Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Family-Centered Empowerment Model implementation on family caregivers’ burden and ability to perform daily living activities of hospitalized patients with stroke in selected teaching hospitals of Shahid Beheshti University of Medical Sciences

Protocol summary

Summary

The purpose of the study is to determine the effect of family-centered empowerment model on family caregivers' burden and the ability to perform daily activities of life in patients with stroke admitted to selected educational hospitals affiliated to Shahid Beheshti University of Medical Sciences Design Study: Randomized, blind, controlled, single center, stage one trial Population of the study: All patients with stroke admitted to the neurology wards of hospitals affiliated to Shahid Beheshti University of Medical Sciences and their family caregivers Main entry criteria of the study: Patient entry criteria: 1. Having disability degree of 3, 4 or 5 according to the standard Rankin scale. 2. Educability. 3. Age 45 years and up. Family Caregiver Entry criteria: 1. Age 18 years old. 2. Having reading and writing skills and ability to speak Persian. 3. Calling possibility. Patient exit criteria: 1. Readmission or death of the patient before the final evaluation. Family care exit criteria: 1. Changing of the family caregiver. Research Area: The neurology wards of selected educational hospitals affiliated to Shahid Beheshti University of Medical Sciences (Imam Hossein, Martyrs of Tajrish and Loghman Hakim Hospitals) Sample size: n=90 (n1=n2=45) B-Intervention: Family-centered empowerment model implementation for caregivers of patients with stroke C-time of intervention: about 6 months (4 days for every caregiver and his/her patient) D-Primary outcomes of the study: Increasing the ability to perform activities of daily living in patients with stroke and reducing the caregivers' burden in the intervention group Secondary outcomes: Increased perceived threat of family caregivers, increased self-efficacy of family caregivers, increased self-esteem of family caregivers, internalization of Health Locus of Control in family caregivers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071835170N1**
Registration date: **2017-07-29, 1396/05/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-29, 1396/05/07

Registrant information

Name

Narjes Deyhoul

Name of organization / entity

Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

narges.deyhoul@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-12-26, 1396/10/05

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Family-Centered Empowerment Model implementation on family caregivers' burden and ability to perform daily living activities of hospitalized patients with stroke in selected teaching hospitals of Shahid Beheshti University of Medical Sciences

Public title
The effect of Family-Centered Empowerment Model in stroke
Purpose
Supportive
Inclusion/Exclusion criteria
Patient entry criteria: 1. Having stroke. 2. disability degree of 3, 4 or 5 in accordance with the standard Rankin scale. 3. Educability. 4. Age 45 years and up. 5. Hospital admission for at least 4 days. 6. Transfer to the home after discharge and being under the care of the family care provider. Family caregiver entry criteria: 1. Lack of previous care of another patient with chronic illness. 2. Not having academic education in the field of medical science in the caregiver or other family members of the patient. 3. Age 18 years old and up. 4. Having reading and writing skills and ability to speak Persian 5. Calling possibility. Patient exit criteria: 1. Readmission or death of the patient before the final evaluation. 2. Not participating in implementation of the education participatory step of family-centered empowerment model. 3. Receiving an educational program except the normal schedule of the hospital during the study period. Family caregiver exit criteria: 1. Changing of the family caregiver. 2. Lack of regular participation in the implementation of family-center empowerment model steps. 3. Receiving an educational program except the normal schedule of the hospital during the study period.
Age
From **45 years** old to **99 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences Ethics committee
Street address
Valiasr Street intersection of Niayesh across the Shahid Rajaei Hospital
City
Tehran
Postal code
Approval date
2016-05-16, 1395/02/27
Ethics committee reference number
IR.SBMU.PHNM.1395.391

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Ability to do daily life activities
Timepoint
Before intervention, immediately after intervention, 2 weeks after intervention, 2 months after intervention
Method of measurement
Barthel Index

2

Description
Burden of care
Timepoint
Before intervention, immediately after intervention, 2 weeks after intervention, 2 months after intervention
Method of measurement
Novak & Guest Caregiver Burden Inventory

Secondary outcomes

1

Description
Perceived threat

Timepoint
Before intervention, immediately after intervention, 2 weeks after intervention, 2 months after intervention
Method of measurement
Researcher-made Questionnaire of Perceived Threat

2

Description
Self-efficacy
Timepoint
Before intervention, immediately after intervention, 2 weeks after intervention, 2 months after intervention
Method of measurement
General Self Efficacy-10

3

Description
Self-Esteem
Timepoint
Before intervention, immediately after intervention, 2 weeks after intervention, 2 months after intervention
Method of measurement
Rosenberg Self_Esteem Scale

