

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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

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Golestan

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Email

Zahraelihaei@gmail.com

Full name of responsible person

Zahra elihaei

Position

Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Email

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Street address

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Email

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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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra elihaei

Position

Nursing

Latest degree

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Other areas of specialty/work

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Nursing

Latest degree

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Other areas of specialty/work

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Email

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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