

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of spirituality-based palliative care training on quality of life, death anxiety and resilience in heart failure patients

Protocol summary

Quality of life, death anxiety, resilience

Study aim

Determining the impact of spirituality-based palliative care training on quality of life, death anxiety and resilience in heart failure patients

Design

The present study will be a randomized clinical trial without blinding. At first, 80 patients will be selected as convenience and then randomly allocated. Three variables of quality of life, death anxiety and resilience will be investigated before, immediately and three months after the educational intervention based on palliative care based on spirituality for two intervention and control groups. The training will be conducted through six one-hour sessions in the form of group discussions, training pamphlets, lectures and training PowerPoint for the intervention group. The control group will only receive the training package and will not receive the training intervention.

Settings and conduct

The present study will be a randomized clinical trial without blinding. The target population in this study will be heart failure patients referring to Vali Asr Fasa Hospital

Participants/Inclusion and exclusion criteria

80 patients with heart failure will first be selected via convenience sampling and then randomly divided into intervention and control groups. inclusion criteria included heart failure class 1 to 3, being literate, not having acute and chronic mental and psychological diseases and Age is between 30 and 55 years. Exclusion criteria included worsening of the disease condition, death of the patient and withdrawal from the study for any reason.

Intervention groups

The training will be conducted through six one-hour sessions in the form of group discussions, training pamphlets, lectures and educational PowerPoint for the intervention group.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N7**

Registration date: **2022-12-05, 1401/09/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-05, 1401/09/14**

Update count: **0**

Registration date

2022-12-05, 1401/09/14

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

2022-11-10, 1401/08/19

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of spirituality-based palliative care training on quality of life, death anxiety and resilience in heart failure patients
Public title	The effect of spirituality-based palliative care training on quality of life, death anxiety and resilience in heart patients
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Class 1 to 3 heart failure Having literacy Not having acute and chronic mental and psychological diseases Age between 30 and 55 years
Exclusion criteria:	Worsening of the disease death of the patient Withdrawal from the study for any reason
Age	From 30 years old to 55 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 80 More than 1 sample in each individual Number of samples in each individual: 40 40 patients in the intervention group and 40 patients in the control group
Randomization (investigator's opinion)	Randomized
Randomization description	80 patients with heart failure will be selected as available and then randomly divided into intervention and control groups. For the purpose of random allocation, 80 cards were placed inside a sealed envelope and the patients were asked to randomly pick one card. Patients who take card A are in the intervention group and patients who take card B are in the control group.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Fasa University of Medical Sciences
Street address	7461686688, Fasa University of Medical Sciences, Ibn Sina Square, Fasa, Fars, Iran.
City	Fasa
Province	Fars
Postal code	7461686688
Approval date	2022-10-19, 1401/07/27
Ethics committee reference number	IR.FUMS.REC.1401.112
Health conditions studied	
<u>1</u>	
Description of health condition studied	Heart failure
ICD-10 code	I50
ICD-10 code description	Heart failure
Primary outcomes	
<u>1</u>	
Description	Quality of life
Timepoint	Before, immediately and three months after the educational intervention
Method of measurement	Minnesota Quality of Life Questionnaire
<u>2</u>	
Description	Resilience
Timepoint	Before, immediately and three months after the educational intervention
Method of measurement	Connor-Davidson Resilience Questionnaire
<u>3</u>	
Description	death anxiety
Timepoint	Before, immediately and three months after the educational intervention
Method of measurement	Templer Death Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training will be conducted through six one-hour sessions in the form of group discussions, educational pamphlets, lectures and educational PowerPoint for the intervention group.

Category

Lifestyle

2

Description

Control group: The control group will only receive the training package and will not receive the training intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

7461686688, Fasa University of Medical Sciences, Ibn Sina Square, Fasa, Fars, Iran.

Full name of responsible person

Mostafa Bijani

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Ibn Sina Square. Fasa University of Medical Sciences.

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bizhani_mostafa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Yasser Mansouri

Street address

7461686688, Fasa University of Medical Sciences, Ibn Sina Square, Fasa, Fars, Iran.

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Mansouri@yahoo.com

Grant name

Grant code / Reference number

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

No

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After completing the study and publishing the results, by requesting the use of the study process and the use of questionnaires, as well as the content of the training program, the author in charge of the documentation will be shared.

When the data will become available and for how long

After completing the study and publishing the results

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

After completing the study and publishing the results, by requesting the use of the study process and the use of questionnaires, as well as the content of the training program, the author in charge of the documentation will be shared.

From where data/document is obtainable

Send a request to use documents to the responsible author via email

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

ending the request for the use of documents to the responsible author via email and sending the documents requested by the responsible author to the requesting person.

Comments**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

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