

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of self-management program based on the Five A model on care burden and APGAR score of family caregivers of stroke patients

Protocol summary

Study aim

The effect of the self-management program based on 5A Model on caregiver burden and Apgar score of family caregivers of patients with stroke.

Design

The present clinical trial was performed with a control group in which 64 caregivers of patients was enrolled

Settings and conduct

The present study was performed at Shahid Beheshti Hospital in Kashan. No blinding was carried out in this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All families of stroke patients who had a stroke a week before, and had a medical record at the hospital indicating a definitive diagnosis of stroke. Non-inclusion criteria: Participation of families in similar studies.

Intervention groups

The intervention group (n= 32) was divided into two groups of 16. Eight one-hour theoretical and practical training sessions were held for each group over five weeks in a classroom in the neurology department of Shahid Beheshti Hospital in the city of Kashan. Control group: received only routine hospital care. At the end of the study, the educational booklet was given to the control group to observe ethical considerations.

Main outcome variables

Burden of care, total Apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042096N1**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Maryam Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5520 5997

Email address

maryamheydari779@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-24, 1398/04/03

Expected recruitment end date

2019-08-03, 1398/05/12

Actual recruitment start date

2019-06-24, 1398/04/03

Actual recruitment end date

2019-08-03, 1398/05/12

Trial completion date

2019-08-03, 1398/05/12

Scientific title

The effect of self-management program based on the Five A model on care burden and APGAR score of family caregivers of stroke patients

Public title

The effect of self-management program on care burden and APGAR score of family caregivers of stroke Patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent for taking part in the study Reading and writing literacy All families of stroke patients who had a stroke one week before, and had a medical record at the hospital indicating definitive diagnosis of stroke

Exclusion criteria:

Participation of families in similar studies.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **64**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual randomization was performed by using a table of random numbers. The numbers in the table were used from the top to the bottom. Even numbers were considered for the experimental group and odd numbers for the control group. Opaque and sealed envelopes and random sequences were used for blinding. Each generated random sequence was written on a card; the cards were placed inside the envelopes; and the envelopes were sealed and placed in a box. At the time of participant registration, based on the order of the inclusion of eligible participants, one envelope was opened and the group to which that participant was allocated was revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

At the outset of the study, explanations about the method were given to the caregivers, but no explanation was provided about group allocation. At the end of the study, an educational pamphlet was given to the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation;
Kkodakyar Ave.; Daneshjo blvd.; Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2019-05-29, 1398/03/08

Ethics committee reference number

IR.USWR.REC.1398.013

Health conditions studied**1****Description of health condition studied**

patients with stroke

ICD-10 code

164

ICD-10 code description

Stroke,not specified as hemorrhage or infarction

Primary outcomes**1****Description**

Burden of care

Timepoint

At the beginning of the study and six weeks after the intervention

Method of measurement

Zarit Burden Interview

2**Description**

Total family Apgar score

Timepoint

At the beginning of the study and six weeks after the intervention

Method of measurement

Smilkstein Family Apgar Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

The experimental group comprised 32 people, divided into two groups of 16. For each group, the theoretical and practical class was provided in eight one-hour sessions for five weeks. The classes were held in the Neurology Ward of Shahid Beheshti Hospital, Kashan, Iran. The self-management program implemented in this

study consisted of group theoretical and practical training as well as follow-up performed online and over the phone, provided for the family caregivers of patients with stroke.

Category

Other

2**Description**

Control group: The control group received only routine hospital care. At the end of the study, the educational booklet was given to the control group to observe ethical considerations.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Maryam Heydari

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Misaq 4 Opposite Barghi School End of Resalat Ave.
Kashan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Mohammadreza Khodaeiardakani

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Kodakyar closed alley, Daneshjo Blvd., Evin.

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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

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Maryam Heydari

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Misaq 4; in front of Barghi School; at the end of
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Street address
Misaq 4 Opposite Barghi School End of Resalat Ave.
Kashan
City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable