Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of transitional care program on care burden and quality of life of family caregivers of patients with multiple chronic diseases

Protocol summary

Study aim
Determining the impact of transitional care program on care burden and quality of life of family caregivers of patients with multiple chronic diseases in selected hospitals of Isfahan University of Medical Sciences 1402

Design
A single blind randomized clinical trial with a control group, with parallel groups, on 68 caregivers using statistical software.

Settings and conduct
This study will be conducted in selected hospitals of Isfahan University of Medical Sciences. The collected data will be analyzed after coding by a researcher unaware of the control and intervention groups.

Participants/Inclusion and exclusion criteria
The person responsible for caring for the patient who needs care by family caregivers due to disability (based on the WHODAS 12-item questionnaire to determine the patient's level of disability, people with severe and very severe disability will be determined. The patient has a score of 24 to obtain the above). Based on the self-declaration of the caregiver, the main responsibility of caring for the patient with heart failure and diabetes at the same time. Caregiver must be over 18 years old. The caregiver is required to be fluent in Farsi. Participating caregivers must be willing to take part in the study. Caregivers of family members suffering from multiple chronic diseases. The caregiver has the primary responsibility of caring for the patient. The caregiver should have the ability to cooperate in care, treatment, and prescribed medicines. The caregiver does not have mental health problems.

Intervention groups
The study is in two groups. In the intervention group, family caregivers of people with diabetes and heart failure will be under care at the same time. In the control group, they receive routine services from the hospital.

Main outcome variables
Care burden and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170625034743N3**
Registration date: **2023-08-31, 1402/06/09**
Registration timing: **prospective**

Last update: **2023-08-31, 1402/06/09**
Update count: **0**

Registration date
2023-08-31, 1402/06/09

Registrant information

Name
Leila Mardanian Dehkordi

Name of organization / entity
Isfahan University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of transitional care program on care burden and quality of life of family caregivers of patients with multiple chronic diseases

Public title
Investigating the effect of transitional care program on care burden and quality of life of family caregivers of patients with multiple chronic diseases
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The person responsible for caring for the patient who needs care by family caregivers due to disability (based on the WHODAS 12-item questionnaire to determine the patient's disability level, people with severe and very severe disabilities will be determined. The patient scored 24 or higher on the World Health Organization's disability assessment tool. Based on the self-declaration of the caregiver, the main responsibility of caring for the patient with heart failure and diabetes at the same time. The caregiver must be over 18 years old. Caregiver must speak Farsi. Caregivers are willing to participate in the study. Caregivers of family members suffering from multiple chronic diseases. The caregiver has the primary responsibility of caring for the patient. The caregiver should have the ability to cooperate in care, treatment, and prescribed medicines. The caregiver does not have mental health problems.
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
First, people will be selected by the available sampling method and will be placed in the intervention (A) and control (B) groups based on four blocks. First, blocks of four will be prepared as follows: AABB, ABAB, ABBA, BBAA, BABA, BAAB, then these blocks will be arranged randomly and people will be allocated according to A and B in two intervention and control groups; These will be repeated continuously until the sample size is completed.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher conducting data analysis will be blinded to the control and intervention groups, analyzing coded data.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hazarjarib St, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-08-29, 1402/06/07
Ethics committee reference number
IR.MUI.NURSEMA.REC.1402.091

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

2

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

Primary outcomes

1

Description
Burden of Care
Timepoint

before the intervention and two months after the intervention

Method of measurement

Zarit Care Burden Questionnaire

2

Description

Quality of Life

Timepoint

before the intervention and two months after the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire 26 questions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before starting the study, the participants complete demographic questionnaires, burden of care, and quality of life, and then they are under the care of a caregiver, Two months after discharge, the questionnaires are completed again by the caregiver.

Category

Treatment - Other

2

Description

Control group: Demographic, burden of care, and quality of life questionnaires are completed before the start of the study and the participants receive the usual care and counseling provided by the hospital. Then, after two months after the discharge, the questionnaires are filled again by the caregiver. The contents of the program will be available to the control group after the intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Training and Research Center

Full name of responsible person

Leila Mardanian Dehkordi

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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Deputy of Research and Technology, Building No.4, Isfahan University of Medical Sciences and Health Services, HazarJarib St., Isfahan

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Maryam Karami

Position
Nursing Graduate Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

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 collected data will be published through a paper.

When the data will become available and for how long
One year after study

To whom data/document is available
Reviewers and authors of the article

Under which criteria data/document could be used
Data are available from the authors upon reasonable request and with permission.

From where data/document is obtainable
Author

What processes are involved for a request to access data/document
By correspondence with the corresponding author via

email

Comments