Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the role of spiritual education in promoting spiritual well-being, the characteristic of gratitude and reducing the consequences of suffering in patients with heart failure.

Protocol summary

Study aim

Investigating the role of spiritual education in promoting spiritual well-being, the characteristic of gratitude, and reducing the consequences of suffering in patients with heart failure.

Design

A clinical trial with the control group, randomized on 30 patients.

Settings and conduct

After receiving the code of ethics from the ethics committee of the Iran University of Medical Sciences, the sample people were selected based on the entry and exit criteria, and then after the initial interview according to SCLD and declaring their desire to participate in the meetings, they were given explanations about the research and written consent. They were asked and assured that participation in the study was voluntary and that the participants could leave the study at any time.

Participants/Inclusion and exclusion criteria

Patients with heart failure aged 18 to 70 years. Willingness to participate in the study of not suffering from severe psychiatric disorders such as bipolar disorders, psychotic spectrum disorders, and cognitive disorders.

Intervention groups

Intervention group: includes all cardiac patients of Tehran city who receive group intervention based on meaning therapy based on the book Meaning-Centered Therapy Manual in eight 60-minute sessions (one session per week). The control group includes heart failure patients who do not receive intervention.

Main outcome variables

Spiritual well-being, self-efficacy, sleep quality, symptoms of fatigue, anxiety and depression, gratitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220829055823N1**
Registration date: **2024-08-05, 1403/05/15**
Registration timing: **retrospective**

Last update: **2024-08-05, 1403/05/15**
Update count: **0**

Registration date

2024-08-05, 1403/05/15

Registrant information

Name

fateme vaezipoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2426 5859

Email address

f_vaezipour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-05-06, 1402/02/16

Actual recruitment start date

2023-01-05, 1401/10/15

Actual recruitment end date

2023-05-06, 1402/02/16

Trial completion date

2023-11-06, 1402/08/15

Scientific title
Investigating the role of spiritual education in promoting spiritual well-being, the characteristic of gratitude and reducing the consequences of suffering in patients with heart failure.

Public title
The spiritual education in promoting spiritual well-being, and reducing the consequences of suffering in patients with heart failure.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have received a definitive diagnosis of heart failure 18 years old and above having at least a diploma interested in attending meetings
Exclusion criteria:
Taking psychiatric and psychoactive drugs Simultaneous participation in other psychological treatments 3 absences in treatment sessions.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**
Actual sample size reached: **30**
More than 1 sample in each individual
Actual sample size in each individual: **15**
Heart failure patients between 20 and 70 years old who were interested in participating in the project

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done by simple randomization method. The unit of randomization is individuals. 30 subjects were divided into intervention and control groups using Microsoft Excel software, part of Rand. Based on this, a table of random numbers was prepared and the Randbetween function was created, and the subjects were placed in two groups of 15 according to the rows of this table.

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
Iran University Spiritual Health Research Center
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2019-11-05, 1398/08/14

Ethics committee reference number
IR.IUMS.REC.1398.836

Health conditions studied

1

Description of health condition studied
Spiritual well-being, gratitude, sleep quality, fatigue, self-efficacy, symptoms of anxiety and depression

ICD-10 code
F54

ICD-10 code description
psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description
Spiritual well-being score in spiritual well-being questionnaire

Timepoint
At the beginning of the study (before the start of the intervention). After the end of the intervention and 6 months after the end of the intervention

Method of measurement
Dashiri spiritual well-being questionnaire

2

Description
Gratitude score in the gratitude questionnaire

Timepoint
At the beginning of the study (before the start of the intervention). After the end of the intervention and 6 months after the end of the intervention

Method of measurement
Appreciation questionnaire

3

Description

Anxiety and depression scores in patients' anxiety and depression questionnaire

Timepoint

At the beginning of the study (before the start of the intervention). After the end of the intervention and 6 months after the end of the intervention

Method of measurement

Depression anxiety questionnaire of patients

4

Description

Score of multidimensional symptoms of fatigue in the list of fatigue symptoms questionnaire

Timepoint

At the beginning of the study (before the start of the intervention). After the end of the intervention and 6 months after the end of the intervention

Method of measurement

Questionnaire of multidimensional symptoms of fatigue

5

Description

Sleep quality score in sleep quality questionnaire

Timepoint

At the beginning of the study (before the start of the intervention). After the end of the intervention and 6 months after the end of the intervention

