

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparing the Effect of PNF Exercises with and without Myofascial Release on the Function and Range of Motion of wrist, and Quality of Life in Patients with cerebral vascular accident (CVA)

Protocol summary

Changing the range of motion of the wrist; change in quality of life; change in wrist function;

Study aim

Considering the high prevalence of stroke and the resulting disabilities and the many harmful effects on the general health of the society, it is necessary to study and understand deeply about this. Various studies have been conducted on stroke rehabilitation, but currently there is little research on the role of combination therapies; Especially since the research is a combination of movement exercises (PNF stretching exercises) with MFR technique, in this research, we try to find a more effective intervention on this condition

Design

A clinical trial with a control group with 2 parallel groups, a blind strain, non-randomized on 45 patients.

Settings and conduct

The research was conducted in a rehabilitation center under the supervision of an occupational therapist, for 4 weeks and 3 sessions per week, and each session lasted between 30 and 45 minutes. The meetings were conducted individually, people did not establish any communication with each other, and in this way, one-way blinding was done

Participants/Inclusion and exclusion criteria

Participants are allowed to enter people who have been diagnosed with a stroke by a neurologist, their age range is between 45 and 60 years, they do not have impaired consciousness and cognition, and they do not have structural problems in the upper limbs.

Intervention groups

In this study, there are 3 intervention groups, in the first group, only PNF exercises are performed, in the second group, PNF exercises are performed along with myofascial release, in the third group, which is the control group, no upper extremity exercises are performed and only lower limb exercises are given. The ethical part of the research should also be respected

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200209046422N1**

Registration date: **2024-02-02, 1402/11/13**

Registration timing: **retrospective**

Last update: **2024-02-02, 1402/11/13**

Update count: **0**

Registration date

2024-02-02, 1402/11/13

Registrant information

Name

Amirhossein Barati

Name of organization / entity

Shahid beheshti

Country

Iran (Islamic Republic of)

Phone

+98 21 2248 3343

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ah_barati@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-26, 1402/11/06

Expected recruitment end date

2024-01-28, 1402/11/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of PNF Exercises with and without Myofascial Release on the Function and Range of Motion of wrist, and Quality of Life in Patients with cerebral vascular accident (CVA)

Public title

PNF and Myofascial Release in patients with CVA

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with CVA diagnosed by a neurologist Age range 45-60 years Spasticity level +1 or 2 according to the Ashworth scale No active phase of the disease Having a stroke once 4 to 8 months have passed since receiving the last rehabilitation services for stroke patients Absence of spinal cord lesions Lack of regular sports activity Failure to receive PNF technique from 6 months ago Personal and informed consent to participate in the study

Exclusion criteria:**Age**

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

During this trial, the participants and their clinical caregiver, which includes their companions, imagine that the same intervention will be done on all groups, because the intervention will be done personally and away from the eyes of other subjects under study, and the subjects under study will not have any communication. They don't have one with the other, as a result, blinding is done in this way

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University

Street address

Shahid Beheshti University., Student Blvd.,Valenjak St.,

City

Tehran

Province

Tehran

Postal code

۱۹۸۳۹۶۹۴۱۱

Approval date

2024-01-22, 1402/11/02

Ethics committee reference number

IR.SBU.REC.1402.156

Health conditions studied**1****Description of health condition studied**

Patients with CVA

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Wrist function

Timepoint

Measurement of wrist function before the start of the research and re-measurement after 12 intervention sessions

Method of measurement

Fugl meyer assessment

2**Description**

Range of motion of wrist

Timepoint

Measurement of range of motion of the wrist before the beginning of the research and its re-measurement after 12 intervention sessions

Method of measurement

Measure with a goniometer

3**Description**

Quality of Life

Timepoint

Measuring the quality of life before the start of the research and measuring it again after 12 intervention sessions

Method of measurement

Using the World Health Organization Quality of Life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: includes 15 people who received PNF exercises for 12 sessions

Category

Rehabilitation

2

Description

The second intervention group: includes 15 people who received PNF exercises along with Graston massage for 12 sessions.

Category

Rehabilitation

3

Description

Control group: Including 15 people who did not receive any intervention

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan Red Crescent Rehabilitation Complex

Full name of responsible person

Nadia Arabahmadi

Street address

Gorgan Red Crescent Rehabilitation Complex., 5 Azar Street.Azar 1st Alley., Mirfenderski2 Alley.,

City

Gorgan

Province

Golestan

Postal code

4917638785

Phone

+98 17 3232 3710

Email

golestan.rcs.news@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan Red Crescent Rehabilitation Center

Full name of responsible person

Mousa Shahini

Street address

Gorgan Red Crescent Rehabilitation Complex., 5 Azar Street.Azar 1st Alley., Mirfenderski2 Alley.,

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Email

golestan.rcs.news@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan Red Crescent Rehabilitation Center

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

Shahid beheshti

Full name of responsible person

Amirhossein Barati

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potentially shareable data is de-identified

When the data will become available and for how long

The start of the access period will be 6 months after the results are printed and registered

To whom data/document is available

Researchers working in academic and scientific institutions will have access

Under which criteria data/document could be used

Academic and scientific researchers are allowed to send requests to receive non-identifiable personal data and analyze them for their research.

From where data/document is obtainable

Applicants can contact the following contact information to receive documents Contact number: 09371591006 Email address: nadia77.aaa@gmail.com In the name of Nadia Arab Ahmadi

What processes are involved for a request to access data/document

After studying the application by the researcher and checking the accuracy of the applicant's information, the data will be sent as soon as possible. The estimated time of this process will be between 2 to 3 days

Comments