

# 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  $\geq 18$ , no prior kidney transplant, no psychiatric history/medications, and physically/mentally fit to respond. Caregiver: a family member with  $\geq 1$  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  $\geq 2$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5244 8105

##### Email address

fateme25671@gmail.com

##### 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

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| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | beginning with block number 5. The randomization procedure was performed using the Random Allocation Software, version 2.                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Scientific title</b><br>The Effect of Narrative Reminiscence Intervention on Care Burden and Resilience among Hemodialysis Patients and their Family Caregivers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Blinding (investigator's opinion)</b><br>Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Public title</b><br>he Effect of Narrative Reminiscence on Care Burden and Resilience among Hemodialysis Patients and their Family Caregivers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Blinding description</b><br><b>Placebo</b><br>Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Purpose</b><br>Education/Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>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)<br><b>Exclusion criteria:</b><br>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 | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Age</b><br>From <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Ethics committees</b><br><b>1</b><br><b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics committee of Gerash University of Medical Sciences<br><b>Street address</b><br>Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran<br><b>City</b><br>Gerash<br><b>Province</b><br>Fars<br><b>Postal code</b><br>58666 - 74417<br><b>Approval date</b><br>2026-02-24, 1404/12/05<br><b>Ethics committee reference number</b><br>IR.GERUMS.REC.1404.027 |
| <b>Phase</b><br>3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Health conditions studied</b><br><b>1</b><br><b>Description of health condition studied</b><br>Hemodialysis patients<br><b>ICD-10 code</b><br>Z49<br><b>ICD-10 code description</b><br>Encounter for care involving renal dialysis                                                                                                                                                                                                                                                                                 |
| <b>Groups that have been masked</b><br><i>No information</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Primary outcomes</b><br><b>1</b><br><b>Description</b><br>Care Burden<br><b>Timepoint</b><br>Before, immediately after, and one month after the intervention<br><b>Method of measurement</b><br>Novak & Guest Caregiver Burden Inventory - CBI                                                                                                                                                                                                                                                                     |
| <b>Sample size</b><br>Target sample size: <b>64</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Randomization description</b><br>"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,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

## 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

##### Street address

Parastar Boulevard, Lamerd County, Fars Province

##### City

Lamerd

##### Province

Fars

##### Postal code

۷۴۴۵۱۱۳۴۷۵

##### Phone

+98 71 5272 2201

##### Email

fateme25671@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Dialysis ward of Fatemeh Al-Zahra Hospital, Mohr County, Fars Province, Iran

##### Full name of responsible person

Fatemeh Ahmadi

##### Street address

Fatemeh Al-Zahra Hospital, Persian Gulf Boulevard, Mehr County, Fars Province, Iran

##### City

Mohr

##### Province

Fars

##### Postal code

۷۴۴۵۱۱۳۴۷۵

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##### Email

fateme25671@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gerash University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Jafari

##### Street address

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

##### City

Gerash

##### Province

Fars

##### Postal code

7441758666

##### Phone

+98 71 5245 2335

##### Email

Jafari@gerums.ac.ir

#### 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**

Gerash University of Medical Sciences

**Full name of responsible person**

Fateme Ahmadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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Boulevard, Imam Hossein (AS) Boulevard, Gerash,  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gerash University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Mohsenzadeh

**Position**

Assistant professor

**Latest degree**

Ph.D.

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Reproductive Biology

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**Person responsible for updating data****Contact****Name of organization / entity**

Gerash University of Medical Sciences

**Full name of responsible person**

Fateme Ahmadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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Boulevard, Imam Hossein (AS) Boulevard, Gerash,  
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**Province**

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**Postal code**

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**Phone**

+98 71 5244 8105

**Fax****Email**

fateme25671@gmail.com

**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