

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of family-centered empowerment intervention on perceived severity of threat in caregivers of patients with hemodialysis

Protocol summary

Summary

This semii-experimental study is a pre-test and post-test design. The study population was all carers of hemodialysis patients referring to Imam Khomeini Hospital Khomein. Convenient sampling was done. At the time of entering the study, caregivers' maturity is based on the Barthel's assessment of the patients under their care, then the caregivers of patients in five blocks (24- 0 with complete dependence, 25-49 with severe dependence, 50- 74 with moderate dependence, 75-89 with mild affiliation and 99-90 with very low dependence and 100 indicating non-dependence). Then, the subjects of each block are randomly assigned to two groups of test and control. The caregivers of the two groups completed the questionnaires before the intervention and then the intervention group received 5 training sessions for the study purposes. . These trainings include anxiety and depression control programs, fatigue elimination, elimination of physical health problems, relief and relief concerns, and eliminating the guilt and fault of the caregiver in order to prevent relapse due to care problems. The Patient Care Instruction Book is also provided to them. For the final evaluation, the test group again completed the perceived severity questionnaire four weeks after the last session of empowerment. The control group also completed the questionnaire four weeks after completing the questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082725843N3**

Registration date: **2017-08-28, 1396/06/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-28, 1396/06/06

Registrant information

Name

Hajar Sadeghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Khomein University of Medical Sciences

Expected recruitment start date

2017-02-08, 1395/11/20

Expected recruitment end date

2017-08-02, 1396/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered empowerment intervention on perceived severity of threat in caregivers of patients with hemodialysis

Public title

The effect of family-centered empowerment intervention on perceived severity of threat in caregivers of patients with hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: willingness to participate in the study; physical and mental ability to take care of the patient; caring for a hemodialysis patient who has been hemodialyzed over the past 6 weeks; 18 years old caregivers or older; have literacy to read and write; caregivers can speak Persian. Exclusion criteria: unwillingness of research or a member of his family to cooperate at every stage of research; patient or caregivers hospitalization; physical or mental problems that lead to disability at any stage of the research.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Arak University of Medical Sciences

Street address
Arak University of Medical Science, Faculty of nursing and midwifery, Sardasht, Arak

City
Arak

Postal code

Approval date
2017-02-08, 1395/11/20

Ethics committee reference number
IR.ARAKMU.REC.1395.427

Health conditions studied

1

Description of health condition studied
Hemodialysis

ICD-10 code
Z49.1

ICD-10 code description
Hemodialysis

Primary outcomes

1

Description
Severity of perceived threat in caregivers

Timepoint
Before and 4 weeks after intervention

Method of measurement
Modified Barthel Index and severity of perceived threat questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group participates in 5 sessions of two-hour training to empower caregivers in family-based care by improving the level of knowledge and awareness of caregivers, about the process of illness and the severity of the complications and the process of treatment, and how to ensure proper care of the patient and adapt to the role of care. . This empowerment is a collection of information, behaviors and practices that are based on the needs of caregivers to reduce and prevent the complications and risks of the disease on the self-care taker, including anxiety and depression control programs, fatigue removal, fixing Careful physical problems, relieve troubles and concerns about recurrence of the disease, and eliminate the feeling of guilt and fault in the caregiver that the disease has not been relapsed due to care problems. Then carers begin to discuss their issues based on their experiences and the researcher has a supportive, guidance and educational background. At the end of each session, after the discussions are finalized, their questions will be answered, and the date and purpose of the next meeting will be determined next week, as well as a handbook on patient care education.

Category
Other

2

Description
Control group: Control group receive routine cares.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Street address

City

Khomein

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Khomein University of Medical Sciences

Full name of responsible person

Hajar Sadeghi

Street address

Saculty of nursing, next to health center, Qods Blvd.

City

Khomein

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Khomein University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Khomein University of Medical Science

Full name of responsible person

Hajar Sadeghi

Position

MSc

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty