

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Effect of humor therapy on fatigue and anxiety in hemodialysis patients

#### Protocol summary

##### Study aim

The aim of this study is determination the effects of humor therapy on fatigue and anxiety in hemodialysis patients.

##### Design

In this research, 62 eligible patients referring to Vasei dialysis center were chosen purposefully and were randomly divided into two groups of control and intervention. Due to the characteristics of the study intervention, blinding and allocation concealment are not applicable for this study.

##### Settings and conduct

Study population consist of all 120 dialysis patients who referee in 2018 to Vasei hospital, Sabzevar, Iran. Due to the characteristics of the study intervention, blinding and allocation concealment are not applicable for this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 18 to 65 years; History of hemodialysis more than 6 months; Patients with dialysis charts in the hemodialysis centers and regular referring to the centers; Absent of disability or chronic disease. Exclusion criteria: Reluctance to continue participating in the Intervention; Presence of disability or chronic disease, Except diabetes or hypertension; Dieing the patient; Kidney transplant; Death

##### Intervention groups

Patients in the experimental group will attend in humor therapy sessions twice a week for a month (a total of 8 sessions). sessions will be held with the three methods; comedy clip, jokes and the fun games. The control group will be received routine care.

##### Main outcome variables

fatigue, anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131113015393N4**

Registration date: **2019-01-01, 1397/10/11**

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

Last update: **2019-01-01, 1397/10/11**

Update count: **0**

##### Registration date

2019-01-01, 1397/10/11

##### Registrant information

###### Name

Narjes Heshmati Far

###### Name of organization / entity

Sabzevar University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 57 1444 6070

###### Email address

nheshmatifar@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of humor therapy on fatigue and anxiety in hemodialysis patients

##### Public title

Effect of humor therapy on fatigue and anxiety in hemodialysis

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Aged between 18 to 65 years  
History of hemodialysis more than 6 months  
Hemodialysis three times a week  
Patients with dialysis charts in the hemodialysis centers and regular referring to the centers  
Absent of disability or chronic disease

### **Exclusion criteria:**

Recruited patients exclude if they voluntarily chose to withdraw from the study  
patients exclude if they incompletely filled out study questionnaire  
patients exclude if they hospitalized in hospital  
patients exclude if they underwent kidney transplant surgery during the study.

## **Age**

From **18 years** old to **65 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **62**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Patients receive dialysis either in odd or even days of the week, select in this study. In order to prevent the leakage of peer education information from the intervention group to the control group, patients who receive dialysis in even days randomly allocate to the intervention group, while patients who receive dialysis in the odd days randomly allocate to the control group. Random allocation do via the coin tossing method by a nurse who is external to the study. Sampling do randomly in the following steps. Initially, the name of each patient who receive dialysis in even days write on a card. Then, all cards mix and place in a bag. After that, one card randomly draw from the bag and the intended patient recruit to the intervention group. The card then return to the bag and a new card select for the next patient. The same process repeat until the determined number of patients recruit. Patients for the control group also recruit through the same process. Due to the characteristics of the study intervention, blinding and allocation concealment not applicable for this study.

## **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**

Sabzevar University of Medical Sciences

##### **Street address**

School of Nursing and Midwifery; Shohadaye Hasteii Boulevard, Sabzevar

##### **City**

Sabzevar

##### **Province**

Razavi Khorasan

##### **Postal code**

9617913112

#### **Approval date**

2018-11-20, 1397/08/29

#### **Ethics committee reference number**

IR.MEDSAB.REC.1397.063

## **Health conditions studied**

### 1

#### **Description of health condition studied**

End stage renal failure

#### **ICD-10 code**

N18.9

#### **ICD-10 code description**

Chronic kidney disease, unspecified

## **Primary outcomes**

### 1

#### **Description**

Fatigue and anxiety in hemodialysis patients

#### **Timepoint**

before and 4 week after intervention

#### **Method of measurement**

Fatigue severity scale (FSS) and Spillberger's anxiety scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: humor therapy is a type of Complementary and alternative treatments. Three methods of treatment in the intervention group are comedy clips, fun games with awards and jokes, each session will be lasted 60 minutes twice a week for 4 weeks

#### **Category**

Behavior

## 2

### Description

Control group: The control group will receive usual care.

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sabzevar Vasei hospital

##### Full name of responsible person

Mehran Hosseini

##### Street address

Shohadaye Hasteii Boulevard, Sabzevar Vasei hospital

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

##### Phone

+98 51 4465 1300

##### Email

nheshmatifar@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mohsen Koshan

##### Street address

Sabzevar University of Medical Sciences

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

##### Phone

+98 51 4401 1000

##### Email

mkoushan@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

##### Full name of responsible person

Narjes Heshmatifar

##### Position

Faculty member of Sabzevar University

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

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## Person responsible for scientific inquiries

#### Contact

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Sabzevar University of Medical Sciences

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## Person responsible for updating data

nheshmatifar@yahoo.com

### Contact

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Sabzevar University of Medical Sciences

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Narjes Heshmati Far

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Boulevard, Sabzevar

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+98 51 4401 1000

**Email**

## 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