

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 range 18 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: 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7756 1721

##### Email address

fatemehosseini@sbmu.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

#### 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 Medical Sciences

#### **Full name of responsible person**

Dr Mahnaz Hejazi

#### **Street address**

School of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences, in front of Bu Ali Hospital, Damavand Street

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1616913111

#### **Phone**

+98 21 7715 9535

#### **Email**

m.hejazishirmard@yahoo.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Dr Javad Mowafaghian Research Center

#### **Full name of responsible person**

Dr Mahnaz hejazi

#### **Street address**

No. 11, Khark Street, Enghelab Street, Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

11339-13813

#### **Phone**

+98 21 6671 6100

**Email**  
m.hejazishirmard@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr Afshin Zarghi  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Shahid Arabi St, Yemen St, Shahid Chamran highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
19839-63113  
**Phone**  
+98 21 2243 9780  
**Email**  
Mpajouhesh@sbmu.ac.ir

#### 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

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Fateme Sadat Hosseini Ramshe  
**Position**  
Master student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
School of Rehabilitation Sciences, Shahid Beheshti  
University of Medical Sciences, in front of Bu Ali  
Hospital, Damavand St, Imam Hossein Square  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1616913111  
**Phone**  
+98 21 7756 1721  
**Fax**  
**Email**  
fatemehosseini@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr Mahnaz Hejazi  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
School of Rehabilitation Sciences Shahid Beheshti  
University of Medical Sciences, in front of Bu Ali  
Hospital, Damavand St, Imam Hossein Square  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1616913111  
**Phone**  
+98 21 7756 1721  
**Email**  
m.hejazishirmard@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Fateme Sadat Hosseini Ramshe  
**Position**  
Master student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
School of Rehabilitation Sciences, Shahid Beheshti  
University of Medical Sciences, in front of Bu Ali  
Hospital, Damavand St, Imam Hossein Square  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**

1616913111

**Phone**

+98 21 7756 1721

**Fax**

**Email**

fatemehosseini@sbmu.ac.ir

## 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**