

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

the effect of family-centered empowerment model implementation on family caregivers burden Parkinson's Elderly

Protocol summary

Study aim

Determining the Impact of Family-Based Empowerment Model on Caregivers Carers in Parkinson's Elderly

Design

This training has two groups of control and intervention and the selection of groups based on simple randomization The sample size of 30 patients for the intervention group and 30 patients for the control group is estimated. In this study, the parallel study design is a pragmatic type of practice.

Settings and conduct

This study will be carried out on the main carers of Parkinson's and Parkinson's elderly patients referred to the special clinic of Ghaem Hospital in Mashhad. The research units will be divided into two groups of intervention and control before intervention. The care burden questionnaire was completed in both groups, then in the intervention group, a family-centered empowerment model consisting of 4 sessions of empowerment education (weekly 2sessions of 45 minutes) will be held. This four-step pattern of perceived threat, problem-solving, participation Training and evaluation. Family-bempowerment program in K School will be held As·hay

Participants/Inclusion and exclusion criteria

Major caregivers to study: Family members and primary caregivers of an elderly patient with Parkinson's disease. He has been taking care of the patient for at least 6 months. The main caregiver will have the desire to participate in the study. The main educator should have read and write literacy.

Intervention groups

In the intervention group, a family-centered empowerment model consisting of 4 sessions of empowerment training (weekly 2 45-minute sessions) will be held. This is a four-step pattern of perceived threat, problem-solving, learning participation, and evaluation.

Main outcome variables

Caregivers Career Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181014041342N1**

Registration date: **2018-11-05, 1397/08/14**

Registration timing: **prospective**

Last update: **2018-11-05, 1397/08/14**

Update count: **0**

Registration date

2018-11-05, 1397/08/14

Registrant information

Name

Somayeh Bagheri aghoei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5229 9245

Email address

bagherias951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	control groups
Scientific title	Placebo
the effect of family-centered empowerment model implementation on family caregivers burden Parkinson's Elderly	Not used
	Assignment
	Parallel
	Other design features
Public title	Secondary Ids
the effect of family-centered empowerment model implementation on family caregivers burden Parkinson's Elderly	empty
Purpose	Ethics committees
Education/Guidance	1
Inclusion/Exclusion criteria	Ethics committee
Inclusion criteria:	Name of ethics committee
Seniority Entry Criteria: Age over 60 A definitive diagnosis of Parkinson's has been confirmed by a brain specialist. Except for Parkinson's disease, there is no other significant disease (cancer, dementia, speech impairment, deafness, debilitating heart disease, respiratory, renal disease) Elderly tend to participate in the study Major caregivers entry rates: Family members and primary caregivers of an elderly patient with Parkinson's disease. Take care of the patient for at least 6 months. The main investigator will have the desire to participate in the study. The main educator should have read and write literacy.	The Ethics Committee of the Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Exclusion criteria:	Street address
Exit criteria. Watch out for study: Refrain from continuing to participate in the study and collaborating with the researcher Disease disease Other diseases The emergence of conditions that the patient's caregiver can not use from the provided training Caring for someone else to take care of Parkinson's disease to another person or to care centers The failure of the main caregiver in more than one session of the classroom Expiry criteria for the study: Unwillingness to participate in the study In the event of a specific disease during the study	Faculty of Nursing and Midwifery, Ibn Sinah Crossroad
Age	City
From 60 years old	Mashhad
Gender	Province
Both	Razavi Khorasan
Phase	Postal code
N/A	9137913199
Groups that have been masked	Approval date
Outcome assessor	2018-09-18, 1397/06/27
Sample size	Ethics committee reference number
Target sample size: 60	ir.mums.nurse.rec.1397.046
More than 1 sample in each individual	
Number of samples in each individual: 1	Health conditions studied
The patient's primary caregiver along with the patient	1
Randomization (investigator's opinion)	Description of health condition studied
Randomized	Parkinson
Randomization description	ICD-10 code
Simply randomize random numbers by using www.randomization.com	G20
Blinding (investigator's opinion)	ICD-10 code description
Single blinded	Parkinson's disease
Blinding description	Primary outcomes
The analyst will be unaware of the intervention and	1
	Description
	Carer Care Times
	Timepoint
	At the beginning of the study (before the intervention) at the end of the intervention and one and two months after the intervention
	Method of measurement
	Zarit's Care Bar Questionnaire
	Secondary outcomes
	empty

Intervention groups

1

Description

Intervention group: A family-centered empowerment model consisting of 4 sessions of empowerment education (weekly 2 45-minute sessions). This is a four-step pattern of perceived threat, problem-solving, training participation and evaluation.

Category

Rehabilitation

2

Description

Control group: In the control group, no intervention will be required, but ethically, all training issues of empowerment sessions will be replicated in the form of pamphlet and instruction book, and will be available to the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurological Clinic Ghaem Hospital in Mashhad

Full name of responsible person

Somayeh Bagheri Aghouie

Street address

Abn cina

City

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Province

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bagherias951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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University blvd

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Najmeh Valizadeh Zare

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available