Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of the Family-Centered Empowerment Model with routine care on family function and caregiver burden in family caregivers of patients with chronic heart failure

Protocol summary

Study aim

To determine the effect of the Family-Centered Empowerment Model compared with routine care on family function and caregiver burden among family caregivers of patients with chronic heart failure.

Design

This is an interventional, two-arm, randomized, controlled, parallel-group clinical trial, conducted on 64 family caregivers. Allocation will be performed using permuted block randomization.

Settings and conduct

The study will be conducted in Hajar and Kashani hospitals and Imam Ali Clinic affiliated with Shahrekord University of Medical Sciences. Eligible caregivers will be allocated after informed consent. Data will be collected before, immediately after, and three months after the intervention. The statistical analyst will be blinded to group codes.

Participants/Inclusion and exclusion criteria

Primary family caregivers of patients with chronic heart failure classified as NYHA class III or IV will be included. Main inclusion criteria are age 18 years or older, at least 6 months of caregiving experience, ability to read and write, and informed consent. Main exclusion criteria are known psychiatric disorder, concurrent participation in another study, severe impairment preventing session attendance or questionnaire completion, and inability to attend sessions.

Intervention groups

The intervention group will receive the Family-Centered Empowerment Model in 8 group sessions, two sessions per week, each lasting 60 to 90 minutes. The control group will receive routine care and education, and the educational package will be provided after study completion.

Main outcome variables

Family function score measured by McMaster Family Assessment Device; caregiver burden score measured by Zarit Burden Interview, before, immediately after, and three months after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042900N7**
Registration date: **2026-07-29, 1405/05/07**
Registration timing: **prospective**

Last update: **2026-07-29, 1405/05/07**
Update count: **0**

Registration date

2026-07-29, 1405/05/07

Registrant information

Name

Shahriyar Salehitali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3334 9321

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-01, 1405/05/10

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of the Family-Centered Empowerment Model with routine care on family function and caregiver burden in family caregivers of patients with chronic heart failure

Public title
Effect of Family-Centered Empowerment on family function and caregiver burden in family caregivers of patients with chronic heart failure
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being the primary family caregiver of a patient with chronic heart failure classified as NYHA functional class III or IV. Family caregivers aged 18 years and older.Having at least 6 months of caregiving experience for the patient. Providing the main part of care for the patient by the family caregiver. Having the ability to read and write. Providing written informed consent to participate in the study.
Exclusion criteria:
Having a known psychiatric disorder or a history of psychiatric disorder based on medical records or caregiver self-report. Concurrent participation of the family caregiver in another research study at the time of enrollment. Having severe physical, cognitive, hearing, or speech impairment that prevents participation in empowerment sessions or completion of questionnaires. Inability of the family caregiver to attend the empowerment program sessions at the time of enrollment.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the unit of randomization will be each eligible family caregiver. After assessing the inclusion and exclusion criteria and obtaining written informed consent, family caregivers will be randomly allocated to one of two study groups: the intervention group receiving the family-centered empowerment model and the control group receiving routine care. Randomization will be performed using permuted block randomization with a fixed block size of four. To cover the total sample size of 64 participants, 16 blocks will be generated. In each block, two participants will be allocated to the intervention group and two participants to the control group, ensuring balanced group sizes throughout the recruitment process. The random allocation sequence will be generated before the start of recruitment by an independent person who is not involved in participant enrollment, using statistical software or Random Allocation Software. Allocation concealment will be maintained by keeping the randomization sequence unavailable to the researcher responsible for recruitment. Allocation will be implemented using sequentially numbered, opaque, sealed envelopes. Each envelope will be opened only after the participant has been definitively enrolled in the study and written informed consent has been obtained.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
There are no other design features.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Kashani Boulevard
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817846935
Approval date
2026-05-18, 1405/02/28
Ethics committee reference number
IR.SKUMS.NUMHE.REC.1405.012

Health conditions studied

1

Description of health condition studied
Chronic heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
The mean caregiver burden score among family caregivers of patients with chronic heart failure
Timepoint
Before the intervention, immediately after the intervention, and three months after the intervention
Method of measurement
Caregiver burden will be measured using the Zarit Burden Interview questionnaire. This questionnaire consists of 22 items, and higher scores indicate a greater caregiver burden.

2

Description
The mean family functioning score among family caregivers of patients with chronic heart failure
Timepoint
Before the intervention, immediately after the intervention, and three months after the intervention
Method of measurement
Family functioning will be measured using the McMaster Family Assessment Device questionnaire. This questionnaire evaluates different dimensions of family functioning, and higher scores indicate poorer family functioning.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Family caregivers in the intervention group will receive a program based on the Family-Centered Empowerment Model. The program will be delivered in 8 group sessions, two sessions per week, each lasting 60 to 90 minutes. The sessions will include perceived threat, improvement of self-efficacy and problem-solving, educational participation, and evaluation. The sessions will be held for small groups of family caregivers, and the educational content will be tailored to the caregiving needs of patients with chronic heart failure
Category
Behavior

2

Description
Control group: Family caregivers in the control group will receive routine care provided in the clinical setting. No additional educational intervention based on the Family-Centered Empowerment Model will be provided during the study period.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital
Full name of responsible person
Fatemeh Afrasiabi Lehdarazi
Street address
Parastar Street, Kashani Boulevard, Shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Shahriar Salehi Tali
Position
Associate Professor
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The deidentified individual participant data will include demographic characteristics of family caregivers, baseline caregiving-related information, Zarit Burden Interview scores, and McMaster Family Assessment Device scores measured before the intervention, immediately after the intervention, and three months after the intervention. The final study protocol, informed consent form, clinical study report, statistical analytic codes, and data dictionary will also be shared. All identifying information will be removed before data sharing.
When the data will become available and for how long
The deidentified data and supporting documents will become available after publication of the main study results and will remain available for 3 years after publication of the main results.

To whom data/document is available

The deidentified data and supporting documents will be available to qualified researchers affiliated with universities, academic institutions, or research organizations who submit a valid and methodologically sound research proposal. Requests from researchers in other sectors will also be considered if the proposed research is consistent with the study objectives and ethical research principles.

Under which criteria data/document could be used

Access to the data and documents will be granted only for research purposes consistent with the objectives of the original study and in accordance with ethical and confidentiality principles. Applicants must submit a research proposal including the study objective, methodology, analysis plan, and intended use of the data. Requests will be reviewed by the responsible investigator and research team. If approved, the applicant will be required to sign a data use and confidentiality agreement. Use of the data for participant identification or unrelated purposes will not be permitted.

From where data/document is obtainable

Applicants can request access to the deidentified data and supporting documents by sending an email to the responsible investigator at sh.salehitali@skums.ac.ir. The request should include a research proposal, the intended purpose of data use, the analysis plan, and the applicant's contact information. Additional communication can be made by telephone at +98 38 3224 0556 if needed.

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

The applicant must submit a formal request and research proposal by email. After receiving the request, the research team will review it for scientific validity, consistency with the study objectives, feasibility of the proposed analysis, and compliance with ethical and confidentiality principles. The review process will usually take up to 4 weeks. If the request is approved, the applicant will be required to sign a data use agreement, and the approved data and documents will then be provided through a secure transfer method.

Comments

All data sharing procedures will be conducted in accordance with research ethics principles, confidentiality requirements, and removal of participants' identifying information.