# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 2026

## The effect of healthy heary based spiritual intrevention on self care ability of patients with stroke

## Protocol summary

**Study aim**
Determining the effect of spiritual intervention caused by a healthy heart on the self-care ability of stroke patients

**Design**
This study will be conducted as a clinical trial on stroke patients hospitalized in the neurology department of Golestan Ahvaz Hospital. The samples will be selected by the available method from the patients with stroke based on the inclusion criteria. The number of samples was calculated based on the formula for determining the sample size, including 10% attrition, and 86 people were randomly divided into two intervention and control groups using sealed envelopes.

**Settings and conduct**
This study will be conducted as a clinical trial on stroke patients hospitalized in the neurology department of Golestan Ahvaz Hospital in 1402.

**Participants/Inclusion and exclusion criteria**
1. Patients with stroke 2. Age above 18 to 80 years 3. Full awareness of time, place and people 4. Not being deaf to communicate effectively Exclusion criteria include Refusal to participate in the study

**Intervention groups**
Spiritual intervention based on a healthy heart will be performed on the self-care ability of stroke patients in the intervention group. Routine care intervention will be implemented in the control group.

**Main outcome variables**
Self-care ability obtained from the Canadian Work Performance Evaluation Scale

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230729058961N1**
Registration date: **2023-08-26, 1402/06/04**
Registration timing: **registered_while_recruiting**
Last update: **2023-08-26, 1402/06/04**
Update count: **0**

**Registration date**
2023-08-26, 1402/06/04

**Registrant information**

**Name**
Zahra Elihaei

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8765 4321

**Email address**
zahraelihaei@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-08-23, 1402/06/01

**Expected recruitment end date**
2024-03-18, 1402/12/28

**Actual recruitment start date**
2023-08-23, 1402/06/01

**Actual recruitment end date**
2024-03-18, 1402/12/28

**Trial completion date**
2024-03-18, 1402/12/28

**Scientific title**
The effect of healthy heary based spiritual intrevention on self care ability of patients with stroke

**Public title**
The effect of healthy heary based spiritual intrevention on self care ability of patients with stroke

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with stroke Age above 18 to 80 years Full awareness of time and space and love Not being deaf to face communication

**Exclusion criteria:**

Refusal to participate in the study Absence in more than one training session Having an acute physical or mental illness

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **86**

Actual sample size reached: **86**

**Randomization (investigator's opinion)**

Not 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**

Jundishapur University of Ahvaz

**Street address**

No. 24, West 19th Street, kianpars, city ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6155884339

**Approval date**

2023-07-19, 1402/04/28

**Ethics committee reference number**

IR.AJUMS.REC.1402.170

## Health conditions studied

### 1

**Description of health condition studied**

Patients with stroke

**ICD-10 code**

I63

**ICD-10 code description**

Cerebral infarction

## Primary outcomes

### 1

**Description**

Self-care ability score obtained from the Canadian work performance evaluation scale

**Timepoint**

Measuring self-care capacity before the intervention and two months after the intervention

**Method of measurement**

Canadian work performance evaluation scale

## Secondary outcomes

### 1

**Description**

**Timepoint**

**Method of measurement**

## Intervention groups

### 1

**Description**

Intervention group: The spiritual care program will be organized based on religious spirituality and based on the improvement of four human relationships (relationship with God, relationship with self, relationship with others and relationship with the environment) and taking into account the different levels of spirituality of individuals and the amount Their interest and the existential capacity of people, the type of intervention will be done according to the patient's choice and desire. The number and time of the sessions will be 5 sessions of 45-60 minutes during 5 weeks. Every day, all the contents of the previous day will be repeated and reminded. A telephone number will also be provided to the patients of the intervention group so that they can contact this telephone number at home and after discharge, in case of any problems or questions.

**Category**

Rehabilitation

### 2

**Description**

Control group: will receive routine ice care.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Golestan Hospital
**Full name of responsible person**
Zahra elihaei
**Street address**
Golestan
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Zahraelihaei@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Zahra elihaei
**Street address**
Golestan
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**Province**
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
0
**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**
Other

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Zahra elihaei
**Position**
Nursing
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
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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)**

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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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