

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of positive thinking training on stress, anxiety, depression and quality of life of hemodialysis patients: A randomized controlled clinical trial

Protocol summary

Study aim

Due to the fact that not much research has been done on the effect of psychological interventions including stress, anxiety and depression on these patients, and in order to improve the effectiveness of therapeutic interventions in these patients, this study was the first to examine the effect of positive training on stress, anxiety, depression and the quality of life of patients undergoing hemodialysis.

Design

The present study is a randomized controlled trial of clinical trials. The statistical population of this study will include hemodialysis patients. Based on the sample size formula and according to similar studies, at least 68 people (34 people in each group) were estimated, which will increase to 78 people (39 people in each group) considering the 10% probability of sample loss. Was. A randomized block method of size 4 was used for randomization.

Settings and conduct

The positive education program is based on research and positive intervention programs, as well as internal and external studies in the field of positivism education. The time and place of the classes will be announced in advance to the patient, then the trainings will be scheduled by a clinical psychologist for 8 sessions. Each session will last 90 minutes. Training sessions will be in the form of lectures, group discussions, and answers.

Participants/Inclusion and exclusion criteria

Patients with chronic renal failure who are undergoing hemodialysis may not be treated with psychedelics at the same time.

Intervention groups

The positive training program was held in the form of 8 sessions of 90-minute and 2 sessions per week. One week after the end of the intervention, quality of life

questionnaires are completed by participants in both groups. The control group did not receive any training during the research.

Main outcome variables

Quality of life: stress: anxiety: depression

General information

Reason for update

Acronym

PTTSADQOL

IRCT registration information

IRCT registration number: **IRCT20200514047435N1**

Registration date: **2020-05-19, 1399/02/30**

Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**

Update count: **0**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

shima sheidaie

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 5331 9374

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of positive thinking training on stress, anxiety, depression and quality of life of hemodialysis patients: A randomized controlled clinical trial

Public title
positive thinking training on stress, anxiety, depression and quality of life of hemodialysis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
willingness to participate in the study age 18-70 years
end-stage renal disease and under hemodialysis a
history of hemodialysis for at least 12 months or more
lack of participation in other training courses at the same time
Exclusion criteria:
history of participate in positive thinking training
treatment with psychotropic drugs

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Four-dimensional block randomization In this way, two patients from the intervention group and two patients from the control group are numbered in the four blocks and randomly assigned to the intervention and control groups, and this is done until all the blocks are finished.

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
Shiraz University of Medical Sciences Ethics Committee
Street address
Namazi Square, zand street
City
fasa
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸

Approval date
2020-04-27, 1399/02/08

Ethics committee reference number
IR.SUMS.REC.1399.133

Health conditions studied

1

Description of health condition studied
Quality of life, Stress, anxiety and depression of hemodialysis patients

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Stress score based on dass-21 questionnaire

Timepoint
One week after the intervention

Method of measurement
dass-21 questionnaire

2

Description
depression score based on dass-21 questionnaire

Timepoint
One week after the intervention

Method of measurement
dass-21 questionnaire

3

Description
anxiety score based on dass-21 questionnaire

Timepoint
One week after the intervention

Method of measurement
dass-21 questionnaire

4

Description

Quality of life based on QOL-sf36 questionnaire

Timepoint

One week after the end of the intervention

Method of measurement

SF-36 Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Positive training program was developed based on research and positive intervention programs, as well as internal and external studies in the field of positive education. The positive training program was held in the form of 8 sessions of 90-minute and 2 sessions per week. The main topics included familiarity with the meaning of positive thinking, positive and negative thinking and the role of emotions in relationships with others, awareness of one's abilities, familiarity with relaxation techniques and attention to one's strengths, as well as ability to control one's inner and outer control in dealing with problems. The control group did not receive any training during the research, but after completing it, in order to observe the principles of ethics in research, they were taught positive thinking content in the form of a 2-day workshop. To hold the workshops, the intervention groups were divided into smaller groups of 7 people. The training sessions were held by a clinical psychologist through lectures, discussions and group participation, modeling and role-playing, intellectual challenge, staging and homework; at the end of each session, the participants' questions were answered and the next sessions commenced with a review of the topics of the previous session. Multimedia facilities such as computers, videos, and software players (PowerPoint) were used to provide training and prevent tiredness in the participants; also, catering and short breaks were used. One week after the end of the intervention, stress, anxiety, depression, and quality of life questionnaires were filled out by the participants in both groups.

Category

N/A

2**Description**

Control group: There is no intervention on them.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Valiasr and Shariati Hemodialysis Center

Full name of responsible person

Mehdi Amirkhani

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Ibn Sina Square

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7451297420

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Nasrallah Teymouri

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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

60

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**

Fasa University of Medical Sciences

Full name of responsible person

Shima Sheidaie

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shima Sheidaie

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shima Sheidaie

Position

پرستار

Latest degree

Master

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

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