Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial the effectiveness of positive thinking training on the hope and adherence in hemodialysis patients

Protocol summary

Study aim
To determine the effect of positive thinking training on the hope and adherencein hemodialysis patients

Design
The study uses an interventional randomized pre-test and post-test design with control group.

Settings and conduct
80 patients referred to hemodialysis departments of Shiraz Namazi and Shahid Faghihi Hospitals are selected by simple random sampling method. They are then divided into two groups of intervention and control by simple random method. The intervention consists of 8 sessions of positive thinking, and the control group does not receive any intervention. Before, immediately and two months after the end of the intervention, both groups will complete hope and adherence to treatment questionnaires. Also, the laboratory values and the weight difference of two successive sessions of dialysis will be measured before and 2 months after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Reading and writing literacy; Ability to speak and understand Persian; Age 18 to 65 years old; Being under hemodialysis two or three times a week
Exclusion criteria: History of psychological disorders (severe depression, psychosis, bipolar disorder), Having angina pectoris and unstable hypertension; Having heart and Hepatic failure;Being under ventilator during the study; Participating in the educational classes and psychological interventions simultaneously

Intervention groups
Intervention group: will receive positive thinking training in 8 sessions each lasting 30 minutes. Control group: will receive routine care of hemodialysis unit, without any intervention.

Main outcome variables
Improvement in hope and adherence to treatment in patients

General information

Reason for update

Acronym
PHAH

IRCT registration information
IRCT registration number: **IRCT20180915041044N1**
Registration date: **2018-12-19, 1397/09/28**
Registration timing: **prospective**

Last update: **2018-12-19, 1397/09/28**
Update count: **0**

Registration date
2018-12-19, 1397/09/28

Registrant information

Name
Fatemeh Sabouri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3229 7396

Email address
sabouri@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-10, 1397/10/20

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
Clinical trial the effectiveness of positive thinking training on the hope and adherence in hemodialysis patients

Public title
The effect of positive thinking training on the hope and adherence in hemodialysis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Reading and writing literacy Ability to speak and understand Persian language Age 18 to 65 years old A definitive diagnosis of chronic renal failure by nephrologist Being under hemodialysis two or three times a week Awareness to time, person and place

Exclusion criteria:
History of known psychological disorders (severe depression, psychosis, bipolar disorder) Having angina pectoris and unstable hypertension Having heart and hepatic failure Having acute myocardial infarction Being under ventilator during the study Participating in the educational classes and psychological interventions simultaneously

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

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
After providing explanations about the goals of the research and obtaining informed consent, 80 patients undergoing hemodialysis will be selected with a simple random sampling method. Then they are divided into the experimental and control groups by simple randomization method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blinding, the person collecting the questionnaires and also statistical specialist who performs data analysis,don't have any information about subjects in experimental and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Central Building of the University of Medical sciences, Zand Ave, Shiraz,Iran

City
shiraz

Province
Fars

Postal code
0098713451978

Approval date
2018-11-13, 1397/08/22

Ethics committee reference number
IR.SUMS.REC.1397.704

Health conditions studied

1

Description of health condition studied
Extracorporeal dialysis

ICD-10 code
Z99.2

ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
hope

Timepoint
before intervention, immediately after, and two months after the end of the intervention

Method of measurement
Adult Hope Scale

2

Description
adherence to treatment

Timepoint
Before intervention, immediately after, and two months after the end of the intervention

Method of measurement
adherence to treatment questionnaire, weight measurement, lab data

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Intervention group will receive positive thinking training in 8 sessions.each session lasts 30 minutes.intervention will be done individually and during hemodialysis.
Category
Behavior

2

Description
Control group: The control group will receive routine cares of hemodialysis unit, without intervention.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
hemodialysis units of Namazi and Faghihi hospitals
Full name of responsible person
Fatemeh Sabouri
Street address
Namazi Square, Zand Av.
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3647 4254
Email
sabouri@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Zand Av.
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3230 5410
Email
ghasemiy@sums.ac.ir
Grant name
Grant code / Reference number
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
Fatemeh Sabouri
Position
MSc Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Namazi Square, Zand Av.
City
Shiraz
Province
Fars
Postal code
713451978
Phone
+98 71 3647 4254
Email
sabouri@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Khademian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Namazi Square, Zand Av.

City
Shiraz
Province
Fars
Postal code
713251978
Phone
+98 71 3647 4254
Email
zahrakhademian@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Sabouri
Position
MSc student in nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Namazi Square, Zand Av.
City
Shiraz
Province
Fars
Postal code
713451978
Phone
+98 71 3647 4254
Email
sabouri@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
After completion of the study, if necessary, the encoded data will be published along with the article.
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
Yes - There is 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
Title and more details about the data/document
Abstract and references
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
Academic Researchers and Academic Institutes
Under which criteria data/document could be used
When referring to this research, mention the name of the researchers.
From where data/document is obtainable
Mailing address, or email address, and phone number, Fatemeh Sabouri
What processes are involved for a request to access data/document
First, the applicant requests via email or telephone. It will be answered on demand within 2 months.
Comments
Please email as much as possible.