Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of cognitive-behavioral therapy intervention on hope and fear of death in patients under hemodialysis

Protocol summary

Study aim
Determining the effect of cognitive-behavioral therapy on hope and fear of death in patients under hemodialysis

Design
In this randomized clinical trial, 84 included patients under hemodialysis, will be allocated into two groups of intervention and control, using stratified-block randomization sampling method.

Settings and conduct
84 included patients under hemodialysis, referring to hemodialysis centers in Ilam, will be allocated into two groups of intervention and control. At the beginning of the study, all subjects of the two groups will be asked to complete the research questionnaires including: demographic information, Herth's hope questionnaire, and the Templer's death anxiety scale. Then, for the intervention group, the cognitive-behavioral therapies will be performed in eight one-hour weekly sessions. The control group would not receive any intervention from the researcher. After completing the intervention, Herth's and Templer's questionnaires will be completed for both group and the results will be compared with each other.

Participants/Inclusion and exclusion criteria
Entry conditions: being alert; under hemodialysis; willingness to participate in the study No entry conditions: history of known mental disorders; history of taking any kind of psychiatric medication; history of unsuccessful kidney transplantation

Intervention groups
Intervention group: receiving cognitive-behavioral therapy for eight one-hour weekly sessions Control group: does not receive any intervention from the researcher

Main outcome variables
Fear of death; hope

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170514033961N3**
Registration date: **2018-01-08, 1396/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-08, 1396/10/18**
Update count: **1**

Registration date
2018-01-08, 1396/10/18

Registrant information

Name
Mandana Saki

Name of organization / entity
Lorestan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 66 3331 6465

Email address
m.saki@modares.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research and technology, Lorestan University of Medical Sciences

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2018-01-21, 1396/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effectiveness of cognitive-behavioral therapy intervention on hope and fear of death in patients under hemodialysis

Public title
The effect of cognitive-behavioral therapy on hope and fear of death

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
would be under hemodialysis treatment and would be willinig to participate in the study would be alert
Exclusion criteria:
Have a history of taking any kind of psychiatric medication Have a history of known mental disorders such as mental retardation, Alzheimer's disease, depression, psychosis, suicidal thoughts or history of suicide attempt Have a history of unsuccessful kidney transplantation

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples with inclusion criteria based on stratified-block randomization will be allocated into two groups of intervention group (cognitive-behavioral therapy) and control group (without any additional intervention by researcher)

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
Ethics committee of Lorestan University of Medical Sciences

Street address
Vice chancellor for research and technology, Lorestan University of Medical Sciences, Pardis Campus, Khorramabad-Boroujerd Road, Khorramabad, Lorestan

City
Khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2017-09-11, 1396/06/20

Ethics committee reference number
LUMS.REC.1396.299

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Fear of death score in Templar’s death anxiety scale

Timepoint
At the beginning of the study (before the intervention) and one week after the completion of cognitive-behavioral therapy sessions

Method of measurement
Templar’s death anxiety scale

2

Description
Hope score in Herth’s hope questionnaire

Timepoint
At the beginning of the study (before the intervention) and one week after the completion of cognitive-behavioral therapy sessions

Method of measurement
Herth’s hope questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group, after completion of the research questionnaires, will receive cognitive-behavioral

therapies for eight sessions, one hour per week and then will complete the questionnaires one week after the intervention.

Category

Rehabilitation

2

Description

Control group: Individuals in this group would not receive any intervention from the researcher and they only will complete the research questionnaires at the beginning and end of the research

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital; Rasool Akram Hospital; Valiasr Hospital; Shohada Hospital

Full name of responsible person

Mandana Saki

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No. 18, Rose Alley, Enghelab Avenue, Khorramabad, Lorestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Morovat Taheri Kalaani

Street address

Vice chancellor for research and technology, Lorestan University of Medical Sciences, Pardis Campus, Khorramabad-Boroujerd Road, Khorramabad, Lorestan

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mandana Saki

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position
Assistant professor

Latest degree
Ph.D.

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The total potential data will be published after unidentifying individuals in the form of information about the main outcomes.

When the data will become available and for how long
Access period will start since 2018

To whom data/document is available
All researchers, teachers, and medical students can receive the published article from the relevant journal

Under which criteria data/document could be used
Undisclosed data will be available to health science researchers for meta-analysis.

From where data/document is obtainable
Send email to Mandana Saki mandana_saki@yahoo.com

What processes are involved for a request to access data/document
After submitting the document by applicant researcher through email, the data will be sent two weeks later.

Comments