Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 (MS E) positive for depression by a clinical psychologist ؛ Other inclusion criteria included a) a left ventricular ejection fraction < 40% by echo cardio graphy ; 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 Committe Vice Chancellor For Research and Technological، Univercityof MedicalL Sciences Za
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 p re -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

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Street address

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City

Zahedan

2

Recruitment center

Name of recruitment center

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Full name of responsible person

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City

Zahedan

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

Hooshang Rafigdoosth

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Dr Hesabi square, Zahedan،Vice chancellorfor research and technology overs Universityof Medical Sciences Zahedan، Iran

City

Zahedan

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

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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