Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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

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
The effectiveness of acceptance and commitment therapy

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 Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

Phone
+98 51 3711 2540

Email address
nejatir2@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
91961264714
Phone
+98 51 3889 4250
Email
info@irankf.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
javad Baharara
Street address
Central Organization 2, 42 EmamiehA, Emamieh Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
91961264714
Phone
+98 51 3620 4001
Email
research@mshdiau.ac.ir
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
Street address
Central Organization 2, 42 Emamieh, Emamieh Blvd, Qasim Abad
City
Mashhad
Province
Razavi Khorasan
Postal code
91961264714
Phone
36204001-051
Email
research@mshdiau.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hossein Share
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Central Organization 2, 42 Emamieh, Emamieh Blvd, Qasim Abad
City
Mashhad
Province
Razavi Khorasan
Postal code

91961264714

Phone

+98 903 926 4520

Email

research@mshdiau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

monireh Poorfarahani

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Central Organization 2, 42 Emamieh, Emamieh Blvd, Qasim Abad

City

Mashhad

Province

Razavi Khorasan

Postal code

91961264714

Phone

+98 51 3663 0781

Email

research@mshdiau.ac.ir

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