

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparing of the effectiveness of acceptance & commitment therapy and Schema therapy based on acceptance and commitment to body image, Self-Compassion, sexual self-esteem and couple burnout in dialysis women

Protocol summary

The effectiveness of acceptance and commitment therapy

Study aim

Comparison of the effectiveness of acceptance and commitment therapy and schema therapy based on acceptance and commitment on the body image of dialysis women

Design

Clinical trial with control group, with parallel groups, blinded, randomized, on 45 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The statistical population of this research consists of all married dialysis women who referred to Khorasan Razavi Dialysis Patients Support Association in 1400-1401. Blinding has not been done and available sampling will be selected and randomly replaced in two groups. The current research is a semi-experimental research with a pre-test-post-test design and a follow-up test with a control group.

Participants/Inclusion and exclusion criteria

Being married, more than 20 years old, passing at least 3 months of chronic kidney disease, having literacy and willing and informed consent to participate in the research; Exit criteria: From patients who had cognitive problems or psychotic disorders, patients who received other psychotherapy at the same time, as well as patients who had kidney transplant experience and missed more than two treatment sessions.

Intervention groups

They will be selected by available sampling and randomly replaced in two groups. The first group includes a group of 15 married women on dialysis who will receive acceptance and commitment treatment. The second group includes a group of 15 married women on dialysis, 15 married women who will be on the waiting list and will not receive treatment.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N60**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

Registration date

2023-01-01, 1401/10/11

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-04-09, 1402/01/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparing of the effectiveness of acceptance & commitment therapy and Schema therapy based on acceptance and commitment to body image, Self-Compassion, sexual self-esteem and couple burnout in dialysis women

Public title

Comparison of the effectiveness of treatment of acceptance and commitment and marital burnout of dialysis women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

being married Age more than 20 years Passing at least 3 months of chronic kidney disease and the need for dialysis Having literacy and willing and informed consent to participate in research.

Exclusion criteria:

Patients with cognitive problems or psychotic disorders
Patients receiving other psychotherapy at the same time
Patients who have kidney transplant experience and absent more than two treatment sessions.

Age

From 20 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 45

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, permutation block method was used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequence was performed using random allocation software and block size four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied.

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 Islamic Azad University Mashhad Medical Sciences Unit

Street address

Qasim Abad (Gharb city, Khorasan, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Approval date

2022-08-24, 1401/06/02

Ethics committee reference number

IR.IAU.MSHD.REC.1401.118

Health conditions studied

1

Description of health condition studied

Sexual self-esteem and marital dissatisfaction of dialysis women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effectiveness of acceptance therapy

Timepoint

One day before the intervention and one day after

Method of measurement

Pre-test - post-test and follow-up test plan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, they are subjected to a pre-test, then they are put into a treatment schema based on acceptance and commitment,(8 sessions, one hour and a half each session during two months) and after the end of the test period, all tow groups will be subjected to a post-test.

Category

Diagnosis

2

Description

First, they undergo the pre-test, they are only placed on the waiting list, and after completing the intervention group, they complete the post-test.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorasan Razavi Dialysis Patients Support Association

Full name of responsible person

Hossein Share

Street address

RazaviKhorasan Kidney Patients Charity Association,
12 Qaim Corner, Ahmedabad, Qaim St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

javad Baharara

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Central Organization 2, 42 EmamiehA, Emamieh
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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

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

Islamic Azad University

Full name of responsible person

Hossein Shareh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Full name of responsible person

monireh Poorfarahani

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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