

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of acceptance and commitment based therapy on some mental health indices and quality of life in patients who live with maintenance dialysis.

Protocol summary

Summary

The aim of this study is to determine the effectiveness of acceptance and commitment based therapy on some mental health indices and quality of life in patients who live with maintenance dialysis. This is a clinical trial with a randomized sampling in groups with the control group. The study population of patients with Chronic Kidney Disease that refer to dialysis unit in Bu-Ali Hospital of Qazvin city. 60 qualified applicants are selected and then randomly divided into three experimental group acceptance and commitment therapy, cognitive-behavioral treatment group and the control group. exclusion criteria: acute or chronic physical illness that cause hardships to endure long meetings. Severe side effects of kidney failure requiring hospitalization or surgery. Report of having any mental disorder (eg, psychosis) that need to be hospitalized. Psychotropic drugs or substance abuse currently. And finally absence of more than three sessions of therapy.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016082729551N1**

Registration date: **2017-01-01, 1395/10/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-01, 1395/10/12

Registrant information

Name

Monireh Nazari

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1548

Email address

m_nazari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-12-09, 1395/09/19

Expected recruitment end date

2017-01-09, 1395/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of acceptance and commitment based therapy on some mental health indices and quality of life in patients who live with maintenance dialysis.

Public title

The effectiveness of acceptance and commitment based therapy (ACT) on quality of life in patients who live with maintenance dialysis.

Purpose

Treatment

Inclusion/Exclusion criteria

Participants must have end stage renal failure treated with maintenance dialysis. Minimum education that is considering is elementary and also participants should

not have experience of being treated with acceptance and commitment based therapy .Also, Individuals should not have a history of substance abuse, psychotic disorders and mental retardation .Exclusion criteria :acute or chronic physical illness that cause hardships to endure long meetings. Severe side effects of kidney failure requiring hospitalization or surgery. Report of having any mental disorder (eg, psychosis) that need to be hospitalized. Psychotropic drugs or substance abuse currently. And finally absence of more than three sessions of therapy.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization model is block design.

Secondary Ids**1****Registry name****Secondary trial Id****Registration date**

2017-11-21, 1396/08/30

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University Of Medical Sciences

Street address

Shahid Beheshti University Of Medical Sciences, near Taleghani Hospital, Arabi street, Daneshjo Blvd. , Evin, Chamran Highway, Tehran

City

Tehran

Postal code**Approval date**

2016-04-24, 1395/02/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.92

Health conditions studied**1****Description of health condition studied**

Chronic Kidney Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

Quality Of Life

Timepoint

pretest before the intervention, post test after the intervention and follow up after 2 month

Method of measurement

Kidney Disease Quality of Life – Short Form version 1.3 for use with Iranian patients

Secondary outcomes**1****Description**

depression

Timepoint

pretest before the intervention, post test after the intervention and follow up 2 month later

Method of measurement

Hospital Anxiety and Depression Scale

2**Description**

anxiety

Timepoint

pretest before the intervention, post test after the intervention and follow up 2 month later

Method of measurement

Hospital Anxiety and Depression Scale

3**Description**

Mental health

Timepoint

pretest before the intervention, post test after the intervention and follow up 2 month later

Method of measurement

Hospital Anxiety and Depression Scale Kidney Disease Quality of Life – Short Form

Intervention groups

1

Description

The second group will receive cognitive behavioral therapy in 8 session. they will continue their previous medications.

Category

Lifestyle

2

Description

The third group is, control group. They will not receive psychological treatment. They just will take their previous medications.

Category

Treatment - Drugs

3

Description

The first group is the ACT group. they will experience acceptance and commitment based therapy in 8 Sessions.Their previous medications will continue as before.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Bo Ali Sina Hospital

Full name of responsible person

Monireh Nazari

Street address

Hemodialysis section, Ferdosi street, Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Full name of responsible person

Street address

City

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Monireh Nazari

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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phd degree in psychlogy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty