

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Title: The effect of education by motivational interviewing on self-care behaviors in depressed patients suffering from heart failure in Zahedan hospital 2016

#### Protocol summary

##### Summary

**Objectives:** This study aimed to determine the effect of motivational interviewing based on self-efficacy and self-care behaviors in depressed patients will suffering from heart failure. **Design :**Not blind clinical trial, 82 patients with heart failure in a hospital in zahedan Ali e b n a bu ta l e b and the Seal of the Beck depression questionnaire and psychiatric examination had been approved , elected **Setting and conduct :** Patients with heart failure and depressed in the hospital the inclusion criteria and are , as a sample in this study are then randomly divided into two groups allocated. The total number of subjects envelope containing group (A controlled and B intervention) were randomly arranged and the determination of the individual qualify for one of the bags in order to assign them down. **Participant :** Inclusion criteria : Hf was diagnosed by the cardiology staff, as recorded in the patient's chart ; a secondary diagnosis of depression was then given if the patient had a positive screening test (Beck's depression inventory [B D I] score of > 21). **Exclusion criteria :** major depression. The control group received the usual training on self-care behaviors over 4 days . (20-minute sessions,) individually in short sessions ( using an educational booklet . The intervention group received 4 individualized sessions of self-care education by motivational interviewing during the final 4 days of hospitalization ( 60-90 minutes). **Main outcome measures variable :** self-care behaviors, self - efficacy in patients , using questionnaires , self-care and self-efficacy questionnaire measured at baseline and 8 weeks late r.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092529954N2**

Registration date: **2016-10-29, 1395/08/08**

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

Last update:

Update count: **0**

##### Registration date

2016-10-29, 1395/08/08

##### Registrant information

###### Name

Ali navidian

###### Name of organization / entity

Zahedan University of Medical Sciences

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research and technology overs  
University of Medical Sciences Zahedan

##### Expected recruitment start date

2016-05-15, 1395/02/26

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Title: The effect of education by motivational

interviewing on self-care behaviors in depressed patients suffering from heart failure in Zahedan hospital 2016

## Public title

Effect motivational interviewing in depressed patients suffering from heart failure

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria : HF was diagnosed by the cardiology staff as recorded in the patient's chart ; A secondary diagnosis of depression was then given if the patient had a positive screening test (Beck's depression inventory [B D I] score of > 21) , and a confirmatory mental status examination (M S E) positive for depression by a clinical psychologist ; Other inclusion criteria included a) a left ventricular ejection fraction < 40% by echo cardiography ; b) being an urban resident accessible for further investigation and follow-up evaluations ; c) age between 20 and 80 years ; d) full consciousness without communication problems or history of drug abuse/addiction ; and e) no simultaneous participation in other rehabilitation and education programs . Exclusion criteria : major depression ; uncooperative patient

## Age

From **20 years** old to **80 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **82**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Vice Chancellor For Research and Technological, University of Medical Sciences Zahedan

##### Street address

University Of Medical Sciences , Dr Hesabi square , Zahedan , Iran

##### City

Zahedan

## Postal code

9816743463

## Approval date

2016-05-15, 1395/02/26

## Ethics committee reference number

IR.ZAUMS.REC;1395.64

## Health conditions studied

### 1

#### Description of health condition studied

Heart Failure; Depression

#### ICD-10 code

I50, F32

#### ICD-10 code description

Heart failure ; Depressive episode

## Primary outcomes

### 1

#### Description

Education by motivational interviewing

#### Timepoint

8 week after intervention

#### Method of measurement

Questioner (SCHFIV6.2) : Self-care heart failure index and questioner self- efficacy scale ( SES6Ge6) in Germany

## Secondary outcomes

### 1

#### Description

Self efficacy and self care behavior

#### Timepoint

8 week after intervention

#### Method of measurement

Questioner self care and Questioner self efficacy

## Intervention groups

### 1

#### Description

Patients with appropriate attributes were selected among hospitalized HF patients , and their informed consent was obtained in writing . The ( B D I) was used to screen for depressive symptoms , and if it was above 21 , a ( M S E) was done by a clinical psychologist to diagnose depression . If both the depression and HF diagnoses were confirmed , the patient was entered into the study as a research subject . The subject population then was randomly split into two groups (Group A = control and Group B = intervention ) . Participants in each group were given a pre -test (self-care questionnaire and Self- efficacy ) . The intervention group ; received 4 individualized sessions of self-care education by

motivational interviewing during the final 4 days In : 60-90 Minutes . (Table 1) of hospitalization . At 8 weeks after discharge , a questionnaire was administered as a post-test procedure by the subjects at home or during a visit to the heart clinic . Education using motivational interviewing was performed by the first author, who had utilized the technique previously for issues of weight loss , hypertension , life-style changes , obsessive-compulsive disorder , addiction , and occupational safety . Table 1 : Structure and concept of educational sessions based on motivational interviewing Session Educational concept 1st Introduction , illness review , definitions , causes, symptoms , the course of illness (practice recognizing the effect of not respecting self-care behaviors on various aspects of life , practice of identification and appellation of feelings) 2nd Importance of self-care , diet , weight control , rest and activities , measuring the volume of urine (describing A typical day of life, evaluation of advantages and disadvantages of lack of respecting self-care behaviors in short term and long term ; and practice of decisional balance) 3rd Monitoring the symptoms of deterioration in heart failure illness and required actions , confinement of alcohol and smoking, taking medicines (practice of identifying and prioritizing top values and developing the clear and evident discrepancy in order to provide intrinsic motivation) 4th Showing a short film about heart failure and debate about topics provided as well as summarizing (rewards for achievement , support self-efficacy, recognition of tempting situation , individuals' degree of self-confidence in control or lack of controlling the behavior in tempting situations).

**Category**

Rehabilitation

**2**

**Description**

control group : received the usual training on self-care behaviors over 4 days in 20 minutes , individually in short sessions, using an educational booklet ; they received post-discharge questionnaires again after the same 8 week interval. The content of the self-care education was determined based on a needs assessment, as previously reported

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Khatamolanbia Hospital, Zahedan , Iran

**Full name of responsible person**

Hajar Mobaraki

**Street address**

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**City**

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**2**

**Recruitment center**

**Name of recruitment center**

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**Full name of responsible person**

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**Street address**

HealthBLVD , Persian golf blvd , Zahedan , Iran

**City**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellorfor research and technology overs University of Medical Sciences Zahedan

**Full name of responsible person**

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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**

Vice chancellorfor research and technology overs University of Medical Sciences Zahedan

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Medicai Sciences University

**Full name of responsible person**

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Psychiatric nursing graduate student

**Other areas of specialty/work**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*