Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of a Family-Centered Empowerment Program on Care Burden and Anxiety of Primary Caregivers of Patients with Epilepsy

Protocol summary

Study aim
To assess the effect of a family-centered empowerment program on reducing caregiver burden among primary caregivers of patients with epilepsy.

Design
This study was a single-blind, parallel, randomized clinical trial.

Settings and conduct
The study was conducted at the Iranian Epilepsy Association (Tehran) in 2023. After ethical approval and informed consent, eligible caregivers were enrolled and baseline assessments were completed online. The intervention group received structured empowerment sessions (details entered elsewhere). Follow-up assessments were completed after the intervention. The trial was single-blind: the data analyst was blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion: First- or second-degree relatives of a person with epilepsy; at least 6 months of caregiving; literacy; access to a smartphone and social networks; age ≥18 years. Exclusion: Unwillingness to participate; serious psychiatric or physical illness in the caregiver.

Intervention groups
The intervention group received a family-centered empowerment program consisting of six weekly 60-minute sessions focused on coping strategies, emotional support, stress management, and caregiving techniques. The control group received routine care and no additional educational content.

Main outcome variables
Caregiver burden; state anxiety; trait anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250702066335N1**
Registration date: **2025-11-07, 1404/08/16**
Registration timing: **retrospective**

Last update: **2025-11-07, 1404/08/16**
Update count: **0**

Registration date
2025-11-07, 1404/08/16

Registrant information

Name
Sepideh Beyrami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 933 814 3765

Email address
sepideh.beyrami1997@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-06, 1404/05/15

Expected recruitment end date
2025-09-21, 1404/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of a Family-Centered Empowerment Program on Care Burden and Anxiety of Primary Caregivers of Patients with Epilepsy

Public title
Family Education to Reduce Caregiver Stress in Epilepsy

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
First-degree or second-degree relative of a patient with epilepsy At least 6 months of caregiving experience Ability to read and write Access to a smartphone and social networks Age above 18 years Ability to use a VPN to access WhatsApp
Exclusion criteria:
Caregivers who are not available at the time of enrollment Caregivers with a known serious psychiatric or physical illness Caregivers who are unable to give informed consent Caregivers experiencing a major stressful life event shortly before enrollment Caregivers with a history of non-adherence in similar studies Any condition that, in the opinion of the research team, makes participation unsafe or unfeasible
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple individual randomization with a 1:1 allocation ratio between the intervention and control groups was applied. Before participant recruitment, an independent statistician (not involved in recruitment, intervention delivery, or outcome assessment) generated the random allocation sequence using the RAND function in Microsoft Excel. For each participant, a random number between 0 and 1 was produced; values below 0.5 were assigned to the intervention group, and values equal to or above 0.5 were assigned to the control group. The unit of randomization was each individual participant. The final allocation list was password-protected and accessible only to the statistician. To ensure allocation concealment, the researcher responsible for participant enrollment had no access to the random sequence or future assignments. After confirming eligibility, the statistician disclosed each assignment sequentially via confidential email or secure phone call. This procedure ensured complete randomization integrity and allocation concealment.
Blinding (investigator's opinion)
Single blinded
Blinding description
This is a single-blind randomized clinical trial. Only the outcome assessors are blinded to group allocation and are not aware of which participants are in the intervention or control groups. Participants and care providers are not blinded due to the nature of the intervention (a family-centered care program delivered via WhatsApp). Data collectors are not involved in outcome evaluation. The principal investigator and data analysts are aware of group assignments.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ethics Committees of School of Nursing & Midwifery & Rehabilitation, TUMS
Street address
Address: 4th Floor, Central Building, Tehran University of Medical Sciences, Ghods Street and Keshavarz Blvd Intersection, Tehran, Iran Affiliated with: School of Nursing and Midwifery & School of Rehabilitation, Tehran University of Medical Sciences
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Province
Tehran
Postal code
1419733171
Approval date
2022-12-26, 1401/10/05
Ethics committee reference number
IR.TUMS.FNM.REC.1401.130

Health conditions studied

1

Description of health condition studied
Epilepsy
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
Caregiver burden measured by the Novak & Guest Caregiver Burden Inventory. This is a primary outcome variable.
Timepoint
Before intervention (baseline), and 4 weeks after intervention
Method of measurement
Caregiver burden will be quantified using the Novak &

Guest Caregiver Burden Inventory, a standardized questionnaire assessing multiple burden dimensions (time-dependence, developmental, physical, social, emotional). Scores will be computed according to the instrument manual.

