Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial

Protocol summary

Study aim
Determining the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial.

Design
Randomized controlled trial, parallel group, single-blind, phase 0, 62 patients. Sealed Envelope Ltd was used for randomization.

Settings and conduct
In the intervention group, three weekly training sessions will be held via telenursing for one month. The aim of this training program is to increase the resilience of caregivers of elderly people undergoing dialysis and reduce their care burden. The sessions will be conducted over the phone and using digital resources such as PDF files, videos, and SMS. The research setting will include hemodialysis centers in hospitals in eastern Guilan. The list will be generated by the Sealed Envelope Ltd service and group allocation will be done using sealed envelopes.

Participants/Inclusion and exclusion criteria
Participants must be at least 18 years old, responsible for caring for an elderly person on dialysis for at least one month, literate, and free of speech, hearing, and mental health issues. They must also have access to a landline and mobile phone and some e-literacy. Elderly participants must be 60 or older, receiving dialysis, and have a home caregiver. Exclusion criteria include death, unwillingness to continue, participation in other studies, communication issues, caring for another patient, and missing more than two sessions.

Intervention groups
A face-to-face meeting will be held before telenursing sessions begin. All sessions will be conducted via phone calls, text messages, and electronic content on a virtual platform (e.g., Telegram). The control group will receive routine care.

Main outcome variables
The main outcomes are resilience and caregiving burden of caregivers of elderly people on hemodialysis.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250414065319N1**
Registration date: **2025-04-22, 1404/02/02**
Registration timing: **prospective**

Last update: **2025-04-22, 1404/02/02**
Update count: **0**
Registration date
2025-04-22, 1404/02/02

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-10-07, 1404/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial

Public title

The effect of telenursing on resilience and caregiving burden

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Being eighteen years of age or older Taking primary responsibility for caring for an elderly person undergoing dialysis for at least one month Having at least basic reading and writing skills No problems with speech and hearing Not having psychological illnesses Having access to a landline and mobile phone for communicating via telenursing Having a minimum level of electronic literacy, including the ability to use a mobile phone (flat or smart) to communicate via text messages and phone calls.

Exclusion criteria:

Death of the patient Unwillingness to continue cooperation Caregivers' inability to communicate Lack of minimum literacy Taking care of another patient at the same time Absent from more than two meetings

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, stratified random sampling will be employed to minimize demographic differences among the caregivers of the elderly and control confounding factors. All eligible caregivers will be randomly assigned to the intervention and control groups using a stratified block randomization method, with block sizes of 4 and 6, in a 1:1 ratio. To generate the randomization list, the online randomization service Sealed Envelope Ltd will be utilized. Allocation Concealment Method: Opaque, sealed envelopes with random sequences (SNOSE) will be used after determining the block randomization sequence. Based on the sample size of the study, a number of envelopes with aluminum foil wrappers (to prevent the visibility of the envelope contents) will be prepared. Each random sequence will be recorded on a card, and the cards will be placed in the envelopes in order. To maintain the random sequence, the envelopes will be numbered on the outside in the same order. Finally, the envelope flaps will be sealed, and the envelopes will be placed in a box in sequential order. During the participant enrollment phase, based on the order of participant entry into the study, one envelope will be opened in turn, revealing the assigned group for that participant.

Blinding (investigator's opinion)

Single blinded

Blinding description

The randomization list will be generated using the online randomization service Sealed Envelope Ltd. Allocation Concealment Method: Opaque, sealed envelopes with random sequences (SNOSE) will be used after determining the block randomization sequence. Based on the sample size of the study, a number of envelopes with aluminum foil wrappers (to prevent the visibility of the envelope contents) will be prepared. Each random sequence will be recorded on a card, and the cards will be placed in the envelopes in order. To maintain the random sequence, the envelopes will be numbered on the outside in the same order. Finally, the envelope flaps will be sealed, and the envelopes will be placed in a box in sequential order. At the time of participant enrollment, based on the order of eligible participants entering the study, one envelope will be opened in turn, revealing the assigned group for that participant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Langrud - Leila Kooh Road - Shahid Yaqoub Sheikhi Street - School of Nursing, Midwifery and Paramedical Sciences, East Guilan

