

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Cognitive Behavioral Therapy (CBT) on mental health and happiness in hemodialysis patients.

Protocol summary

Study aim

Determination and comparison of mean happiness score before and after cognitive behavioral therapy interventions in intervention group and control group .
Determining and comparing the mean score of mental health before and after cognitive behavioral therapy interventions in the intervention group and the control group.

Design

A clinical trial with two groups of intervention and control group, selecting samples based on non-phase block random sampling on 40 patients.

Settings and conduct

The interventions will be randomly selected on 40 patients in Farabi Bastak Hospital Hemodialysis Center. Related training by a trained researcher for the intervention group will be presented in 8 weekly sessions, each session of 90 minutes. The control group receives routine care.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Men and women range in age from 18 to 65 years. Minimum cycle literacy. 3 months from the beginning of hemodialysis and 2 to 3 sessions per week and 4 hours per session under hemodialysis. Exclusion Criteria have a history of hospitalization due to mental health problems.

Intervention groups

Interventions include cognitive behavioral therapy .In order to improve the effectiveness of this treatment on mental health and happiness of hemodialysis patients. According to the protocols related to the intervention group, patients will be trained in 8 weekly sessions and each session for 90 minutes and patients will be asked for assignments. The goal of treatment will be to change behavior. The control group receives routine services of hemodialysis center during the study period and there will be no intervention on this group.

Main outcome variables

The mental health score in keyes mental health

questionnaire consisted of 14 questions. The happiness score in the Oxford Happiness Questionnaire, designed by Argyle and Lou, has 29 questions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048729N1**

Registration date: **2020-09-27, 1399/07/06**

Registration timing: **prospective**

Last update: **2020-09-27, 1399/07/06**

Update count: **0**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

Faeqheh Paravar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Cognitive Behavioral Therapy (CBT) on mental health and happiness in hemodialysis patients.

Public title
Impact of Cognitive Behavioral Therapy (CBT) on hemodialysis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 At least 3 months have passed since the onset of hemodialysis. No use of psychological drugs by patients. Patients undergo hemodialysis for 2 or 3 weekly sessions and each session for 4 hours.
Exclusion criteria:
 Patients have a history of hospitalization due to psychological problems.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
 The subjects will be randomly divided into two groups of intervention and control group, each group will be 20 patients. The subjects were randomly divided into two groups of intervention and control. Letter A is assigned to the samples of intervention group and letter B to the samples of the control group, In this method, six modes of ABBB, BBAA, BABA, ABBA, BAAB and ABAB are written in separate worksheets and placed inside a container. Then go to Randomly take one of the sheets out of the container, assuming ABAB. We put the first patients in Group A, the second in Group B, the third in Group A, and the fourth in Group B, and this leaf. And that's why, based on these six modes, 24 patients are selected and entered into groups. We repeat this method until 40 patients are selected. Since the sample size in this study is 40 patients, this operation is repeated twice.

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 Arak University of Medical Sciences

Street address

Enghelab

City

Bastak

Province

Hormozgan

Postal code

7961613153

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.ARAKMU.REC.1399.024

Health conditions studied

1

Description of health condition studied

Coronic Kidny Diseass

ICD-10 code

I12.0

ICD-10 code description

Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease

Primary outcomes

1

Description

Mental health score in Keyes ' mental health questionnaire

Timepoint

Measuring mental health questionnaire before intervention in the intervention group, then 8 weekly sessions of cognitive behavioral therapy training, and re-measurement of mental health questionnaire in the intervention group.

Method of measurement

Keys Mental Health Questionnaire

2

Description

Happiness Score in Oxford Happiness Questionnaire

Timepoint

Measuring Oxford Happiness Questionnaire before intervention in intervention group, then 8 weekly sessions of cognitive behavioral therapy training, and again, the questionnaire of happiness in the intervention group.

Method of measurement

Oxford Happiness Questionnaire

Secondary outcomes

empty

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

Intervention group: This study is an interventional clinical trial with the intervention and control groups that will be done by random sampling on 40 patients referred to Farabi Bastak Hospital Hemodialysis Center. Patients will be entered into the study after completing the consent form. Patients will be randomly divided into two groups of intervention and control group. 20 patients will be placed in each group. At first, patients will complete the Oxford Mental Health and Happiness Questionnaire before they begin their interventions. Then, cognitive Behavioral Therapy interventions will be taught to the intervention group in 8 weekly sessions and 90 minutes per session according to the protocols of this treatment by the trained person. Sessions are briefly included: valuable progressive muscle relaxation, familiarity with stress and stressors, familiarity with self-control strategies, substitution of negative thoughts with positive thoughts, familiarity with different types of cognitive errors (thinking mistakes), familiarity with a variety of assertive behaviors, familiarity with strategies to increase self-esteem, and familiarity with skills strategies. After all the sessions, both questionnaires will be completed by the patients again. Data will be analyzed using spss software. The data will be analyzed using spss software.

Category

Behavior

2**Description**

Control group: the control group in the study will be a group with 20 patients after random selection. At first, both key mental health questionnaire and Oxford happiness questionnaire will be completed by the members of the group. During the study period, no training or intervention will be done on this group and will receive routine services of hemodialysis center. After 8 weeks, they will again complete the mental health and happiness questionnaires. The results obtained by this group will be analyzed using spss software, and according to the objectives of the study, it will be discussed and concluded.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farabi Hospital

Full name of responsible person

Faegheh Paravar

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

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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
Arak University of Medical Sciences
Full name of responsible person
Faeqheh Paravar
Position
graduate student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

After the end of the study the data files and individual data files including age , sex , duration of hemodialysis and ...) patients can be shared after non recognizable.

When the data will become available and for how long

After the end of the study , the release of documents / data files The release of the data file (access to information mental health questionnaire and happiness questionnaire) is published six months after the publication of the published results.

To whom data/document is available

After the end of the study , the documentation is permitted for all those interested in the study.

Under which criteria data/document could be used

After the end of the study, the use of data or study documents to use in other studies is provided as the source of the study.

From where data/document is obtainable

in order to obtain the documentation, Faeqheh Paravar, with the postal address of province Hormozgan, Bastak City, Enghelab street Send mail to paravar.faeq @ gmail. com send Whatsapp No. 09184872690 to Faeqheh paravar

What processes are involved for a request to access data/document

people interested in receiving study documentation, can send their request to me The request will usually be

answered in the shortest possible time, usually 2 hours.
paravar.faeqheh@gmail.com The text of the request will

be sent to whatsapp number 09184872690.
Comments