

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of Effectiveness of Cognitive Behavioral Therapy and Dialectic Behavioral Therapy on Medication Adherence in Patients Undergoing Hemodialysis

#### Protocol summary

##### Study aim

Comparison of the effectiveness of Cognitive Behavioral Therapy and Dialectical Behavior Therapy on adherence to drug therapy in renal hemodialysis patients.

##### Design

With considering dropout rate, 60 individuals will be selected as available, and we will randomly place the eligible individuals into three groups (two experimental and one control).

##### Settings and conduct

This study is performed on patients undergoing hemodialysis who do not follow drug treatment. The research environment of hospitals equipped with hemodialysis in Isfahan. After calling for participation in the hospital and informing the people who enter the research, they will receive individual cognitive-behavioral therapy and another group of dialectical behavioral therapy. No blinding is performed in this study.

##### Participants/Inclusion and exclusion criteria

Patients with renal insufficiency treated with hemodialysis; Conditions for non-admission of patients with renal insufficiency who are not undergoing hemodialysis treatment and other diseases.

##### Intervention groups

One experimental group receives cognitive-behavioral therapy (CBT) individually for 8 sessions of 45 minutes and the other experimental group receives dialectical behavioral therapy (DBT) individually for 8 sessions of 45 minutes. The control group does not receive any medical intervention, only the questionnaire will be obtained from the control group and it is possible to receive the desired treatment on the control group after the end of the research.

##### Main outcome variables

Medication adherence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200206046394N1**

Registration date: **2020-07-16, 1399/04/26**

Registration timing: **prospective**

Last update: **2020-07-16, 1399/04/26**

Update count: **0**

##### Registration date

2020-07-16, 1399/04/26

##### Registrant information

##### Name

Arman Mehrazin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5263 0259

##### Email address

armanmehrazinn@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of Effectiveness of Cognitive Behavioral Therapy and Dialectic Behavioral Therapy on Medication Adherence in Patients Undergoing Hemodialysis

## Public title

Comparison of Effectiveness of Cognitive Behavioral Therapy and Dialectic Behavioral Therapy on Medication Adherence in Patients Undergoing Hemodialysis

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Minimum 18 years and maximum 60 years  
Minimum diploma literacy  
Ability to complete the questionnaire  
Willingness to participate in the study  
Hemodialysis twice or more per week  
Lack of mental disability or known severe mental illness or functional (bone muscular) disability  
Fully alert  
Listening and speaking ability

### Exclusion criteria:

With known severe mental illness or functional disability (muscle, bone)  
Drug addiction  
Being hospitalized in the intensive care unit  
Unwillingness to participate in the study

## 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

Sixty patients are selected in a convenient way, by providing informed consent form to the hemodialysis patients, and then patients with poor and moderate medication adherence score in the Morisky Medication Adherence Scale will be selected and we will randomly place eligible individuals into three groups (two experimental and one control). The method of assigning individuals in control and intervention groups is simple randomization and randomization tool is the lottery.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

Due to the spread of the new corona virus in Iran, it is not possible to determine the exact time of onset and end of the choose a patient, so there is a possibility of a slight change in these times.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Islamic Azad University - Isfahan Branch (Khorasgan)

##### Street address

Esteghlal St., Neighborhood A3, Parking 3, Block 3

##### City

Khorasgan

##### Province

Isfahan

##### Postal code

84918-36489

#### Approval date

2020-06-10, 1399/03/21

#### Ethics committee reference number

IR.IAU.KHUISF.REC.1399.059

## Health conditions studied

### 1

#### Description of health condition studied

Kidney failure

#### ICD-10 code

V15.81 (Z9)

#### ICD-10 code description

Nonadherence to Medical Treatment (726)

## Primary outcomes

### 1

#### Description

Medication adherence

#### Timepoint

Measurements of drug treatment adherence are completed before the intervention and 14 days after the start of the intervention and immediately after the intervention, and questionnaires are re-completed one month after the intervention.

#### Method of measurement

Morisky Medication Adherence Scale

## Secondary outcomes

### 1

#### Description

Accompanying depression score

#### Timepoint

Before and after the intervention, the questionnaires will be completed by the subjects in order to follow up on the effect of the interventions one month after the interventions.

#### Method of measurement

Beck's second depression inventory

## 2

### **Description**

Accompanying anxiety score

### **Timepoint**

Before and after the intervention, the questionnaires will be completed by the subjects in order to follow up on the effect of the interventions one month after the interventions.

