

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

**Street address**

Misaq 4 Opposite Barghi School End of Resalat Ave.  
Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8716896641

**Phone**

+98 31 5520 5997

**Email**

maryamheydari779@gmail.com

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

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Dr. Mohammadreza Khodaei Ardakani

**Street address**

Kodakyar closed alley, Daneshjo Blvd., Evin.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۵۷۱۳۸۳۴

**Phone**

+98 21 2218 0036

**Email**

maryamheydari779@gmail.com

**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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**Person responsible for updating data****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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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