

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Application of Roy's Adaptation Model to Promote Psychosocial Status of Patients with CVA

#### Protocol summary

##### Summary

The aim of this study was to Application of biological aspect of Roy's Adaptation Model to Promote Psychosocial Status of Patients With Cerebrovascular accident. Participation in care plan by the doctors ; awareness of time, place, and individuals ; absence of visual and hearing problem, of musculoskeletal disorders that prevent fulfillment of care plan, experiencing CVA for the first time ; tendency, motivation and ability to receive training and execute care plan. Exclusion criteria: Disinclination of the patients to continue care plan and absence for minimal two sessions during the study was considered as exclusion criteria. In this clinical trial, 50 CVA patients through accessibility sampling were selected from hospitals of Isfahan during 2014-2015 and randomly assigned to two groups of similar size. The data was collected through researchers' developed form of recognition and review of Roy's model. The care plan was developed based on the maladaptation behaviors and their stimuli which were implemented in the intervention group and follow-up study was also done. The control group received routine cares. The effect of program based on Roy model in psychosocial level of adaptation in stroke patients were studied.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015061618339N2**  
Registration date: **2015-10-13, 1394/07/21**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-13, 1394/07/21

#### Registrant information

##### Name

Nasrollah Alimahammadi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2918

##### Email address

alimohammadi@nm.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Isfahan University of Medical Sciences

#### Expected recruitment start date

2013-12-02, 1392/09/11

#### Expected recruitment end date

2014-02-20, 1392/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Application of Roy's Adaptation Model to Promote Psychosocial Status of Patients with CVA

#### Public title

Roy Adaptation Model

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: Participation in care plan by the doctors ; awareness of time, place, and individuals ; absence of visual and hearing problem, of musculoskeletal disorders that prevent fulfillment of care plan, experiencing CVA for the first time ; tendency,

motivation and ability to receive training and execute care plan Exclusion criteria: Disinclination of the patients to continue care plan and absence for minimal two sessions during the study was considered as exclusion criteria

#### **Age**

From **18 years** old to **80 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **50**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of the Isfahan University of Medical Sciences

###### **Street address**

Isfahan University of Medical Sciences , Street Hezarjarib

###### **City**

Isfahan

###### **Postal code**

8174673461

##### **Approval date**

2013-12-01, 1392/09/10

##### **Ethics committee reference number**

11/3473/3

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

Brain Stroke

##### **ICD-10 code**

I69.4

##### **ICD-10 code description**

Sequelae of stroke, not specified as haemorrhage or

infarction

### **Primary outcomes**

#### 1

##### **Description**

Psychosocial Status

##### **Timepoint**

Before Intervention and 2 Months after Intervention

##### **Method of measurement**

Adaptationl Questionnaire

### **Secondary outcomes**

#### 1

##### **Description**

Adaptation Level

##### **Timepoint**

Preintervention and 2 months after Intervention

##### **Method of measurement**

Adaptation Level Questionnaire

### **Intervention groups**

#### 1

##### **Description**

"Control Group:One Educational Session"

##### **Category**

Rehabilitation

#### 2

##### **Description**

"Intervention Group:The training program based on the Roy adaptation model of the four sessions of 90-60 minutes and one month follow-up

##### **Category**

Rehabilitation

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Isfahan Al Zahra Hospital

###### **Full name of responsible person**

Doctor Nasrollah Alimohammadi

###### **Street address**

Nursing and Midwifery Faculty, Isfahan University of Medical Sciences, Isfahan, Iran

###### **City**

Isfahan

### **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Mehdi Nematbakhsh

**Street address**

Vice Chancellor for Research of Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Nasrollah Alimohammadi

**Position**

Nursing phd, Vice-Chancellery for Education, Nursing and midwifery faculty

**Other areas of specialty/work****Street address**

Nursing and Midwifery faculty, University of Medical Sciences, Hezarjar Street b

**City**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 2918

**Fax**

+98 31 3669 9398

**Email**

alimahammadi@nm.mui.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Nasrollah Alimohammadi

**Position**

Nursing PhD

**Other areas of specialty/work****Street address**

Nursing and Midwifery faculty, Isfahan University of Medical Sciences, Hezarjrib Street

**City**

Isfahan

**Postal code****Phone**

+98 34 3792 2950

**Fax****Email**

alimahammadi@nm.mui.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Doctor Nasrollah Alimohammadi

**Position**

Nursing PhD

**Other areas of specialty/work****Street address**

Nursing and Midwifery faculty, Isfahan University of Medical Sciences, Hezarjerib Street

**City**

Isfahan

**Postal code****Phone**

+98 31 3792 7516

**Fax****Email**

alimahammadi@nm.mui.ac.ir

**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*