2

Description
State anxiety of caregivers measured by the Spielberger State-Trait Anxiety Inventory (state subscale). This is a primary outcome variable.
Timepoint
Before intervention (baseline), and 4 weeks after intervention
Method of measurement
State anxiety will be measured using the state subscale of the Spielberger State-Trait Anxiety Inventory (STAI-S), a validated self-report instrument. Scores are calculated per the STAI manual.

3

Description
Trait anxiety of caregivers measured by the Spielberger State-Trait Anxiety Inventory (trait subscale). This is a primary outcome variable.
Timepoint
Before intervention (baseline), and 4 weeks after intervention
Method of measurement
Trait anxiety will be measured using the trait subscale of the Spielberger State-Trait Anxiety Inventory (STAI-T). Scores are calculated according to the STAI manual.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group received a structured problem-solving coping skills training program designed to support family caregivers of patients with epilepsy in managing caregiver burden and anxiety. Four in-person sessions were conducted over two weeks (two sessions per week, each lasting 60 minutes) at the Tehran Epilepsy Association. The sessions included lectures, group discussions, question-and-answer, and role-playing, supported by educational slides and booklets. The training content covered understanding epilepsy and its complications, methods of patient support, stress management, and information about medications. To enhance effectiveness and interaction, a WhatsApp group was created including study participants and the research team. Participants completed baseline assessments of caregiver burden and anxiety via online links prior to the intervention.
Category
Behavior

2

Description
Control group: The control group received only routine care without any structured educational intervention during the study. Baseline assessments of caregiver burden and anxiety were collected using the same standardized questionnaires as in the intervention group. After completion of the study, all educational materials were provided to the control group.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
The recruitment center for this study was the Iranian Epilepsy Association, Tehran Branch
Full name of responsible person
Sepideh Beyrami
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Iranian Epilepsy Association, No. 123, Valiasr Street, Before Valiasr Square, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr. Ramin Kordi (Acting Vice-Chancellor for Research and Technolgy
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Grant name
Office of the Vice-Chancellor for Research, Tehran University of Medical Sciences (Investigator-initiated thesis supported by the School of Nursing and Midwifery)
Grant code / Reference number
Not applicable – investigator-initiated academic thesis; no formal grant code assigned.
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Title: De-identified Participant Data on Anxiety and Caregiver Burden Details: This includes pre- and post-intervention scores on the Spielberger State-Trait Anxiety Inventory and the Novak & Guest Caregiver Burden Inventory. All data are anonymized and do not contain any personally identifiable information.

When the data will become available and for how long

The data will become available 6 months after the publication of the thesis or main article and will remain accessible for up to 3 years.

To whom data/document is available

Data will be available to academic researchers affiliated with recognized institutions and organizations who submit a justified scientific request.

Under which criteria data/document could be used

Access will be granted to researchers who provide both ethical approval and a scientifically sound proposal for secondary analysis. The data will be shared exclusively for non-commercial, academic research purposes. All requests will be reviewed by the principal investigator in coordination with the institutional ethics committee.

From where data/document is obtainable

Requests should be directed to: Name: Sepideh Beyrami Affiliation: Tehran University of Medical Sciences Email: Sepideh.beyrami1997@gmail.com Phone: +98 9338143765 Address: School of Nursing and Midwifery, Valiasr Street, Tehran University of Medical Sciences, Tehran, Iran

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

The applicant must submit a formal request via email, including a brief description of the study, ethical approval, and justification for data use. The review process may take up to 4 weeks, after which the applicant will be notified by email.

Comments

None