

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of psychological interventions on pain, anxiety and physiological parameters in the patients with cerebral stroke hospitalized in the intensive care unit: a parallel randomized clinical trial

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluating the effects of psychological interventions on pain, anxiety, and physiological parameters in patients with stroke hospitalized in the intensive care unit: a parallel randomized clinical trial

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Design

Randomized, sham controlled clinical trial with a parallel group, 24 people are randomly divided into control and experimental groups using the block randomization method.

Registrant information

Name

Reza Mohammadpourhodki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

Psychological interventions include acupuncture, relaxation with guided imagery and music therapy once a day for five consecutive days in intensive care unit Hazrat Abolfazl hospital

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Patients (man or woman) experiencing the first unilateral cerebral stroke, who do not have other neurological disorders, diagnosed and referred by a neurologist

Intervention groups

All patients receive conventional evidence-based treatment for the care of patients with cerebral stroke. The control group receives only the conventional treatment, and the intervention group receives psychological interventions including Benson's skewing, music therapy, compression massage and guided imagery in addition to the conventional treatment.

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Pain; anxiety; physiological parameters

Scientific title

Evaluating the effects of psychological interventions on pain, anxiety and physiological parameters in the patients with cerebral stroke hospitalized in the intensive care unit: a parallel randomized clinical trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180711040432N4**

Registration date: **2020-12-30, 1399/10/10**

Public title

Effects of psychological interventions on pain, anxiety, and physiological parameters in patients with cerebral stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consciousness level based on the Glasgow Coma Index (GCS) greater than 9 The diagnosis of hemorrhagic or ischemic cerebral stroke The age of 18 to 75 years

Exclusion criteria:

The death of patient during the study The exacerbation of stroke during the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

During the study and due to the small sample size, based on consultation with a statistician, it was decided to use the block randomization method. Blocking is usually done to create a balance in the number of the samples assigned to each of study groups. As we had two study groups, the statistician using a statistical software designed 6 blocks of 4 members.

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 Mashhad University of Medical Sciences

Street address

Knowledge and Health Town, between Shaheed Javan and Al-Shahidi squares, Shaheed Fakouri Blvd (In front of Fakouri 94), Mashhad, Iran

City

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Province

Razavi Khorasan

Postal code

IR.MUMS.REC.1399.516

Approval date

2020-12-05, 1399/09/15

Ethics committee reference number

IR.MUMS.REC.1399.516

Health conditions studied

1

Description of health condition studied

Cerebral stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Pain

Timepoint

Before the start of intervention at the first session and after the end of intervention at the last session

Method of measurement

VAS questionnaire

2

Description

Anxiety

Timepoint

Before the start of intervention at the first session and after the end of intervention at the last session

Method of measurement

VAS questionnaire

3

Description

Changes of the physiological parameters of patients with cerebral stroke

Timepoint

Before the start of intervention at the first session and after the end of intervention at the last session

Method of measurement

The monitor used in the intensive care unit and a mercury thermometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group, patients will receive

only the usual care of the department (these include: physician's examination, daily drug therapy, serum therapy).

Category

N/A

2

Description

Intervention group: Patients with cerebral stroke during five intervention sessions on five consecutive days receive compression massage and relaxation along with guided imagery and music therapy for approximately 55 minutes per session.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Abolfazl hospital

Full name of responsible person

Reza Mohammadpourhodki

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Janbaz Street, Kashmar, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical 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

Mashhad University of Medical Sciences

Full name of responsible person

Reza Mohammadpourhodki

Position

University lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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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