

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 adherence in 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.

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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

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+98 71 3230 5410

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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

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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

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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
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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.