4

Description
Health Locus of Control
Timepoint
Before intervention, immediately after intervention, 2 weeks after intervention, 2 months after intervention
Method of measurement
Multidimensional Health Locus of Control scale

Intervention groups

1

Description
Intervention group: Implementation of family-centered empowerment model for family caregivers in the intervention group, in 4 sessions of two hours and in 4 consecutive days during the hospitalization of the patient in the classroom in the ward. The following is a detailed description of the interventions of each step in this model. o The first step (to increase the perceived threat): At this stage, the perceived threat of family caregivers will increase, through the mechanism of perceived susceptibility and perceived severity with increasing knowledge and attitudes towards stroke, the risk and its complications for family members. Accordingly the researcher will explain educational materials to the family caregiver including the importance of stroke, definition, symptoms, risk factors, prevention, treatment, complications and the proper care of patients focused on providing the solutions to enhance the ability to perform daily activities of life (personal grooming, bathing, eating, toilet and purity, going up and down stairs, getting dressed, bowel control, bladder control, gait and mobility) face to face and through methods lectures, discussion of questions and answers, Using the educational slides and practical illustrations, during two 2-hour sessions in 2 consecutive days. The perceived threat of family caregivers before, immediately, 2 weeks, and 2 months after the implementation of the family-centered empowerment model will be examined by the researcher-made questionnaire of perceived threat. O The second step (increasing self-efficacy): At this stage, self-efficacy and a sense of control over the conditions in the caregiver will be enhanced through problem-solving. Researcher and caregive will have a face-to-face consultation and discussion session during a two-hour meeting. At this stage, family caregivers are faced with their problems and the process of problem solving, and will be discussed by the researcher, with objective examples of their own situation and what to do to improve the similar problem. So they can learn skills needed to find solutions and apply the problem solving process. Self-efficacy of family caregivers will be examined before, immediately, 2 weeks and 2 months after the implementation of the family-centered empowerment model by the general self-efficacy scale-10. O Step Three (Increasing self-esteem): At this stage, self-esteem will be promoted through collaborative education. It should be noted that in implementing this step from the family-centered empowerment model, learning to increase self-esteem is considered. So, the pamphlets and educational package will be provided to family caregivers, and he/she will be asked to provide a summary of the lessons taught and in a simple and understandable say to the patient family member during the two-hour session in the presence of the researcher. In this way, the researcher will implement a strategy to increase self-esteem in family caregivers and ensure the accuracy of learning the contents taught in previous steps. The family caregiver is also requested to explain again educational package to the patient in the first week of discharge. At the end of the session. Self-esteem of family caregivers will be examined before, immediately, 2 weeks and 2 months after the implementation of the family-centered empowerment model by Rosenberg Self-esteem Scale. O Step four (Evaluation): This step of the model will be carried out in two ways: the process evaluation (process evaluation is evaluation of the steps of model mentioned above including the evaluation of the effectiveness of implementing family-centered empowerment model on perceived threat, self-efficacy, self-esteem and health locus of control of family caregivers) and the final evaluation. The final evaluation is also evaluation the effect of implementing the family-centered empowerment model on family caregivers' burden and the ability to perform activities of daily life in patients with stroke before, immediately, 2 weeks, and 2 months after full implementation of the model steps.
Category
Lifestyle

2

Description
Control group: there are no interventions in this group. Measures for measuring the variables of the research will be carried out as in the intervention group.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital (AS)
Full name of responsible person
Narjes Deyhoul
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Shahdaye Tajrish Hospital
Full name of responsible person
Narjes Deyhoul
Street address
City
Tehran

3

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Narjes Deyhoul
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parvaneh Vasli
Street address
Valiasr Street intersection of Niayesh across the Shahid Rajaei Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Nursing and Midwifery, Shahid Beheshti 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
Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Narjes Deyhoul
Position
MSc Student of Community Health Nursing
Other areas of specialty/work
Street address
Valiasr Street intersection of Niayesh across the Shahid Rajaei Hospital
City
Tehran
Postal code
Phone
+98 21 8865 5366
Fax
Email
narges.deyhoul@sbmu.ac.irnarges.dyhl@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parvaneh Vasli
Position
Ph.D of Nursing
Other areas of specialty/work
Street address
Valiasr Street intersection of Niayesh across the Shahid Rajaei Hospital
City
Tehran
Postal code
Phone
+98 21 8865 5366
Fax
Email
p-vasli@sbmu.ac.irparvanehvasli@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Narjes Deyhoul

Position
MSc Student Community Health Nursing

Other areas of specialty/work

Street address
Valiasr Street intersection of Niayesh across the Shahid Rajaei Hospital

City
Tehran

Postal code

Phone
+98 21 8865 5366

Fax

Email
narges.deyhoul@sbmu.ac.irnarges.dyhl@gmail.com

Web page address

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