

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effect of Multimedia Education Based on reflective learning on Quality of Life, Cardiac Anxiety and Adherence to therapeutic regimen in Patients with Heart Failure

Protocol summary

Study aim

The effect of multimedia education with reflective learning on quality of life, cardiac anxiety and adherence to treatment in heart failure patients

Design

This study is a randomized clinical trial Without blinding

Settings and conduct

The statistical population of this study will be heart failure patients admitted in CCU ward of Peymanieh Jahrom Hospital in 1999-98. In this study, the sample size of the study was based on studies using two means comparison method for each group. The sampling method in this study is convenience. Then patients will be randomly assigned to intervention and control groups

Participants/Inclusion and exclusion criteria

Age under 55 years, Grade 1 to 3 heart failure

Intervention groups

The first intervention group will be multimedia education. In the second intervention group, in addition to multimedia training, the reflective method will be used. In the third group the control group. Only the training CD will be given,

Main outcome variables

Quality of life, cardiac anxiety, adherence to treatment regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N1**

Registration date: **2020-02-05, 1398/11/16**

Registration timing: **retrospective**

Last update: **2020-02-05, 1398/11/16**

Update count: **0**

Registration date

2020-02-05, 1398/11/16

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Multimedia Education Based on reflective learning on Quality of Life, Cardiac Anxiety and Adherence to therapeutic regimen in Patients with Heart Failure

Public title

The Effect of Education on Quality of Life, Cardiac Anxiety and Adherence to Treatment in Heart Failure Patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

To under 55 years old, Grade 1 to 3 heart failure,

Exclusion criteria:

Patients' unwillingness

Age

From **40 years** old to **55 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, sampling will be done by convenience method and then randomly divided into two groups of control and intervention. For this purpose, 120 cards will be provided first, 40 cards A, 40 cards B and 40 cards C, these 120 cards will be placed in an envelope and each patient will be asked to carry one card. Take a coincidence. Each card with the names A, B, C actually represents two intervention groups (multimedia learning) , (multimedia learning with reflective learning) and a control group).

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

Ethical Committee of Fasa University of Medical Sciences

Street address

Fars Province, Fasa, Ibn Sina Square, Fasa University of Medical Sciences and Health Services

City

Fasa

Province

Fars

Postal code

86688-74616

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.FUMS.REC.1398.099

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50.9

ICD-10 code description

heart failure

Primary outcomes

1

Description

Quality of life

Timepoint

Immediately - one month later - three months later

Method of measurement

Minnesota Living with Heart Failure Questionnaire (MLHFQ)

2

Description

Cardiac Anxiety

Timepoint

Immediately - one month later - three months later

Method of measurement

The cardiac anxiety questionnaire Eifert

3

Description

Adherence to treatment regimen

Timepoint

Immediately - one month later - three months later

Method of measurement

Morisky Medication Adherence Scale (MMAS)

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, multimedia education will be provided. The multimedia method will use video, slide show and educational pamphlets. The training program will be held in four two-hour sessions. The content of the training film will be produced with the advice of a cardiologist, nutritionist and psychologist and nursing faculty members. The film will be filmed at the Fasa University of Medical Sciences virtual training center and the educational content will be approved by the professors and director of the Department of Cardiology, Nutrition, Psychology and Nursing at Fasa University of Medical Sciences. Including 1- Symptoms and Symptoms

of Heart Failure and Prevention of Heart Failure

Category

Lifestyle

2

Description

In the second intervention group, in addition to multimedia training, the training will be followed in a reflective learning based on the Johns model. This model consists of five steps -1. Event description: At this stage the event or experience describes the important causes and contextual factors associated with it, and in general, key issues in describing the event are addressed to clarify the experience.2. Reflection: This phase examines the thoughts and feelings of oneself and others and the consequences of the actions taken. Sample questions at this stage are: What was I trying to achieve? Why did I do it? What are the consequences of my actions [for the patient and family, for myself, for the people I work with]? When it happened, how did I feel about that experience? What was the patient feeling about it? How do I know what the patient is feeling about it?3. Investigating the influential factors: In this phase, the influence of internal, external and individual factors on the individual's decisions and actions is examined. Questions at this stage can include the following. What internal factors influenced my decision making and actions? What external factors influenced my decisions and actions? What sources of knowledge have or should have influenced my decision making and actions?4. Evaluating Alternative Strategies: At this point, the questions are: Could I handle this situation better? What other options were there for action? What were the consequences of the other choices?5. Learning: This stage describes the changes that have occurred in one's experiences, knowledge, ethical attitudes and self-awareness as a result of an event. An example of the question at this stage is: Given my past experience and future performance, how can I make sense of this experience? How do I feel about this experience right now? Am I considering taking effective action to support myself and others as a result of this experience? How has this experience changed my approach to performance? All stages of the Johns model will be discussed after viewing the film and based on the film content.

Category

Other

3

Description

Control group: The control group will received a training package on heart failure

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Payamanieh hospital in Jahrom

Full name of responsible person

Mostafa Bijani

Street address

Shahid Sattari Street

City

Fasa

Province

Fars

Postal code

74617-47377

Phone

+98 71 5331 5012

Fax

+98 71 5331 4021

Email

bizhani_mostafa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Fargham

Street address

Fars Province, Fasa, Ibn Sina Square, Fasa University of Medical Sciences and Health Services

City

Fasa

Province

Fars

Postal code

86688-74616

Phone

+98 71 5335 0994

Email

bizhani_mostafa@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Assistant Professor - Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fars Province, Fasa, Ibn Sina Square, Fasa University of Medical Sciences and Health Services

City

Fasa

Province

Fars

Postal code

86688-74616

Phone

+98 71 5335 0994

Email

bizhani_mostafa@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Assistant professor, Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fars Province, Fasa, Ibn Sina Square, Fasa University of Medical Sciences and Health Services

City

Fasa

Province

Fars

Postal code

86688-74616

Phone

+98 71 5335 0994

Email

bizhani_mostafa@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Assistant professor- Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fars Province, Fasa, Ibn Sina Square, Fasa University of Medical Sciences and Health Services

City

Fasa

Province

Fars

Postal code

86688-74616

Phone

+98 71 5335 0994

Email

bizhani_mostafa@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The consent form will be completed by the participants

When the data will become available and for how long

Complete the study and publish the article

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

Implementation in other centers or other disease

From where data/document is obtainable

Mostafa Bijani Assistant Professor Department of Nursing, School of Nursing and Midwifery Fasa University of Medical Science. bizhani_mostafa@yahoo.com

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

Send project manager email. Mr. Mostafa Bijani bizhani_mostafa@yahoo.com

Comments