Techniques on fatigue, anxiety and symptoms burden of patients under hemodialysis

##### Design

Randomized controlled trial, double blind, parallel group, systematic sampling, 100 patients

##### Settings and conduct

The research environment is the hemodialysis center of Shiraz Imam Reza clinic. Informed and written consent is obtained from the participants. In the intervention, the participants are taught a series of positive and negative sentences to say three times and each time after saying a positive or negative sentence, hit certain points of the body seven times. Participants of both groups receive routine medical care. The participants, the data collector and the data analyst are blinded to the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 years and older, At least 6 months have passed since the start of hemodialysis, Perform hemodialysis 2 to 4 times a week, Ability to understand and speak Farsi language. Exclusion criteria: The existence of a known chronic mental illness (confirmed by the attending physician), A patient with retinopathy.

##### Intervention groups

After allocating the participants in the intervention and control groups, they will complete the questionnaires. During a short interview with the intervention group, unpleasant factors that caused them discomfort are identified. Then, the intervention group is encouraged to focus on these unpleasant factors and perform Emotional Freedom Techniques. This technique will be performed by the participants for 4 weeks and 3 days per week (once a day).

##### Main outcome variables

Fatigue: Anxiety: Symptom Burden

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191021045178N5**

Registration date: **2024-02-29, 1402/12/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-29, 1402/12/10**

Update count: **0**

##### Registration date

2024-02-29, 1402/12/10

##### Registrant information

##### Name

Nilofar Pasyar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3623 6293

##### Email address

pasyarn@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-24, 1402/12/05

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The assessment of effect of the Emotional Freedom Technique on fatigue, anxiety and symptoms burden of patients under hemodialysis

#### Public title

The effect of the Emotional Freedom Techniques on fatigue, anxiety and symptoms burden of patients under hemodialysis

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient with an 18 - year - old and more at least 6 months since the dialysis started Doing hemodialysis 2 to 4 times at week. The ability to understand and speak persian

##### Exclusion criteria:

The presence of chronic mental illness known by a physician's diagnosis A patient suffering from retinopathy

#### Age

From 18 years old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: 100

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

For blinding in this study, The participants are unaware of the characteristics of the study groups. Data collection and completion of questions will be conducted by the first research assistant who does not know about the division of groups. It is also the statistician who does data analysis as blind to groups.

#### Placebo

Not used

#### Assignment

Other

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Moral Committee of shiraz Medical science

university

#### Street address

Vice Chancellor for Research, 7th floor, Shiraz University of Medical Science, Zand st.

#### City

shiraz

#### Province

Fars

#### Postal code

7134814336

#### Approval date

2024-02-04, 1402/11/15

#### Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.132

## Health conditions studied

### 1

#### Description of health condition studied

Kidney dialysis

#### ICD-10 code

Y84.1

#### ICD-10 code description

Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

## Primary outcomes

### 1

#### Description

Anxiety scores in Spielberger's state-trait anxiety questionnaire

#### Timepoint

Before the intervention and four weeks after an intervention (Emotional Freedom Techniques)

#### Method of measurement

Spielberger state- trait anxiety inventory

### 2

#### Description

Fatigue scores on the Multidimensional Fatigue Inventory

#### Timepoint

Before the intervention and four weeks after an intervention (Emotional Freedom Techniques)

#### Method of measurement

Multidimensional Fatigue Inventory

### 3

#### Description

Physical and mental symptom burden score in dialysis Symptoms burden Index questionnaire

#### Timepoint

Before the intervention and four weeks after an intervention (Emotional Freedom Techniques)

#### Method of measurement

Dialysis Symptoms burden Index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After Informed consent and completing the questions by the intervention group, in a short interview with the patient, it is clear that the situation has caused unhappiness. Then with an unpleasant concentration, a series of positive and negative words are introduced to the patient in order to comfort themselves by those words. In our first phase in the intervention group, we want patients to say the positive and negative tree times like, (I'm always nervous about being dependent on the dialysis device, but I accept myself as I am) and every time they says that, with the top of the middle finger hit to the karate chop point in the other hand Gently 7 times , so that the dominant hand might bend over the wrist. At the next stage they said negative words (I'm always nervous about being dependent on the dialysis device) and hit to the meridian points Including: the top of head, the beginning of the eyebrows, side of the eyes, under the eyes, the distance between the nose and upper lip, the chin, under the clavicle and armpit 7 times. next they said positive words (I accept myself as I am) and again they hit every point 7 times. This technique goes on for 4 weeks and every week for three days. The people in the control group only receive normal medical care.

#### Category

Behavior

### 2

#### Description

Control group: After informed consent and completing the questionnaires, participants in the control group will receive only routine medical care.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Day and Night Clinic

##### Full name of responsible person

fatemeh parvizi

##### Street address

Rehmat Blvd., Serah Darul Rahma, Imam Reza Day and Night Clinic

##### City

shiraz

##### Province

Fars

##### Postal code

7165944639

##### Phone

+98 71 3735 5853

##### Email

npasyar@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

mohammad hashem hashempur

##### Street address

خیابان زند، ساختمان مرکزی دانشگاه علوم پزشکی شیراز، طبقه هفتم، معاونت تحقیقات و فناوری

##### City

shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3212 2430

##### Email

vcrdep@sums.ac.ir

##### Grant name

##### Grant code / Reference number

29224

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

Yes

##### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Nilofar pasyar

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursing Education

##### Street address

Shiraz, Namazi Square, the entrance to Namazi Hospital, Hazrat Fatemeh College of Nursing and Midwifery.

**City**

shiraz

**Province**

Fars

**Postal code**

13119-71936

**Phone**

+98 71 3647 4254

**Email**

npasyar@sums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Nilofar pasyar

**Position**

Associate professor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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13119-71936

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+98 71 3647 4254

**Email**

Npasyar@sums.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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available