Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of resilience Training on the Quality of Life, Depression, Stress and Anxiety in Hemodialysis patients

Protocol summary

Study aim
Investigating the effect of resilience training on stress, anxiety, depression and quality of life of hemodialysis patients

Design
Study using pre-test-post-test method with control group

Settings and conduct
Due to the prevalence of depressive disorders, anxiety and stress in hemodialysis patients and the need for minimally invasive interventions, including training in these patients, this study is a group resilience training on the intervention group and pre-test and post-test with the control group on Fars-Fasa hemodialysis patients will be performed.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the study were as follow: 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, no history of resilience training, and lack of treatement with psychotropic drugs. Patients who refused to continue their participation for any reason or were absent for more than two sessions were excluded

Intervention groups
In this study, resilience training intervention group is held in the form of 12 sessions of 90 minutes and two sessions per week by a clinical psychologist. Both pre- and post-test interventions are performed before and after the intervention. There is no intervention on the control group, and only at the end of the study, a two-day workshop will be held to observe ethical principles.

Main outcome variables
Stress؛ Anxiety؛ Depression؛ quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200414047074N1**
Registration date: **2020-05-27, 1399/03/07**
Registration timing: **retrospective**

Last update: **2020-05-27, 1399/03/07**
Update count: **0**

Registration date
2020-05-27, 1399/03/07

Registrant information

Name
Mehdi Amirkhani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 71 5333 3541

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-06, 1399/02/17

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of resilience Training on the Quality of Life, Depression, Stress and Anxiety in Hemodialysis patients

Public title

The Effect of resilience Training on the Quality of Life, Depression, Stress and Anxiety in Hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

age under 70 years at least 12 months history of hemodialysis no mental and physical problems non-attending similar training classes

Exclusion criteria:

Patient dissatisfaction

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method In this study, the quadratic blocking method with a size of four was used in such a way that "training and control groups were named in groups A and B, each participant was given a short code," and two people were randomly assigned each time. Group A Two members of Group B are assigned to the four blocks, this continues until all participants are assigned to the blocks.

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

ZAND

City

SHIRAZ

Province

Fars

Postal code

6461797411

Approval date

2020-04-30, 1399/02/11

Ethics committee reference number

IR.SUMS.REC.1399.132

Health conditions studied

1

Description of health condition studied

Educational effectiveness

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

QUALITY OF LIFE

Timepoint

One week after training

Method of measurement

QUESTIONER

Secondary outcomes

empty

Intervention groups

1

Description

In order to develop a resilience education program, we reviewed research and resilience enhancement programs that had previously been conducted for different groups, as well as internal and external studies on resilience(29-33). Then, it was approved by the teachers of Fars University of Medical Sciences who had academic and clinical experience in this field. The intervention group received 12 sessions of training workshops on resilience skills. 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 resilience content in the form of a 2-day workshop. To hold the workshops, the intervention groups were divided into smaller groups of 10 people. 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 beginning of the next sessions was accompanied by a review of the topics of the previous session. In order to ensure proper productivity of the training process and also to create diversity in training, the final 10% of all training sessions were used for peer training. Peer groups are better able to encourage their peers to choose appropriate health behaviors, and they are able to share strengths and weaknesses and common experiences. Peer education is

an ongoing approach in which he/she establishes a long-term friendly and intimate relationship with the patient and shares his information with him. In order to use peer education in this study, we randomly selected 3 hemodialysis patients who were not members of the participating groups. These individuals had at least one level of education with a diploma and appropriate expressiveness, had at least one year of hemodialysis experience, and according to the DASS-21 questionnaire, did not suffer from stress, anxiety and depression or were at a mild level. The training of the peers was such that in the presence of the instructor of the training program, under her supervision and guidance, they shared their experiences and strengths with the patients. Multimedia facilities such as computers, film and software players (PowerPoint) were used to provide training and to prevent tiredness in the participants; also, educational videos related to resilience, catering and short breaks were used. One week after the end of the intervention, stress, anxiety, depression, and quality of life questionnaires were completed by the participants in both groups

Category

N/A

2

Description

Control group: They take the pre-test and post-test but do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina's Hemodialysis

Full name of responsible person

SHIMA SHEIDAIE

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Fars

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۱۴۳۳۶ - ۷۱۳۴۸

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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

50

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

MEHDI AMIRKHANI

Position

STUDENT

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

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
All data except personal information is available

When the data will become available and for how long
unlimited

To whom data/document is available
unlimited

Under which criteria data/document could be used
EDUCATIONAL

From where data/document is obtainable
executor of plan Mehdi Amirkhani
m.amir2006@yahoo.com

What processes are involved for a request to access data/document
Send to the executor via e-mail address and receive a reply

Comments