Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of a Proprioceptive Neuromuscular Facilitation (PNF)-based virtual reality intervention versus real PNF exercises on motor, cognitive and occupational performance in chronic stroke survivors

Protocol summary

Study aim
Comparison of the effect of a Proprioceptive Neuromuscular Facilitation (PNF)-based virtual reality intervention versus real PNF exercises on motor, cognitive, mood (depression and anxiety) and occupational performance in chronic stroke survivors

Design
A single blind clinical trial with parallel groups, 28 samples from chronic stroke survivors, Randomization through a table of random numbers and the method of classified random blocks

Settings and conduct
Chronic stroke patients are enrolled in the study based on the inclusion criteria and by giving informed consent. After the initial assessments, participants are randomly assigned to PNF-based virtual reality intervention group and real PNF exercises group and receive an 8-week occupational therapy services at Mowafaghian Smart Rehabilitation Center. Then the final evaluation and after 1month follow-up evaluation will be done

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range18 to 64 years, First stroke, 6 months to a maximum of 4 years since stroke, Ability to sit independently on a chair, Ability to understand and follow instructions, Brunnstrom stage 3 or higher for upper extremity؛ Exclusion criteria criteria: severe visual impairment, history of previous mood disorders or use of related medications

Intervention groups
The participants are randomly assigned to the PNF-based virtual reality intervention group and the real PNF exercises group. At first of each session, participants in both groups receive conventional occupational therapy for 30minutes.Then, the participants in the PNF-based virtual reality intervention group perform exercises based on the PNF approach through the virtual reality system for 30minutes,and the other group performs the same exercises in the real therapy environment for 30minutes

Main outcome variables
Upper Extremity motor performance, cognitive performance, occupational performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240406061422N1**
Registration date: **2024-08-05, 1403/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-05, 1403/05/15**
Update count: **0**

Registration date
2024-08-05, 1403/05/15

Registrant information

Name
Fatemeh Sadat Hosseini Ramshe

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 7756 1721

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-08-05, 1403/05/15

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of a Proprioceptive Neuromuscular Facilitation (PNF)-based virtual reality intervention versus real PNF exercises on motor, cognitive and occupational performance in chronic stroke survivors

Public title

Comparison of the effect of a Proprioceptive Neuromuscular Facilitation (PNF)-based virtual reality intervention versus real PNF exercises in stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First stroke experience A minimum of 6 months to a maximum of 4 years since stroke Ability to sit independently on a chair during the intervention Ability to understand and follow instructions Brunnstrom stage 3 or higher for upper extremity

Exclusion criteria:

Severe visual impairment that makes it difficult to interact with virtual reality tool History of previous mood disorders or use of related medications

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering the impact of gender on some of the variables, participants are initially divided into two categories based on gender. Then, within each category, patients are randomly assigned in equal numbers to one of two intervention groups ,PNFbased virtual reality intervention group and the real PNFexercises group, using block randomization of size 4.The criterion for choosing each of the 6 possible block states is rolling a dice. That is, two patients out of4similar patients are assigned to the intervention group in the virtual environment and the other two are assigned to the real exercise group. This process continues until the patients are grouped by gender into two homogeneous groups and, additionally, the numbers in both groups are made equal.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluation process will be performed by another master's student with clinical experience in patients with neurological disorders, who is not aware of how patients are assigned to groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Near Taleghani hospital, Arabi Street, Yemen Street, Shahid Chamran Highway

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Province

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Postal code

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Approval date

2023-11-12, 1402/08/21

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.437

Health conditions studied

1

Description of health condition studied

Chronic Stroke Survivors

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Upper Extremity motor performance

Timepoint

Pre ,Post, After 1 month follow up

Method of measurement

Fugl-Meyer Assessment, Motor Activity Log

2

Description
Cognitive performance
Timepoint
Pre ,Post, After 1 month follow up
Method of measurement
Montreal Cognitive Assessment, Wisconsin Card Sorting Test ,Forward and backward Digit Span Test

3

Description
Occupational performance
Timepoint
Pre ,Post, After 1 month follow up
Method of measurement
Canadian Occupational Performance Measure

Secondary outcomes

1

Description
Depression and Anxiety
Timepoint
Pre, Post, After 1 month follow up
Method of measurement
Hospital Anxiety and Depression Scale

Intervention groups

1

Description
Intervention group: Participants in the Proprioceptive Neuromuscular Facilitation (PNF)-based virtual reality intervention group receive 24 sessions of intervention over 8 weeks. At the first of each session, they receive conventional interventions for 30 minutes. Then, they also receive a 30-minute PNF intervention through the smart rehabilitation system Sana at the Mowafaghian rehabilitation center. The kinetic camera of this virtual reality tool determines the joint angles of the patient and presents them as an avatar on the screen, providing one-handed and two-handed exercises in the form of reaching, tracking, and rotation scenarios. These exercises are designed based on diagonal patterns of the upper limbs in PNF approach. Colorful balls of various sizes appear as targets on the screen during the exercises, and the patients follow PNF patterns to complete the exercises. The precision, repetition, and speed of exercise are adjusted according to the therapist's opinion and the patient's progress. Additionally, appropriate auditory and visual feedback is received through the screen based on the individual's performance during the exercises.
Category
Rehabilitation

2

Description
Control group: Participants in the real Proprioceptive Neuromuscular Facilitation (PNF) exercises group will receive 24 sessions of occupational therapy intervention over 8 weeks, and receive 30 minutes of conventional occupational therapy interventions at the first of each session. They will then perform the same PNF-based exercises in a real manner for 30 minutes. Balls will be used to simulate scenarios of virtual reality tools in the therapeutic environment, and in the same form of reaching, tracking, and rotation scenarios the ball in diagonal patterns of the upper limbs in PNF approach will be executed by the patients. The precision, repetition, and speed of exercise will be adjusted according to the therapist's opinion and the patient's progress, and feedbacks provide by the therapist.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Occupational Therapy Clinic, School of Rehabilitation Sciences, Shahid Beheshti University of Medica
Full name of responsible person
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
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Position
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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

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

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

Data Dictionary

Not applicable

Title and more details about the data/document

Information related to primary and secondary outcomes

When the data will become available and for how long

After publishing the articles

To whom data/document is available

Researchers intending to research in this field

Under which criteria data/document could be used

Obtaining written permission from the research team, Mention the source of information

From where data/document is obtainable

- Fatemeh Sadat Hosseini Ramshe : School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences, Damavand St, Imam Hossein Square. Email Adress: fatemehosseini@sbmu.ac.ir , - Dr Mahnaz Hejazi Shirmard : School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences, Damavand St, Imam Hossein Square. Email Adress: :M.hejazishirmard@yahoo.com

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

After sending the email to the researcher and requesting the document, the researcher will request the opinion of other members of the research team regarding the provision of this information and, if the members agree, the documents will be sent as soon as possible but sending the documents requires the acceptance of the criteria mentioned above.

Comments