Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of In-Person and Virtual Dignity Therapy on Quality of Life and Life Satisfaction in Patients with Heart Failure

Protocol summary

Study aim
Determining the effect of in-person and virtual Dignity Therapy on the quality of life and life satisfaction of patients with heart failure

Design
A controlled clinical trial, non-randomized, conducted on 90 patients.

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 90 patients with class II, III, or IV 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, the Chronic Heart Failure Quality of Life Questionnaire (CHFQOLQ-20), the Satisfaction With Life Scale (SWLS), and the Generalized Anxiety Disorder 7-item scale (GAD-7) will be completed by participants in all three groups at two time points: before the intervention and one month 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 Ability to use a smartphone and access to the internet Exclusion Criteria: Deterioration of the patient's health condition 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 in-person intervention group receives Dignity Therapy through face-to-face sessions, and the virtual intervention group receives Dignity Therapy via video calls.

Main outcome variables
Quality of life; Life satisfaction

General information

Reason for update
Misspelling

Acronym

IRCT registration information
IRCT registration number: **IRCT20250714066482N1**
Registration date: **2025-07-15, 1404/04/24**
Registration timing: **prospective**

Last update: **2025-07-19, 1404/04/28**
Update count: **1**

Registration date
2025-07-15, 1404/04/24

Registrant information

Name
Mahsa Khedmatizare

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6692 7171

Email address
khedmatizare_m@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-05, 1404/05/14

Expected recruitment end date
2025-11-05, 1404/08/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of In-Person and Virtual Dignity Therapy on Quality of Life and Life Satisfaction in Patients with Heart Failure

Public title
The Effect of Dignity Therapy on Quality of Life and Life Satisfaction in Patients with Heart Failure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of class II, III, or 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, depression, suicidal thoughts, obsessive-compulsive disorder, or other psychological disorders, according to the patient's medical records Ability to use a smartphone and access the internet Adequate hearing and speaking abilities to participate in interviews Minimum literacy in reading and writing in Persian No cognitive impairments Age over 18 years

Exclusion criteria:
Lack of willingness to continue participation in the study Deterioration of the patient's health condition Participation in educational or therapeutic sessions similar to the intervention Death Re-hospitalization

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
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
2025-07-09, 1404/04/18

Ethics committee reference number
IR.TUMS.FNM.REC.1404.085

Health conditions studied

1

Description of health condition studied
Patients with heart failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Ǫuality of life

Timepoint
Before intervention and one month after the end of intervention

Method of measurement
Chronic heart failure health-related quality of life questionnaire (CHFQOLQ-20)

2

Description
life satisfaction

Timepoint
Before intervention and one month after the end of intervention

Method of measurement
Satisfaction With Life Scale (SWLS)

Secondary outcomes

1

Description
Anxiety
Timepoint
Before the intervention and one month after the end of the intervention
Method of measurement
Generalized Anxiety Disorder (GAD-7)

Intervention groups

1

Description
Intervention group: In the in-person group, the intervention is carried out through a structured process consisting of three face-to-face sessions, each lasting 30 to 60 minutes, with intervals of 24 to 48 hours.In the first session, participants are introduced to the study and the Dignity Therapy interview framework. They are given the opportunity to reflect on the questions before the formal interview begins.In the second session, the researcher conducts an interview with the patient, asking specific questions to explore their life history, values, beliefs, and concerns in order to identify what matters most to them. With the participant's consent, the interview is recorded using a voice recorder.After the second session, based on the information gathered, the researcher prepares a written narrative that includes the patient's important memories, accomplishments, values, and messages for their family and loved ones.In the third session, the written narrative is reviewed together with the patient to ensure it accurately reflects their views and emotions. Any necessary revisions are made. Finally, the completed version is presented to the patient as a booklet and, if desired, to their family.
Category
Other

2

Description
Intervention group: In the virtual group, the intervention is conducted through a structured process consisting of three individual sessions held via video calls, each lasting 30 to 60 minutes, with intervals of 24 to 48 hours.In the first session, participants are introduced to the study and the Dignity Therapy interview framework. They are given time to reflect on the questions before the formal interview begins.In the second session, the researcher conducts a virtual interview with the patient, asking specific questions to explore their life history, values, beliefs, and concerns in order to identify what matters most to them. With the participant's consent, the interview is recorded using a voice recorder.After the second session, based on the collected information, the researcher prepares a written narrative that includes the patient's meaningful memories, achievements, values, and messages for their family and loved ones.In the third session, the written narrative is reviewed with the patient to ensure that it accurately reflects their thoughts and feelings. Any necessary revisions are made. Finally, the finalized version is presented to the patient as a booklet and, if desired, to their family.
Category
Other

3

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.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
Street address
6th floor of Research and Technology Vice-Chancellor,, Central Organization of the University, corner of Quds St,Keshavarz Blvd. Tehran Town
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir

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
Mahsa Khedmatizare
Position
Master's student in Medical-Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Tehran University of Medical Sciences., School of Nursing and Midwifery., Dr. Mirkhani St (East Nosrat)., Towhid Sq.
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
mahsa.khzare@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Arpi Manookian
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tehran University of Medical Sciences., School of Nursing and Midwifery., Dr. Mirkhani St (East Nosrat)., Towhid Sq.
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
ar-manookian@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahsa Khedmatizare
Position
Master's student in Medical-Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Tehran University of Medical Sciences., School of Nursing and Midwifery., Dr. Mirkhani St (East Nosrat)., Towhid Sq.
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
mahsa.khzare@gmail.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
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