

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The impact of self-efficacy on self-care ability of patients with stroke: a clinical trial study

#### Protocol summary

##### Summary

Stroke is a stressful event which brings about various physical, psychological, social and economic problems that affect different aspects of the patient's life. Therefore, this study is conducted to investigate the impact of a self-efficacy program on self-care ability of patients with stroke. This study is conducted as a clinical trial which includes two group and three stages with a test plan before, immediately after and one month after stroke occurrence. 50 patients with stroke, who are hospitalized in the neurology department of Kashani Hospital in Isfahan city, are selected by the simple continuous method and are placed randomly in two groups of test and control. Patients of the test group are divided into 5 groups of 5 people and the self-efficacy program is implemented for them in 6 sessions. Then, Barthel questionnaire is completed for both groups before and after the intervention and one month after the intervention and the results are analyzed statistically by using descriptive and inferential statistics and software of SPSS version 18.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041733481N1**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-09, 1396/03/19

##### Registrant information

##### Name

Zahra Rafiee

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 420 7290

##### Email address

zahra.rafaee@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of self-efficacy on self-care ability of patients with stroke: a clinical trial study

##### Public title

The impact of self-efficacy on self-care ability of patients with stroke: a clinical trial study

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: The occurrence of stroke for the first time; willingness to participate in the study; aged between 50 and 70 years; lack of addiction to alcohol and drugs; lack of simultaneous participation in another study; no loss of consciousness level; capable of responding to questions and getting scores more than 23 from the Mini-Mental State Exam; having self-care ability

and earn scores above 50 from Barthel index; having at least literacy to read and write; the ability to understand conversation in Farsi and lack of malignant physical illness. Exclusion criteria: The absence of more than 2 times in meetings; not wanting to continue the intervention; the incidence of new diseases that cause more disability in these patients.

#### **Age**

From **50 years** old to **70 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**

50 qualified patients are divided into two equal case and control groups with Sealed envelope method.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

Ethics committee of Isfahan University of Medical Sciences

##### **Street address**

Isfahan

##### **City**

Isfahan

##### **Postal code**

#### **Approval date**

2015-04-21, 1394/02/01

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

IR.MUI.REC.1395.3.783

## **Health conditions studied**

### 1

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

Stroke

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

I69.4

## **ICD-10 code description**

Sequelae of stroke, not specified as haemorrhage or infarction

## **Primary outcomes**

### 1

#### **Description**

self-care ability

#### **Timepoint**

before, immediately after and one after clinical trial

#### **Method of measurement**

Barthel questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: includes 6 sessions with aim of introduction, improvement of patient's independency, improvement of self-esteem and introduction to use problem solution technique

#### **Category**

Lifestyle

### 2

#### **Description**

Control group: pharmacotherapy and 2 educational sessions about the disease, side-effects of it and consumed medicines

#### **Category**

Lifestyle

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Neurology department of Kashani hospital

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

Ali Mohammadi

##### **Street address**

Hezar Jerib St, Isfahan University of Medical Sciences, Isfahan, Iran

##### **City**

Isfahan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research of Isfahan University of

Medical Sciences  
**Full name of responsible person**  
Mehdi Nemat Bakhsh  
**Street address**  
HezarJerib St, 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**  
Vice chancellor for research of 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**  
Faculty of Nursing and Midwifery  
**Full name of responsible person**  
Ali Mohammadi  
**Position**  
PHD  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*