Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Feasibility, Adaptability, Acceptability, and Effectiveness of Dignity Therapy in Patients with Heart Failure: a mixed methods study

Protocol summary

Study aim
A Mixed Methods Study for assess the Feasibility, Adaptability, Acceptability, and Effectiveness of dignity therapy in patients with heart failure

Design
A randomized, single-blind clinical trial with a control group will be conducted on 66 patients. For random allocation, given the two-group design of the study, a balanced block randomization method with blocks of size 4 will be used.

Settings and conduct
The present study is a clinical trial with two intervention groups and one control group, using a convenience sampling method. The target population consists of 66 patients with class II or III heart failure who are referred to Imam Khomeini Hospital Complex, affiliated with Tehran University of Medical Sciences. The Dignity Therapy protocol will be implemented in three sessions for the intervention groups. A four-part questionnaire including demographic information, Spiritual Well-Being Scale (FACIT-Sp-12), Herth Hope Index (HHI) and Patient Dignity Inventory (PDI) questionnaires will be completed by participants in all two groups before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Diagnosis of heart failure by a specialist physician, Mental health stability and absence of psychological disorders according to the medical record Exclusion Criteria: Patients with heart failure who have not completed the consent form, Any life threatening emergency situation, Participation in educational or therapeutic sessions similar to the intervention

Intervention groups
The control group receives monitoring and the routine treatments and care provided by the center. In addition to this, the intervention group receives Dignity Therapy.

Main outcome variables
Spiritual Well-Being; Hope Level; Patient Dignity Inventory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130424013110N14**
Registration date: **2026-05-08, 1405/02/18**
Registration timing: **prospective**

Last update: **2026-05-08, 1405/02/18**
Update count: **0**

Registration date
2026-05-08, 1405/02/18

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-15, 1405/02/25

Expected recruitment end date
2026-09-16, 1405/06/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Feasibility, Adaptability, Acceptability, and Effectiveness of Dignity Therapy in Patients with Heart Failure: a mixed methods study

Public title
Feasibility, Adaptability, Acceptability, and Effectiveness of Dignity Therapy in Patients with Heart Failure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of class II or III IV heart failure based on the New York Heart Association (NYHA) classification by a specialist physician Willingness and informed consent to participate in the study Absence of severe illness related conditions that would prevent participation in the intervention Mental health stability and no significant psychological issues such as severe anxiety and depression according to the patient's medical records Age over 18 years and lower 65 years

Exclusion criteria:
Patients with heart failure who have not completed the consent form. Participation in educational or therapeutic sessions similar to the intervention Any life threatening emergency situation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
For allocating participants to the intervention and control groups, a randomized block design with a fixed block size will be used. In this study, blocks with a size of 4 will be generated from the letters T and C (where these letters indicate the intervention and control groups). In each block, two participants are assigned to the intervention group and two participants are assigned to the control group. The allocation sequence within each block will be placed in a sealed packet and will be selected randomly, and the order of participants for allocation to the intervention or control group for each patient will be determined according to which block is selected, upon the start of the intervention for that patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
According to the intervention, blinding of patients, healthcare providers and outcome assessors is not possible.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Faculty of Nursing, Midwifery, and Rehabilitation

Street address
Central Building, Tehran University of Medical Sciences, Intersection of Qods Street, Keshavarz Boulevard, Secretariat of the Ethics Committee in Biomedical Research, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2025-11-24, 1404/09/03

Ethics committee reference number
IR.TUMS.FNM.REC.1404.180

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Spiritual Well-Being

Timepoint
Before and after intervention

Method of measurement
Spiritual Well-Being Scale (FACIT-sp-12)

2

Description
Hope level

Timepoint
Before and after intervention

Method of measurement
Herth Hope Index (HHI)

3

Description
Patient Dignity
Timepoint
Before and after intervention
Method of measurement
Patient Dignity questionnaire (Patient Dignity Inventory (PDI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group receives the dignity therapy intervention over three sessions, with approximate intervals of 48 to 72 hours between them. Session 1: This session is conducted through a semi-structured interview within a time frame of 30 to 60 minutes, which may be extended depending on the flow of the interview. This session focuses on reviewing the patient's life, identifying strengths, personal and professional achievements, and expressing future hopes and aspirations. The content of this session is recorded and documented at this stage. Session 2: This session involves reviewing and discussing the content prepared in the first session with the patient's participation, and receiving feedback for final editing and making any necessary revisions. Session 3: This session involves the preparation and presentation of the final version as a lasting document to the patient and their family.
Category
Other

2

Description
Control group: Participants in the control group will undergo monitoring and receive the routine treatments and care provided by the center.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Arpi Manookian
Street address
Imam Khomeini Hospital Complex, Dr. Gharib St, end of Keshavarz Blvd, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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6th floor of Research and Technology Vice-Chancellor,, Central Organization of the University, corner of Quds St,Keshavarz Blvd. Tehran Town
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mehdi Harorani
Position
PHD student in Nursing
Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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