Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Effectiveness of acceptance and commitment therapy on depression, social function and fatigue in hemodialysis patients

Protocol summary

Study aim

The purpose of this study was to determine the efficacy of acceptance and commitment therapy on self-care and fatigue and role impairment due to physical health of hemodialysis patients.

Design

In this study, 60 hemodialysis patients who were admitted to hospital were selected. The participants were divided into intervention and control groups.

Settings and conduct

The research method was pretest-posttest with control group. The statistical population of this study was all hemodialysis patients who referred to dialysis department of Bou-Ali hospital in Ardebil in the second half of 1394. The sample size was 60 people who were selected by available sampling method and were randomly assigned into two experimental and control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria include the age of patients aged 20-70 years, the absence of a history of an accident or an illness in the last six months, the absence of history of depression, or admission to psychiatric causes before kidney failure, and hemodialysis, lack of physical or mental disability, minimum hemodialysis For 6 months and above the cut-off point "14" based on the BDI-II Depression Inventory, the outcomes included: reluctance to continue cooperation, the occurrence of any illness or severe disability, and transplantation

Intervention groups

Effectiveness of treatment based on admission and commitment to care, fatigue and role impairment due to physical health of hemodialysis patients

Main outcome variables

According to the results of this study, acceptance and commitment therapy to increase self-care, decreasing fatigue and role impairment have a significant effect on physical health in hemodialysis patients, and in increasing self-care, decreasing fatigue and role impairment due to physical health of patients, this study yielded significant improvements.

General information

Reason for update

Acronym

ACT

IRCT registration information

IRCT registration number: **IRCT20171027037028N2**
Registration date: **2018-06-15, 1397/03/25**
Registration timing: **retrospective**

Last update: **2018-06-15, 1397/03/25**
Update count: **0**

Registration date

2018-06-15, 1397/03/25

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 1669

Email address

parisapari070@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

2015-12-01, 1394/09/10

Actual recruitment end date

2016-01-01, 1394/10/11

Trial completion date
empty

Scientific title
Effectiveness of acceptance and commitment therapy on depression, social function and fatigue in hemodialysis patients

Public title
The Effectiveness of Acceptance and Commitment Therapy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of patients aged 20-70, No history of incident or bad experience during the last six months Not having history of depression or hospitalization for psychological causes before kidney failure and hemodialysis Not having physical or mental disabilities Perform hemodialysis for at least 6 months and counting above the cut-off point "14" based on the BDI-II Depression Inventory

Exclusion criteria:
Unwillingness to continue cooperation It was the onset of any serious illness or disability and transplantation.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **3**
60 people-30 received 30 treatment recipients.
Actual sample size reached: **60**
More than 1 sample in each individual
Actual sample size in each individual: **3**
Self-care Depression Quality of Life

Randomization (investigator's opinion)
Randomized

Randomization description
In this method, members of the community are numbered from 1 to N, then a table row and column are randomly selected. The point of the intersection of the selected row and column is the starting point for sampling, from this point one to plus and a multiplicity is drawn. All numbers that are added on or over to it are selected as sample members. It should be remembered that instead of drawing a multiplicity or addition, the hand can be moved on this table continuously and continues until the sample is selected

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants in the experimental group received 8 consecutive 90-minute treatment groups based on acceptance and approval. Patients in the control group received another training in 8 sessions of 90 minutes to control the effect of Huthorn and placebo

Placebo
Used

Assignment
Single

Other design features
NO

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ardabil Azad university

Street address
Ardabil NAYEBI SQUARE

City
Ardabil

Province
Ardabil

Postal code
5614773895

Approval date
2016-02-17, 1394/11/28

Ethics committee reference number
11920701932112

Health conditions studied

1

Description of health condition studied
Self-care, fatigue and role impairment due to physical well-being of hemodialysis patients

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
According to the results of this study, acceptance and commitment therapy to increase self-care, decreasing fatigue and role impairment have a significant effect on physical health in hemodialysis patients, and in increasing self-care, decreasing fatigue and role impairment due to physical health of patients, this study yielded significant improvements I was born.

Timepoint
3MOUNTS

Method of measurement
Beck depression questionnaire-Adjusted self-care questionnaire-Chinese version-Quality of life SF-36

Secondary outcomes

empty

Intervention groups

1

Description
Thirty-one had a placebo-controlled study and 30 received acceptance and commitment-based treatment
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
dialysis unit of Bu-Ali hospital in Ardabil
Full name of responsible person
Akram Azemi Zeinal
Street address
Ardebil Street Naibi
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5614773895
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Akram Azemi Zeinal
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Fax
Email
parisapari070@gmail.com
Web page address
Grant name
Author responsible for the budget
Grant code / Reference number
کد بودجه وجود ندارد
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
akram azemi zeynal
Position
نیروی طرحی
Latest degree
Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
scientific theft
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