

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

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 sizeTarget 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

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Isfahan

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

Khurshid educational, therapeutic and research complex

Full name of responsible person

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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

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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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