

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of family-centered purposeful and early sensory stimulation on function and cognition rehabilitation in patients with disorder of consciousness after stroke

Protocol summary

Study aim

Determination of the effect of family-centered purposeful early sensory stimulation of function and cognition rehabilitation in patients with disorder of consciousness after stroke

Design

Two parallel group randomised trial with blocking and blinded

Settings and conduct

Visual stimulation is done by moving the flash light in patient's visibility and showing the colorful cards and telling him/her the name of the color, smelling stimulation is done with coffee or a known smell, tasting stimulation is done with blobbing lemon juice to sides of the patient's glossa, tactile stimulation is done by blobbing cotton on the hand's skin and then drawing simple shapes by finger and telling the patients the name of the shapes and hearing stimulation is done with sweet reminiscences. all of these stimulation are done by family member for 15 days and use the scales in days of 0, 5, 10 and 15. patients and analyst and person who collect the data with scales are blind.

Participants/Inclusion and exclusion criteria

72 hours after stroke age more than 18, GCS 5-10, without any brain attack, without visual and hearing problem, family adhesion, having a family member for doing the stimulations, not being pregnant women, without former stroke, not being under ventilation, not use t-pa therapy (tissue plasminogen activator)

Intervention groups

case group: patients are stimulated 5 sense: visual, hearing, tactile, tasting and smelling by family member. control group: patients are cared with routine care in ICU ward

Main outcome variables

Function and cognition rehabilitation by use of GCS,

FOUR Score and DRS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024342N6**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Vida Shafipour

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of family-centered purposeful and early sensory stimulation on function and cognition rehabilitation in patients with disorder of consciousness after stroke

Public title
The effect of family-centered purposeful and early sensory stimulation on function and cognition rehabilitation in patients with disorder of consciousness after stroke

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 72 hours after stroke age more than 18 GCS 5-10 without any brain attack without visual and hearing problem family adhesion having a family member for doing the stimulations
Exclusion criteria:
 pregnant women former stroke be under ventilation use t-pa therapy (tissue plasminogen activator)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
blocking

Blinding (investigator's opinion)
Double blinded

Blinding description
patients and analyst and the person who collect the data are blind

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Vice-Chancellor for Research, Mazandaran University of Medical Sciences

Street address

vesale shirazi avenue, amir mazandarani street, emem khomeini squer, sari

City

sari

Province

Mazandaran

Postal code

4815733971

Approval date

2018-05-05, 1397/02/15

Ethics committee reference number

IR.MAZUMS..REC.1397,1529

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Function and Cognition Rehabilitation

Timepoint

Every 5 days for 15 days

Method of measurement

Gloscow Coma Scale (GCS); FOUR Score; Disability Rating Scale (DRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5 sense stimulation including visual stimulation with moving the flashlight in patient's visibility and showing the colorful cards them and telling them the color of the card, smelling stimulation with coffee or a known smell, hearing stimulation by sweet reminiscences, tasting stimulation by lemon juice to sides of the glossa, tactile stimulation is done by touching and blobbing cotton on the patient's skin and drawing simple shapes on the patient's skin and telling them the name of the shapes. all of these stimulation are

done by a family member of the patients.

Category

Rehabilitation

2

Description

Control group: patients in this group are cared with ICU ward's routine cares.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Sina hospital

Full name of responsible person

Lale Alipoor

Street address

Booali sina Hospital; Pasdaran Blvd; Sari

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2

Recruitment center

Name of recruitment center

Emam Ali Hospital

Full name of responsible person

Vida Shafipour

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Emam Ali hospital; Dr Javadian Blvd; Noor Ave;

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Mazandaran University of Medical Science; Valiasr Ave; Emam Sqe; Sari

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vidashafipour@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Vida Shafipour

Position

Phd.Educational Nursing-faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Web page address**Latest degree**

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Web page address

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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Vida Shafipour

Position

Phd.Educational Nursing-faculty member