Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the Effectiveness of a Problem-Solving Skills Educational Intervention on Caregiver Burden and Resilience among Family Caregivers of Elderly Hemodialysis Patients Referred to Healthcare Centers

Protocol summary

Study aim

Determining the Effectiveness of a Problem-Solving Skills Training Intervention on Resilience and Caregiver Burden Among Family Caregivers of Older Adults Undergoing Hemodialysis

Design

A two-group, randomized, non-blinded quasi-experimental study with a pretest–posttest design and follow-up was conducted on 68 caregivers. Random allocation was performed using the RAND function in Microsoft Excel.

Settings and conduct

This study will be conducted at a hemodialysis center in Shiraz. After obtaining the required approval and coordinating with the head nurse, eligible caregivers will be identified through review of patients' medical records and interviews. Those who meet the inclusion criteria will be enrolled in the study after providing informed consent. The study will be conducted in a non-blinded manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria for caregivers: Being the primary caregiver who provides at least 4 hours of care per day; having no diagnosed psychiatric disorders; and being able to read and write. Inclusion criteria for older adults: Age 65 years or older; absence of severe cognitive impairment; having no more than two diagnosed chronic diseases; and having a primary family caregiver. Exclusion criteria: Patient's death; caregiver absence from two educational sessions; diagnosis of a new illness in the patient; unwillingness to continue participation; or occurrence of a family crisis during the study period.

Intervention groups

Thirty-four caregivers in the intervention group will be divided into five small subgroups of 5–8 participants and will attend five weekly educational sessions (approximately one hour each). The sessions will be conducted by the nurse researcher and will include a combination of brief lectures, PowerPoint presentations, group discussions, and question-and-answer segments.

Main outcome variables

Caregiver Burden , Resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260215068868N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **prospective**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date

2026-02-16, 1404/11/27

Registrant information

Name

shaghayegh yadollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effectiveness of a Problem-Solving Skills Educational Intervention on Caregiver Burden and Resilience among Family Caregivers of Elderly Hemodialysis Patients Referred to Healthcare Centers

Public title

Evaluating the Effectiveness of a Problem-Solving Skills Educational Intervention on Caregiver Burden and Resilience among Family Caregivers of Elderly Hemodialysis Patients Referred to Healthcare Centers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria for caregivers: having no diagnosed psychiatric disorders Willingness to participate in the study. Ability to read and write. Age between 18 and 65 years No participation in similar educational programs during the past six months Inclusion criteria for older adults: Age 65 years or older No severe cognitive impairment or dementia Having no more than two diagnosed chronic diseases. No history of kidney transplantation Having a primary family caregiver for home care

Exclusion criteria:

Patient death Caregiver absence from two educational sessions Diagnosis of a new illness in the patient Caregiver’s unwillingness to continue participation during the study Occurrence of a family crisis (such as divorce, financial crisis, or death of a first-degree family member) during the study period

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are allocated to either the intervention or control group through simple randomization using the last two digits of their national ID numbers. Specifically, if the last two digits of the national ID number are even, the individual is assigned to the intervention group, and if they are odd, they are assigned to the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Jiroft University of Medical Sciences

Street address

Research and Technology Vice-Chancellery Building, Pasdaran Blvd, Jiroft, Iran

City

Jiroft

Province

Kerman

Postal code

7861634200

Approval date

2025-09-23, 1404/07/01

Ethics committee reference number

IR.JMU.REC.1404.032

Health conditions studied

1

Description of health condition studied

Caregiver Burden and Resilience among Family Caregivers of Elderly Hemodialysis Patients

ICD-10 code

N19

ICD-10 code description

Unspecified kidney failure

Primary outcomes

1

Description

Resilience

Timepoint

Data will be analyzed using descriptive statistics, independent t-test, paired t-test, and, if necessary, non-parametric tests

Method of measurement

The Connor- Davidson Resilience Scale, and the Zarit Burden Interview

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group:In this group, 34 caregivers will be allocated through simple randomization (based on whether the last two digits of their national ID number are even or odd). Participants will attend five weekly problem-solving skills training sessions over five consecutive weeks (each session lasting approximately one hour). The sessions will be conducted by the nurse researcher and will include a combination of brief lectures with PowerPoint presentations, group discussions, and question-and-answer segments. At the end of the first session, an educational booklet will be provided to participants. Questionnaires will be completed at three time points: before the intervention, immediately after completion of the sessions, and one month after the end of the intervention.

Category
Other

2

Description
Control group: Another 34 caregivers who are randomly assigned to the control group will receive no training or intervention during the study period and will only complete the questionnaires at the same three time points as the intervention group. To adhere to research ethics principles, after the completion of the study, the educational content will be delivered to this group in a two-hour session, and the educational booklet will also be provided to them.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Educational and Medical Center, Shiraz
Full name of responsible person
Dr Mohammad Rahmanian
Street address
Namazi Educational and Medical Center, Namazi Square, Zand Street, Shiraz
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2

Recruitment center
Name of recruitment center
Abu Ali Sina Organ Transplantation Hospital, Shiraz, Iranی
Full name of responsible person
Dr Bagher Khosravi
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Sadra New City, Phase 2, toward Dokouhak, opposite Pardis Garden City, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jeeroft University of Medical Sciences
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Central Headquarters of Jiroft University of Medical Sciences and Health Services, Shohadaye Ashayer Building, Enghelab Square, Jiroft
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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
Jeeroft 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

Jeeroft University of Medical Sciences

Full name of responsible person

Shaghayegh Yadollahi

Position

Student

Latest degree

Master

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Based on the findings of the study, educational content tailored to the needs of family caregivers of older adults undergoing hemodialysis will be developed. This content will be designed in the form of simple, easy-to-understand educational brochures using non-technical language and practical instructional images. In addition, a short educational video focusing on problem-solving skills training and strategies to enhance caregivers' resilience will be produced. This video can be presented in dialysis centers, health education programs, and health-related social media platforms. In developing these materials, the scientific findings of the study and the real needs of caregivers will be utilized to ensure that the content is practical, effective, and understandable for the general public.

When the data will become available and for how long

After completion of the study

To whom data/document is available

Submission of the research findings to Shiraz University of Medical Sciences Presentation of the findings at meetings of Clinical Ethics Committees and Quality Improvement Committees in healthcare centers Publication of the article in reputable national or international scientific journals Sharing the findings with associations related to older adults, caregivers, and patients with kidney disease

Under which criteria data/document could be used

Follow-up and evaluation of learning through questionnaires and home-based exercises Designing simple and practical tools (such as brochures and problem-solving checklists) for caregivers to use in the home setting

From where data/document is obtainable

Submission of the research findings to Shiraz University of Medical Sciences Presentation of the findings at meetings of Clinical Ethics Committees and Quality Improvement Committees in healthcare centers Publication of the article in reputable national or international scientific journals Sharing the findings with associations related to older adults, caregivers, and patients with kidney disease

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

Submission of the research findings to Shiraz University of Medical Sciences Presentation of the findings at meetings of Clinical Ethics Committees and Quality Improvement Committees in healthcare centers Publication of the article in reputable national or international scientific journals Sharing the findings with associations related to older adults, caregivers, and patients with kidney disease

Comments