

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

**The effectiveness of acceptance and commitment therapy (ACT) before dialysis, and exercises with mindfulness in dialysis time on hemodialysis patients in terms of dialysis adequacy, biological and psychological indicators.**

### Protocol summary

#### Study aim

determination of The effectiveness of acceptance and commitment therapy before dialysis, and exercises with mindfulness in dialysis time; on hemodialysis patients in terms of dialysis adequacy, biological and psychological indicators.

#### Design

The clinical trials with control group and two parallel intervention groups will be performed on 60 hemodialysis patients. Sampling was done randomly using Excel software

#### Settings and conduct

the present study will be conducted in presence of patients and education, with a questionnaire on patients at the Imam zaman hospital. After the pre - test, training sessions, mindfulness and sports exercises will be conducted. the experimental indices of patients will be measured and recorded before and after the intervention to investigate the changes and effectiveness of the therapeutic approach.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: effective AV fistula; the form of permission ; Physical ability through walking testing; Having a bachelor's degree of education; Age of patients up to 60 years; The history of dialysis for six months; Having a desire to participate in research Exclusion criteria: kidney transplant experience; chemotherapy or radiotherapy; No hospitalizing during intervention; diabetes and blood pressure; Lack of consciousness at places and time; Mental and physical disability and infection and leg wounds

#### Intervention groups

first group:ACT intervention is performed before the dialysis. The second group: training exercises with the mindfulness during their dialysis. Third group: control group that will not interfere with any intervention.

#### Main outcome variables

Dialysis efficacy; Psychological indices; Biological indices;

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200604047657N1**

Registration date: **2020-07-22, 1399/05/01**

Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**

Update count: **0**

#### Registration date

2020-07-22, 1399/05/01

#### Registrant information

##### Name

Ali Kazemidaluee

##### Name of organization / entity

The University of Imamreza

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3847 9808

##### Email address

alikalazemidaluee1350@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-08-04, 1399/05/14

#### Expected recruitment end date

2020-08-09, 1399/05/19

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of acceptance and commitment therapy (ACT) before dialysis, and exercises with mindfulness in dialysis time on hemodialysis patients in terms of dialysis adequacy, biological and psychological indicators.

**Public title**

The effectiveness of psychological treatments and exercises on life efficacy and treatment of hemodialysis patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

having an effective arterial and venous fistula, completing the testimonial form, having a minimum diploma, minimum age of 60, doing hemodialysis for 6 months, having a desire to participate in research, lack of participation in other psychological periods.

**Exclusion criteria:**

The experience of kidney transplantation, chemotherapy or radiotherapy, no hospitalizing in interaction period, lung disease need to oxygen therapy, diabetes and blood pressure, lack of consciousness in place and time, mental and physical disability, infection, and leg wounds, are excluded from the group in the event of an illness in the exercise time.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The simple randomization method will be done , using the random numbers table and assigning each number to a patient.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of birjand university of medical sciences

**Street address**

Emam zaman hospital, sarakhs Ave, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9175756422

**Approval date**

2020-06-23, 1399/04/03

**Ethics committee reference number**

IR.BUMS.REC.1399.116

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

Chronic Renal Failure

**ICD-10 code**

I13.11

**ICD-10 code description**

Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

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

Dialysis efficacy

**Timepoint**

Once a month from 15 August( since get the patient)

**Method of measurement**

Daugirdas index to assess the quality of dialysis

**2****Description**

depression

**Timepoint**

Once a month from 15 August( since get the patient)

**Method of measurement**

Doss scale of depression

**3****Description**

Avoidance

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Avoidance questionnaire

#### **4**

#### **Description**

Disease Rumination

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Multidimensional Rumination scale

#### **5**

#### **Description**

Disease Perception

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Illness Perception Questionnaire

#### **6**

#### **Description**

Hope

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Snyder Hope Scale

#### **7**

#### **Description**

Emotional efficacy

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Emotion efficacy scale

#### **8**

#### **Description**

Global health

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Health questionnaire

#### **9**

#### **Description**

Spiritual health

#### **Timepoint**

Once a month from 15 August( since get the patient)

#### **Method of measurement**

Spiritual well-being questionnaire

### **Secondary outcomes**

#### **1**

#### **Description**

Biological index

#### **Timepoint**

Once a month from 15 August( get the patient)

#### **Method of measurement**

Monthly Routine Tests

### **Intervention groups**

#### **1**

#### **Description**

Intervention group1: Effectiveness of ACT before dialysis: Training the ACTto dialysis patients and study the effect of this treatment model on mental health and dialysis efficacy in this patients.

#### **Category**

Treatment - Other

#### **2**

#### **Description**

Intervention group2 : Training exercises with mindfulness in dialysis period and study its effect on mental health and dialysis efficacy

#### **Category**

Treatment - Other

#### **3**

#### **Description**

Control group: There is no intervention in the group.

#### **Category**

Treatment - Other

### **Recruitment centers**

#### **1**

#### **Recruitment center**

#### **Name of recruitment center**

Emam zaman hospital

#### **Full name of responsible person**

Mahmood khadem Al khamseh

#### **Street address**

Emam zaman hospital, sarakhs Ave, Mashhad

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9175756422

#### **Phone**

+98 51 3365 2000

#### **Email**

alikalzomidaluee1350@gmail.com

### **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. ali abadi

**Street address**

end of Ghafari Ave

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717813111

**Phone**

+98 56 3432 5502

**Email**

f.shahabizadeh@yahoo.com

**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**

Emam reza university

**Full name of responsible person**

Ali kazemi daluee

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No0 327, jahanara7Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9175756422

**Phone**

0098 51 8479808

**Email**

alikalzemidaluee1350@gmail.com

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Emam reza university

**Full name of responsible person**

Ali kazemi daluee

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No327, jahanara7Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9175756422

**Phone**

0098 51 8479808

**Email**

alikalzemidaluee1350@gmail.com

### Person responsible for updating data

#### Contact

**Name of organization / entity**

Emam reza university

**Full name of responsible person**

Ali kazemi daluee

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No327, jahanara7Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9175756422

**Phone**

0098 51 8479808

**Email**

alikalzemidaluee1350@gmail.com

### 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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All of the statistical data of patients

**When the data will become available and for how long**

six months after publishing the evidences

**To whom data/document is available**

Professors, patients, treatment personals

**Under which criteria data/document could be used**

For increase the treatment efficacy

**From where data/document is obtainable**

[www.aubir.ac.ir](http://www.aubir.ac.ir)

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

Asking from the azad university of birjand or visit the website of university

**Comments**