

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of cognitive-behavioral based education in comparison with conventional education on the depression , adjustment and self-care behaviors in patients with depression and heart failure hospitalized in Zahedan instructional hospitals in 2018

#### Protocol summary

Depression; Adaptation to disease; Self-care behaviors

#### Study aim

Determining the Effect of Cognitive-Behavioral Education in Comparison with Normal Training on Depression, Adaptation and Self-care Behaviors of Depressed Heart Disease Patients Admitted to Zahedan Educational Hospitals in 1397

#### Design

Clinical trial with two groups of regular education and cognitive-behavioral teaching, factorial, single-blind, simple random

#### Settings and conduct

Educational hospitals in Zahedan, Iran - Selection of patients by available sampling method and then their non-randomization divided into two groups: regular education and cognitive-behavioral education

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of heart failure (Grades 2 and 3) based on cardiology and recorded in patient records Not being infected with other known psychiatric illnesses - Obtain a score of at least 21 from the Beck Depression Test and confirm the depression in the psychiatric examination. - Resident of the city and accessible for follow up. - Awareness and full awareness and ability to communicate. -No addiction and substance abuse - Lack of experience in rehabilitation, counseling or training programs at the same time. -Delay at least 6 months of illness No lack of communication Exit criteria: - Critical illness, death, or any unplanned event during the study; - Clearance earlier than a week. Absence or absence of more than one treatment session.

#### Intervention groups

Regular training group and cognitive-behavioral group. Because of the usual training, an intervention is considered. The group's follow-up is considered as intervention.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160924029954N9**

Registration date: **2018-08-25, 1397/06/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-25, 1397/06/03**

Update count: **0**

##### Registration date

2018-08-25, 1397/06/03

##### Registrant information

##### Name

Ali navidian

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3344 2482

##### Email address

alinavidian@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2018-10-23, 1397/08/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### **Scientific title**

The effect of cognitive-behavioral based education in comparison with conventional education on the depression , adjustment and self-care behaviors in patients with depression and heart failure hospitalized in Zahedan instructional hospitals in 2018

#### **Public title**

The effect of cognitive-behavioral based education in comparison with conventional education on the depression , adjustment and self-care behaviors in patients with depression and heart failure hospitalized in Zahedan instructional hospitals in 2018

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Definitive diagnosis of heart failure (Grades 2 and 3) based on cardiology and recorded in patient records Not being infected with other known psychiatric illnesses - Obtain a score of at least 21 from the Beck Depression Test and confirm the depression in the psychiatric examination. - Resident of the city and accessible for follow up. - Awareness and full awareness and ability to communicate. -No addiction and substance abuse -No addiction and substance abuse -Delay at least 6 months of illness No lack of communication

##### **Exclusion criteria:**

- Critical illness, death, or any unplanned event during the study;- Clearance earlier than a week. Absence or absence of more than one treatment session.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

First of all, from patients with heart failure diagnosis based on the criteria for entering the study, a sample is selected according to the sampling method. We ask patients to choose a sheet from a bag contains 80 sheets. 40 sheets in blue represent the usual training group, 40 sheets in red represent the cognitive-behavioral group. People who select the red card will be in the cognitive-behavioral group and those who choose the blue tab will be placed in the regular training group.

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

does not have

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee Of Zahedan University Of Medical Sciences & Health Services

##### **Street address**

Administrative Complex Of Zahedan Medical Science Campus, Persian Gulf Blvd. Dr. Hesabi Square, Zahedan

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

98167-43463

#### **Approval date**

2017-07-01, 1396/04/10

#### **Ethics committee reference number**

IR.ZAUMS.REC.1397.175

## **Health conditions studied**

### 1

#### **Description of health condition studied**

heart failure patients

#### **ICD-10 code**

I50

#### **ICD-10 code description**

Heart failure

### 2

#### **Description of health condition studied**

depressive disorder

#### **ICD-10 code**

F32

#### **ICD-10 code description**

Major depressive disorder, single episode

## **Primary outcomes**

### 1

#### **Description**

"The percentage of people who have a backseat score of over 21."