Method of measurement

Sleep quality questionnaire

6

Description

Self-efficacy score in the self-efficacy questionnaire of Sullivan cardiac patients

Timepoint

At the beginning of the study (before the start of the intervention). After the end of the intervention and 6 months after the end of the intervention

Method of measurement

Sullivan Cardiac Self-Efficacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group included all patients with heart failure referred to the heart failure department of Shahid Rajaei Hospital in Tehran, who received group intervention based on meaning therapy based on the book Meaning-Centered Therapy Manual in eight 60-minute sessions (one session per week). Dr. Mary S. and colleagues provide this treatment and it was translated in Iran in the form of a book titled Existential Psychology Guide to Meaning-oriented Therapy by Fatemeh Vaazipour. The content of the sessions related to the intervention group includes: The content of the first session: getting to know the members of the group and their expectations, determining the policy of the group, establishing a relationship with the members, explaining Research questionnaires, a brief explanation of the treatment method, and an analysis of meaning therapy and existential analysis were done. The second session was devoted to investigating and discovering meaning and identity. The third session was devoted to the ontology of the human body and soul, and the multidimensional aspects of human existence and its unique dimensions. In the fourth session, the sources of human strength and inner abilities and simple techniques to reduce stress in life were explained. In the fifth session, the existential aspects of a person, the movement from meaninglessness to a meaningful existence, and the expression of the triangle of meaning therapy optimism in the face of adversity were examined. The sixth session was devoted to the extraction of meaning in suffering and the expression of meaning therapy as a special meaning. The seventh session was devoted to personal growth and transformation and development of abilities after injury. Finally, in the eighth session, life in its true meaning and the sources of meaning in life and a life with meaning and purpose were discussed and the sessions were summarized and the intervention post-test was performed.

Category

Treatment - Other

2

Description

Control group: The control group included all patients with heart failure who referred to the heart failure department of Shahid Rajaei Hospital in Tehran, and they also received group training based on meaning therapy after the training for the intervention group based on the book Meaning-Centered Therapy Manual in eight sessions of 60 minutes. They received one session per week. This treatment is provided by Dr. Mary S. and colleagues, and it was translated in Iran in the form of a book titled Existential Psychology, a Guide to Meaning-oriented Therapy by Fatemeh Vaazipour. The content of the sessions related to the control group includes: the content of the first session: getting to know the group members and their expectations, determining the group policy, establishing a relationship with the members, explaining the research questionnaires, explaining the essence of the treatment method, and examining the therapeutic meaning and existential analysis. paid. The second session was devoted to the investigation and discovery of meaning and identity. The third session was devoted to the ontology of the human body and soul and the multidimensional aspects of human existence and its unique dimensions. In the fourth session, sources of human strength and inner abilities and simple techniques to reduce stress in life were explained. In the fifth session, the aspects of a person's existence, and the movement from meaninglessness to a meaningful existence, and the expression of the triangle of meaning therapy optimism in the face of adversity were

examined. The sixth session was devoted to the extraction of meaning in suffering and the expression of meaning therapy as a special meaning. The seventh session was dedicated to personal growth and development and development of abilities after injury. And finally, in the eighth session, life and its true meaning, the sources of meaning in life, a life with meaning and purpose, and the summary of the sessions were discussed.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Faculty of Behavioral Sciences and Mental Health

Full name of responsible person
Mohammad-Kazem Atef-Vahid

Street address
Spiritual Health Research Center. Department of Health Psychology. School of Behavioral Sciences and Mental Health (Tehran Institute of Psychiatry), Iran University of Medical Sciences, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
Kazemv@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Kazem Malakoute

Street address
Shahid Hemmat Highway.Tehran، Tehran،IRAN

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
f_vaezipour@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohammad-Kazem Atef-Vahid

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
kazemv@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad-Kazem Atef-Vahid

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City
Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Fax

Email

kazemv@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fateme Vaezipoor

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Spiritual Health Research Center. Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Fax

Email

F_vaezipour@yahoo.com

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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

The main report will publish in appropriate articles

When the data will become available and for how long

6 Months after Article Publication

To whom data/document is available

Only for Scientific and Academic Researchers

Under which criteria data/document could be used

Only for Analysis and Researches around the main topic of this study

From where data/document is obtainable

After 6 months from the publication of the article, to the responsible author (Mohammad-Kazem Atef-Vahid) see kazemv@yahoo.com

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

Documents will send to his email address, approximately 2 month after request

Comments