

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

: Comparison of Effectiveness of Meta cognitive Therapy and Acceptance and commitment Therapy(ACT) on Depression& Post Traumatic Growth &Blood presher in Hemodialysis patients.

Protocol summary

Study aim

Determining of effectiveness of Meta cognitive Therapy and Acceptance and commitment Therapy on depression, post-traumatic growth and hypertension in dialysis patients

Design

Clinical trial with control group and in parallel, without blinding and randomized, phase 3 on 54 women who write numbers on small papers by simple random method and will be selected by lot in three groups.

Settings and conduct

This research will be performed as a clinical trial with control and experimental groups. Pre-test, intervention, post-test and follow-up will be performed. The venue will be in the dialysis ward of Alborz Imam Ali and Shahid Rajaei Hospital.

Participants/Inclusion and exclusion criteria

log in:Age over 30 years At least 3 months have passed since they started dialysis No entry:Reluctance to enter into cooperation Do not have informed written consent No severe mental disorders Existence of verbal, hearing and dementia problems

Intervention groups

Pre-test will be taken from the intervention and control group, then the metacognitive therapy intervention group will receive 8 sessions 60-minute and the acceptance and commitment intervention group will receive 8 sessions 90-minute training individually.

Main outcome variables

Depression, Post Traumatic growth and Blood preshe

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201118049430N1**

Registration date: **2020-12-10, 1399/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**

Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-30, 1399/09/10

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: Comparison of Effectiveness of Meta cognitive Therapy and Acceptance and commitment Therapy(ACT) on Depression& Post Traumatic Growth &Blood presher in Hemodialysis patients.

Public title

The effect of psychocho therapy dialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 30 years At least 3 months have passed since they started dialysis

Exclusion criteria:

Reluctance to enter into cooperation Do not have informed written consent No severe mental disorders Existence of verbal,hearing and dementia problems

Age

From **30 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the individuals, we write the numbers on small pieces of paper in a simple random way and place them in three groups, two intervention groups and one control group by drawing lots.

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**

Islamic Azad University, Parand Branch

Street address

Unit5,No. 27,13 West St,Rajai Shahr,Karaj

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Postal code

3148953378

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.IAU.REC.1399.006

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

Kidney dialysis

ICD-10 code

Y84.1

ICD-10 code description

Kidney dialysis

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

Depression

Timepoint

Before the intervention, immediately after the intervention and three months after the intervention

Method of measurement

Beck Depression Inventory

2**Description**

Post-traumatic growth

Timepoint

Before the intervention, immediately after the intervention and three months after the intervention

Method of measurement

Post-traumatic growth scale

3**Description**

Blood pressure

Timepoint

Before each intervention, immediately after each intervention and three months after the intervention

Method of measurement

Hand barometer

Secondary outcomes

empty

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

Control group: In order to observe the principles of ethics, the control group will receive educational content based on metacognitive therapy approach and treatment based on acceptance and commitment after the intervention process in the experimental group in the form of educational booklets.

Category

Prevention

2

Description

Intervention group1: Acceptance and commitment therapy that uses the processes of acceptance, mental focus, commitment, and behavioral change processes to create flexibility. Acceptance and commitment therapy based on the theoretical foundations of treatment (Izadi and Abedi, 2014) will be performed in 8 sessions of 90 minutes. The first session establishes a therapeutic relationship, acquaintance and general explanation of the therapeutic approach, concluding a therapeutic contract, psychological training, discussing experiences and evaluating them, efficiency as a measure, creating creative frustration of the therapist based on acceptance and commitment. The client should give up feeling better and thinking differently. The second session examines patients' problems from an ACT perspective (extracting the experience of avoidance, integration, and individual values, and that control is the problem, not the solution). Creative frustration refers to abandoning behaviors or strategies that the client's experience has shown to be ineffective. The third session expresses control as a problem, clarifying the inefficiency of controlling negative events using metaphors, introducing tendency as another response, engaging in purposeful actions (ie, general and desirable directions of life that are verbally set). Session 4: Applying Cognitive Fault Techniques (One of the less invasive ways of presenting fault techniques is to introduce thoughts as thoughts or products of the mind. See as thoughts: The purpose of breaking is not all thoughts, but the breaking of those thoughts that cause problems when they are considered reality. The fourth session is the observation of the self as the context of the "self" and the attachment in which events are experienced, but at the same time distinct from those events (weakening of self-concept and self-expression as an observer, showing separation between oneself, experiences Internal and Behavior) Continuous non-judgmental contact with psychological and environmental events, as they are. Session 5 Application of mental techniques, modeling exit from the mind, learning to experience inner experiences as a process. Session 6 :Identifying patients' life values and measuring values based on their importance in life, showing the dangers of focusing on results, discovering practical life values. Session 7: Determining patterns of action commensurate with values (the step-by-step process of creating a complete and integrated life, based on one's deepest desires and aspirations to use metaphors), planning for a commitment to pursuing values. The eighth session :summarizes the concepts explored during the sessions, asking patients to explain their achievements in treatment and their plan for survival.

Category

Prevention

3

Description

Intervention group2: : Enabling the patient to interact with their thoughts differently and to develop flexible metacognitive control and awareness, and to prevent

processing through worry and rumination and threat review. Cognitive therapy derived from the theoretical foundations of treatment (Malihi Al-Dhakerini, 2016, Lena Jelink et al., 2016) will be performed in 8 sessions of 60 minutes. The first session of establishing a therapeutic relationship, familiarity and general explanation of the therapeutic approach, concluding a treatment contract, familiarity with depressive disorder and mental refinement (identifying negative points), over-generalization (using the word all and nothing) and changing views and correcting cognitive assessment. The second session of conceptualizing depression based on metacognitive model, examining memory and concentration, practicing attention training technique, presenting homework and discussing its importance in the treatment process. Session 3 Homework Review, Introduction to Dictatorship Technique / Phrase "Must" Analyze Profit and Loss Strict Criteria, Devaluing Positive Points (Expecting Negative Feedback, Rejecting Positive Feedback), Thinking Black and White, Finding the Right Balance, Homework Presentation. Session 4: Reviewing members' homework, identifying values (observable behaviors, invisible states), strategies for living with values (identifying positive points), practicing self-esteem enhancement techniques, and homework. Fifth session of homework review, zoom in and out, document style (for negative event and positive event), homework presentation. Sixth session of homework review, discussion about the importance of rumination in the continuation of the disorder and postponement of mental rumination and its practice, practice of relaxation search technique and breathing exercises, relaxation exercises, withdrawal and use of strategies to break withdrawal and rumination Provide homework. Session 7 Presenting a summary of sessions, hasty conclusions, mind reading, catastrophic prediction, reviewing possible outcomes, and re-evaluating probabilities. Session 8: Understanding emotions, reasoning emotion, understanding non-verbal cues, examining emotions and practicing identifying it and presenting homework, performing a relapse prevention program (identifying the factors that will cause recurrence and ways to deal with it).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Mahboubeh Boroumand

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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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
Islamic Azad University
Full name of responsible person
Samira Haddadi
Position
student
Latest degree
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Person responsible for updating data

Contact

Name of organization / entity

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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

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

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

After printing and publishing

To whom data/document is available

Researchers of prestigious universities and scientific institutes.

Under which criteria data/document could be used

Similar and complementary studies

From where data/document is obtainable

Samira Haddadi shaddadi657@gmail.com

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

Communication via email, sending research and scientific documents of the applicant, after confirmation, information will be available.

Comments