#### **Timepoint**

"Measuring depression at the beginning of the study and 30 days after intervention"

**Method of measurement**

Beck Depression Inventory

**2**

**Description**

"Compliance Score in the Compliance with the Disease Questionnaire"

**Timepoint**

"Measuring compliance at the beginning of the study and 30 days after intervention"

**Method of measurement**

"PAIS Compliance Inventory"

**3**

**Description**

"Self-care score in self-care questionnaire in cardiac patients"

**Timepoint**

"Self-care measurements before and 30 days after intervention"

**Method of measurement**

Self-care Questionnaire for Heart Patients

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

"Intervention group ": Cognitive-behavioral group, 5 separate sessions take an average of 60 minutes on the patient's bedside. Contents of the sessions: Session 1: Life with heart failure: Knowledge transfer about heart failure, signs and symptoms of symptoms, care and treatment. Session 2: Depression and Cardiac Failure: Includes a summary of the contents of the previous session, knowledge transfer about the identification of depression, the relationship between depression and heart failure, identifying concerns about depression and how to treat depression. Session 3: Behavioral Activation: Provide a brief overview of the contents of the previous session, the relationship of behavior, thoughts and creations, identifying the automatic thoughts, behavioral assessment, behavioral training, and preparing a favorite behavior table. Session 4: Solving Collaboration Problems: Provide a brief overview of the contents of the previous session, identify and understand the patient from problems, problem-solving training and problem-solving in a constructive manner, problem solving practice. Session 5: Spiritual Evolution and Aggregation: Specifies a summary of the content of the previous session, cognitive rehabilitation, self-esteem, a checklist for dealing with potential obstacles.

**Category**

N/A

**2**

**Description**

"Control group": routine training,4 separate sessions are held on the patient's bedside for an average of 30 minutes. The sessions include: Session 1: definitions of deficiency, causes and symptoms and symptoms of the disease. Session 2: A summary of the contents of the previous session, the importance of self-care, diet, weight control, rest and activity, measurement of urine volume. Session 3: Provide a brief overview of the contents of the meeting, monitoring signs of worsening and necessary measures, vaccination, alcohol and tobacco restrictions, the importance of taking medication. Session 4: Provide a brief overview of the content of the previous session, short video presentation, questions and answers on the topics discussed and the conclusions.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Aliebn Abitaleb Hospital

**Full name of responsible person**

Reyhane Khayati

**Street address**

Healthblvd , Persian Golf Blvd , Zahedan , Iran

**City**

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**Province**

Sistan-va-Balouchestan

**Postal code**

9813797396

**Phone**

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**Email**

khayati.rkh@gmail.com

**2**

**Recruitment center**

**Name of recruitment center**

Khatamolanbia Hospital, Zahedan , Iran

**Full name of responsible person**

Reyhane Khayati

**Street address**

Jam Jam BLVDL , Educational Hospital in Zahedan, Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr Normohamad Bakhshani

**Street address**

Dr Hesabi Square, Zahedan, Vice Chancellor for  
Research And Technology Overs University of Medical  
Sciences Zahedan, Iran

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bakhshani@zaums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan University of Medical Sciences

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Reyhane Khayati

**Position**

Master Student Of Psychiatric Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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khayati.rkh@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Ali Navidian

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Faculty

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## Person responsible for updating data

**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Ali Navidian

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Mashahir Street Univercity Of Nursing - Midwifery

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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**

Participants information is confidential

### **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**

No - There is not a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

No - There is not a plan to make this available

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

the method of implementation of the plan is explained in the thesis

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

The post-graduation study protocol is described in the thesis

### **To whom data/document is available**

The analysis is done in the dissertation.

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

There is no plan to publish it

### **From where data/document is obtainable**

The thesis is explained

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

There is no plan to publish it

### **Comments**

There is no plan to publish it