Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Narrative Reminiscence Intervention on Care Burden and Resilience among Hemodialysis Patients and their Family Caregivers

Protocol summary

Study aim
Determining the impact of narrative reminiscing intervention on care burden and resilience among hemodialysis patients and their home caregivers

Design
A Phase 3, randomized, unblinded (open-label), parallel-group controlled clinical trial conducted on 64 patients. Random allocation software was used for randomization

Settings and conduct
Hemodialysis patients and their home caregivers attending centers in Lamerd and Mehr counties will be selected via random sampling. Block randomization will then be used for group allocation. The intervention group will receive the structured group reminiscence protocol, delivered by the researcher in 6 group sessions (60–90 minutes each).

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patient: undergoing hemodialysis for chronic kidney disease, aged ≥18, no prior kidney transplant, no psychiatric history/medications, and physically/mentally fit to respond. Caregiver: a family member with ≥1 year of caregiving experience for this patient (per patient's report). Exclusion Criteria: atient: death, hospitalization for relapse/transplant, or a social/family crisis during the study. Caregiver: development of serious physical/neurological/psychiatric disorders impairing care ability, withdrawal from the study, or missing ≥2 sessions

Intervention groups
Intervention group: Participants receive a structured group reminiscence protocol. This protocol involves narrating one's life story from childhood to the present day, covering topics such as school, occupation, marriage, children, and leisure activities (including travel, cooking, gardening, and pets/animals). Control group: The control group did not receive any additional training and only received the routine standard education provided by the hemodialysis centers

Main outcome variables
Care Burden

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260725070340N1**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date
2026-08-01, 1405/05/10

Registrant information

Name
Fateme Ahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-10-23, 1405/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effect of Narrative Reminiscence Intervention on Care Burden and Resilience among Hemodialysis Patients and their Family Caregivers

Public title
he Effect of Narrative Reminiscence on Care Burden and Resilience among Hemodialysis Patients and their Family Caregivers

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The samples should demonstrate voluntary willingness to participate in the research Participants should require hemodialysis due to chronic kidney disease Patients should be familiar with the Persian language Patients should have no history of prior kidney transplantation Patients should be at least 18 years of age. Patients should have the physical and mental readiness to answer the questions Patients should have no history of mental illness or use of psychiatric medications. The caregiver should have a family relationship with the patient. The caregiver should have been responsible for the care of the hemodialysis patient for at least one year (based on the patient's report)

Exclusion criteria:
Occurrence of any social or family crisis during the study. Absence from more than one session Unwillingness of the patients to continue participation in the research Hospitalization of the patient due to disease recurrence or transplant surgery Death of the patient during the study stages Withdrawal of the individual from continued cooperation with the research team during the study The caregiver developing serious physical problems during the study to the extent that they lose their ability to care for the patient Failure of the designated caregiver to participate in two or more sessions

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
"Randomized block randomization was used to allocate the participants. A total of 16 blocks, each containing four allocations, were considered for the randomization process. Within each block, the sequence of allocations was randomly arranged. After determining the blocks and their sequences, the starting block was selected using a die (e.g., block 5). Subsequently, participants (or pairs) were assigned to the predetermined sequence groups according to their order of entry into the study, beginning with block number 5. The randomization procedure was performed using the Random Allocation Software, version 2.

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 Gerash University of Medical Sciences

Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran

City
Gerash

Province
Fars

Postal code
58666 – 74417

Approval date
2026-02-24, 1404/12/05

Ethics committee reference number
IR.GERUMS.REC.1404.027

Health conditions studied

1

Description of health condition studied
Hemodialysis patients

ICD-10 code
Z49

ICD-10 code description
Encounter for care involving renal dialysis

Primary outcomes

1

Description
Care Burden

Timepoint
Before, immediately after, and one month after the intervention

Method of measurement
Novak & Guest Caregiver Burden Inventory - CBI

Secondary outcomes

1

Description
Resilience
Timepoint
Before, immediately after, and one month after the intervention
Method of measurement
Connor-Davidson Resilience Scale

Intervention groups

1

Description
Intervention group: Participants receive a structured group reminiscence protocol. This protocol involves narrating one's life story from childhood to the present day, covering topics such as school, occupation, marriage, children, and leisure activities (including travel, cooking, gardening, and pets/animals).
Category
Lifestyle

2

Description
Control group: The control group did not receive any additional training and only received the routine standard education provided by the hemodialysis centers
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis ward of Haj Mahmoud Haj Heydar Hospital, Lamerd, Fars Province, Lamerd County, Iran
Full name of responsible person
Fatemeh Ahmadi
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2

Recruitment center
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Dialysis ward of Fatemeh Al-Zahra Hospital, Mohr County, Fars Province, Iran
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Sponsors / Funding sources

1

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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
Gerash 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
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Fateme Ahmadi
Position
Student
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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