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Rasht

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4477166595
Approval date
2025-03-17, 1403/12/27
Ethics committee reference number
IR.GUMS.REC.1403.538

Health conditions studied

1

Description of health condition studied
Resilience and caregiving burden in caregivers of elderly people undergoing hemodialysis treatment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
In the study "Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial," the primary outcome could be the resilience of caregivers of elderly people undergoing hemodialysis treatment, which is measured using the "Connor-Davidson Resilience Scale Questionnaire."
Timepoint
In the study "Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial," the time points for measuring resilience were at the beginning of the study (before the intervention) and after the intervention for 4 weeks.
Method of measurement
In the study "Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial," the outcome variable was measured using the "Connor-Davidson Resilience Scale Questionnaire."

2

Description
In the study "Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: A randomized controlled trial," the primary outcome could be the caregiving burden of caregivers of elderly people undergoing hemodialysis treatment, which is measured using the "Zarit Psychological Burden Questionnaire."
Timepoint
In the study "Investigating the effectiveness of family-centered education based on telenursing on the resilience and caregiving burden of caregivers of elderly people undergoing hemodialysis treatment: a randomized controlled trial," the time points for measuring caregiving burden were at the beginning of the study (before the intervention) and after the intervention for 4 weeks.
Method of measurement
In the study "Investigating the Effectiveness of Family-Centered Education Based on Telenursing on Resilience and Caregiving Burden of Elderly Caregivers Undergoing Hemodialysis Treatment: A Randomized Controlled Trial," the outcome variable (caregiving burden) was measured using the "Zarit Caregiving Burden Scale Questionnaire."

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, three weekly telenursing training sessions are held for one month for caregivers of elderly people undergoing dialysis. These sessions include scientific and practical content to increase resilience and reduce caregiving burden. The content of the sessions is provided via telephone, PDF files, videos, and SMS. The first week is dedicated to familiarizing with caregiving needs, physical and psychological problems. The second week focuses on stress management and resilience. The third week emphasizes social and psychological support, and the fourth week focuses on time management and reducing caregiving burden. Training is also provided by telephone and in 10-15 minute intervals from 8 am to 8 pm. Finally, the impact of the interventions is examined by re-evaluating caregiving burden and resilience.
Category
Other

2

Description
Control group: Control group: The control group in this study consists of caregivers of elderly people undergoing hemodialysis who receive only routine hospital training and no specific intervention such as family-centered telenursing training is applied to them. This training is provided in a general and standardized manner and includes basic information about kidney disease and hemodialysis treatment, but lacks telephone follow-up or specific educational content to reduce caregiving burden and increase resilience. The purpose of the control group is to compare the effects of the experimental group intervention with a group that receives only routine interventions, in order to assess the real effect of telenursing training on resilience and caregiving burden.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Pirouz Hospital, Lahijan

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Mahdi Fallah Heydarinezhad

Position
Master's degree student in Geriatric Nursing

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
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

Title and more details about the data/document
The data related to this study include the results obtained from the Connor-Davidson Resilience and Zarit Caregiver Burden Questionnaires that were collected. These data include scores obtained from caregivers of elderly people undergoing hemodialysis treatment, from whom questionnaires measuring resilience and caregiving burden were received during the study. The data volume includes responses collected from participants and is stored in Excel and CSV formats. These data were collected specifically to analyze the effect of telenursing-based family-centered education on the resilience and caregiving burden of elderly caregivers and will be made available for research purposes. Also, the documentation includes clinical reports and educational data related to the interventions performed in the intervention and control groups, which are made available to academic and treatment centers in the form of PDF files and written reports.

When the data will become available and for how long
6 months after publication of the article

To whom data/document is available
Researchers working in academic and scientific institutions and medical centers

Under which criteria data/document could be used
Data is accessible through academic coordination and direct communication with the person in charge.

From where data/document is obtainable
Communication with the responsible person as well as academic institutions.

What processes are involved for a request to access data/document
Communication will be established via email and correspondence and a response will be provided within a week at most.

Comments