### **Method of measurement**

Beck Anxiety Inventory

## 3

### **Description**

Medicinal beliefs of patients or medicinal beliefs of individuals

### **Timepoint**

Before and after the intervention, the questionnaires will be completed by the subjects in order to follow up on the effect of the interventions one month after the interventions.

### **Method of measurement**

Questionnaire and drug belief tool for patients (BMQ), which higher scores indicate a stronger belief of patients in each of the subscales.

## **Intervention groups**

### 1

#### **Description**

Control group: They do not receive any intervention.

#### **Category**

N/A

### 2

#### **Description**

Cognitive-behavioral intervention will be performed by embezzlement from Farquhar. Its steps include: The first step is to identify the patient's problem and the reason for the patient's non-compliance through a face-to-face interview. (Questions such as: Why don't you follow your medication regimen? What is the biggest obstacle to your adherence to the medication regimen? ...). The second stage of the intervention is to create commitment and self-confidence in the patient in order to correct the wrong behavior. At this stage, with the help of the researcher, the patient recognizes the problems and obstacles related to his non-commitment, and at this time a contract is created between the patient and the researcher to improve compliance, which is through increasing the patient's motivation to change behavior. By saying positive affirmations, the researcher tries to increase the patient's self-confidence and create interest in changing the patient's misbehavior. At the end of the session, the patient is also asked to write down all the things he or she does during the next week and the next session as a daily report in order to follow the medication regimen throughout the day. In the second week of the third stage of the intervention, all the patient's daily reports on adherence to the medication

regimen and the patient's self-reported statements are reviewed and summarized. In this way, according to the patients' report, the obstacles and factors affecting the patients' adherence to the medication regimen are examined. In the fourth stage, the intervention of the designed program is provided to the patients face to face. This program includes training on following the medication regimen of hemodialysis patients (in the form of an educational pamphlet) and also provides patients with the necessary information about the implementation of the designed program. In the fourth week, the fifth and sixth stages of the intervention are performed, and in fact in this stage, it is evaluated to what extent the designed program is effective in improving patient compliance. It seems that this behavior is maintained through the use of motivational sentences. These steps will be followed by a structured face-to-face motivational interview in four 30-40 minute sessions.

#### **Category**

Treatment - Other

### 3

#### **Description**

Second intervention group: Dialectical behavioral therapy interventions are performed under the auspices of Marsha Linhan (1993), Mito McKay et al. (2007), and Melanie Gordon, Sheets (2009). Its steps include: The first session is familiar with the concept of mindfulness and three mental states (logical mind, emotional mind and mindfulness). The second session includes teaching two categories of skills to achieve mindfulness: the first category of "what" skills (including observation, description and description) and the second category of "how" skills (including non-judgmental, self-conscious and efficient self-awareness). to act, to act upon, surgery). The third step involves teaching strategies to distract and distract the mind with acceptance skills (activities, participation, comparisons, distractions, thoughts, and feelings). The fourth stage involves self-relaxation training with five senses. The fifth step involves teaching the pattern of identifying emotions and labeling them, which leads to increased emotion control. The sixth session includes training on creating positive emotional experiences by creating short-term positive emotional experiences. The seventh session includes situations for effective communication and interpersonal efficiency (proportionality of one's desires with the desires of others; the ratio of desires to needs). The eighth session includes effective communication goals and interpersonal efficiency (achieving goals in a situation and coping with resistance and conflict.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Al-Zahra Hospital  
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Dr. Mehdi Nasresfahani  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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**Full name of responsible person**  
Dr. Farid Naeemi  
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site@iaukhsh.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Islamic Azad University, Khomeini Shahr Branch  
**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**

Arman Mehrazin  
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**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

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**

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**

The data of the subjects can be shared as a group after identifying the people who can share both the total data and the part of the data such as information about the main consequence or the like.

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

Start the access period 6 months after printing the results.

**To whom data/document is available**

Magazines, newspapers, magazines that need these documents to publish an article.

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

Under the terms and conditions of confidentiality and for the purposes of scientific progress and observance of the anonymous principles of the participants.

**From where data/document is obtainable**

Please refer to the first author and the author, in charge of Arman Mehrazin by e-mail armanmehrazinn@gmail.com and phone number 09384743599.

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

Please send an email or phone number to the first author and the responsible author to receive research documents or data files. The applicant's requested documents and files will be provided to the applicant no later than one month after the applicant's application.

**Comments**

Given that each magazine has its own form, I don't have a specific plan at the moment.