Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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
Depression; Adaptation to disease; Self-care behaviors

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

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Iran (Islamic Republic of)

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+98 54 3344 2482

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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

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Healthblvd ، Persian Golf Blvd ، Zahedan ، Iran

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Position
Master Student Of Pychiatric Nursing

Latest degree
Bachelor

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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