

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Sep 2026

comparison the effect of teach back and media education on self- care and social support of patients heart failure and mental health of carers

Protocol summary

Study aim

Comparison of the effect of teach back and media Education on self-care and social support of patients heart failure and mental health carers

Design

3arm parallel group randomised trial with Random number table

Settings and conduct

The teach back training method provides the necessary training on the nature of the disease, signs and symptoms of illness, treatment, weight control, diet and medication, physical and sexual activity, and post-treatment follow-up. The method of teaching the media provides the same training through CD. Combined training, training the same topics through CD and teach back will be taught

Participants/Inclusion and exclusion criteria

For patients :age more than 18; heart failure; no experience in attendance; ability to read and write and understand persian; hearing and defect Cognitive and memory, being alert, not having chronic disease ,have not mental illness, being telephone and having a DVD player.not be a member of the healthcare team, unwillingness to continue the study, not contactable by telephone and cannot apply attendance , , the stressful event during follow-up and death. For caregivers: adults, living in the same household as the patient with HF,ability to reading and writing, ability and willingness to take care of the patient, owning a cellular DVD, not be a member of the healthcare team, not have mental illness and disability.

Intervention groups

case group teach back:The patient and his caregiver are trained in a teach back based manner . The media intervention group: the patient and his caretaker, are under media training. Combined intervention group: patient and carer are combined

Main outcome variables

Self-care improvement, social support of patients and

mental health care providers using Self-care questionnaire, perceived social support and Goldberg's mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024342N5**

Registration date: **2018-09-14, 1397/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-14, 1397/06/23**

Update count: **0**

Registration date

2018-09-14, 1397/06/23

Registrant information

Name

Vida Shafipour

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the effect of teach back and media education on self- care and social support of patients heart failure and mental health of carers

Public title

"The effect of education on self -care of patients and mental health carers"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: age more than 18. Heart failure according to echo-cardiologist and cardiologist. no experience in attendance, ability to read and write and understand persian, hearing and defect Cognitive and memory(Alzheimer) , being alert, not having Chronic disease(Cancer , COPD, CRF , Cirrhosis, Thyroid), have not mental illness, being telephone and having a DVD player. Inclusion caregivers: adults. Living in the same household as the patient with HF, ability to reading and writing , ability and willingness to take care of the patient Owing a cellular DVD ,

Exclusion criteria:

Exclusion criteria: not be a member of the healthcare team, unwillingness to continue the study, not contactable by telephone and cannot apply attendance , the stressful event during follow-up and death Exclusion caregivers: not be a member of the healthcare team , not have mental illness and disability

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **150****Randomization (investigator's opinion)**

Randomized

Randomization description

Random assignment based on random number table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee mazandaran University of Medical Sciences

Street address

Moalem Square

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Sari

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4817844718

Approval date

2018-04-30, 1397/02/10

Ethics committee reference number

IR.MAZUMS.REC.1397.1151

Health conditions studied**1****Description of health condition studied**

Heart Failure, Mental health carers

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self- care

Timepoint

Before training, before discharge, weeks 4 and 8 after discharge

Method of measurement

European Heart Self-care Behavioure Scale(EHScBS)

2**Description**

Social support

Timepoint

Before training, before discharge, weeks 4 and 8 after discharge

Method of measurement

Multi-dimensional questionnaire of perceived social support

3**Description**

Mental health

Timepoint

Before training, before discharge, weeks 4 and 8 after discharge

Method of measurement

General Health Questionnaire(G.H.Q)

Secondary outcomes

1

Description

Self care

Timepoint

Before training, before discharge, weeks 4 and 8 after discharge

Method of measurement

European Heart Self-care Behavioure Scale(EHScBS)

2

Description

Social Support

Timepoint

Before training, before discharge, weeks 4 and 8 after discharge

Method of measurement

Multi-dimensional questionnaire of perceived social support

3

Description

Mental Health

Timepoint

Before training, before discharge, weeks 4 and 8 after discharge

Method of measurement

General Health Questionnaire (G.H.Q)

Intervention groups

1

Description

Intervention group 1: group teach back (patient-caregiver) post-needle training group, on the first day after admission to the waiting room, a teach back approach was developed in four areas (the nature of the disease, signs and symptoms, treatment, diet and medication, physical activity, and Sexual and follow-up after discharge will be done for 20-30 minutes within 4 consecutive days, if the patient does not want to be trained, the training will be postponed until the end of the session for 20-15 minutes by check list of educational content will be asked from the patient and his caregiver, if necessary, the training material will be repeated

Category

Behavior

2

Description

Intervention group 2: In the media group (patient-caregiver), after the needle-setting, the first day after admission to 4 educational fields (the nature of the disease, signs and symptoms, treatment, diet and medication, physical activity and sexuality, and post-

clearance follow-up) 4 consecutive days for 20-30 minutes by educational CD and DVD player in the waiting room, and the training will be sent to the carers through the virtual program (telegram). At the end of each training session A period of 20-15 minutes will be used to check the patient-caregiver's checklist, if necessary, the content will be repeated

Category

Behavior

3

Description

Intervention group3: After the patient's need-caregiver, take care of the patient from the first day after admission for 4 consecutive days in 4 fields of training for 20-30 minutes in the waiting room, through teach back training and electronic file (educational CD). Became At the end of each session, the patient-caregiver will be asked for a 20-15 minute checklist. If necessary, the content will be repeated again

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

fatemeh Zahra Hospital

Full name of responsible person

Dr. Vida Shafi Pour

Street address

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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

Mazandaran University of Medical Sciences

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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Vida Shafi Pour

Position

PhDEducation Nursing - faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable