

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparing upper cervical and cranium joint dysfunctions by measuring sonographic data of muscles / Effect of eye movement exercises on instantaneous blood pressure changes in hypertensive and normotensive groups with craniocervical joint dysfunctions

#### Protocol summary

##### Study aim

Main goals : 1) Comparing upper cervical and cranium joint dysfunctions between normotensive and hypertensive groups by measuring neck muscle thickness using sonographic data 2)Comparing changes of instantaneous blood pressure before and after of eye gaze exercise therapy 3)Considering dynamic MRI as a measurement tool for cranial rhythmic impulse measurement /comparing cranial rhythmic impulse between normotensive and hypertensive groups using dynamic MRI

##### Design

Randomized Control Trial

##### Settings and conduct

Rehabilitation sonography device Dynamic MRI  
Biofeedback Heart Rate Variability sensor Laser Headset for Range Of Motion

##### Participants/Inclusion and exclusion criteria

Hypertension systolic blood pressure 13 to 17.9 mmHg  
Hypertension Diastolic blood pressure 80 to 11.9 mmHg  
Age 20-50 Primary hypertension ( atherosclerosis )  
Cardiac disease Renal disease Pulmonary disease  
Vertebral malalignment Surgery history Age higher than 50

##### Intervention groups

one group will receive eye gaze exercises and the other group will receive placebo ( just staring at a point , not to move head or eye )

##### Main outcome variables

Sonographic (CSA) data of deep neck flexors and extensors Dynamic MRI of cranium for cranial rhythmic impulse Heart rate variability Neck ROM

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190815044535N1**

Registration date: **2023-03-05, 1401/12/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-05, 1401/12/14**

Update count: **0**

##### Registration date

2023-03-05, 1401/12/14

##### Registrant information

##### Name

Pezhman Masoudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2285 7585

##### Email address

masoudip2002@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-04, 1401/11/15

##### Expected recruitment end date

2023-06-20, 1402/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing upper cervical and cranium joint dysfunctions by measuring sonographic data of muscles / Effect of eye movement exercises on instantaneous blood pressure changes in hypertensive and normotensive groups with craniocervical joint dysfunctions

#### Public title

Cervicocranium joint dysfunctions / eye movement exercise blood pressure effects in normotensive and hypertensive groups

#### Purpose

Basic science

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Hypertension systolic blood pressure 13 to 17.9 mmHg  
Hypertension Diastolic blood pressure 80 to 11.9 mmHg  
Age 20-50

##### Exclusion criteria:

Primary hypertension ( atherosclerosis ) Cardiac disease  
Renal disease Pulmonary disease Vertebral malalignment  
Surgery history Age higher than 50 Taking drugs for hypertension

#### Age

From **20 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomized block design

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The groups will be blind to procedure of exercise therapy and the way it may work to reduce blood pressure

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of university of social welfare and rehabilitation

###### Street address

Daneshyar alley , Daneshjoo Blv , Daneshjoo Square

, Velenjak, Tehran

##### City

tehran

##### Province

Tehran

##### Postal code

1985713871

##### Approval date

2023-03-02, 1401/12/11

##### Ethics committee reference number

IR.USWR.REC.1401.237

### Health conditions studied

#### 1

##### Description of health condition studied

Hypertension, Cervicocranium joint dysfunction

##### ICD-10 code

I15

##### ICD-10 code description

Secondary hypertension

### Primary outcomes

#### 1

##### Description

Instantaneous blood pressure

##### Timepoint

Before and just after intervention

##### Method of measurement

Blood pressure measuring device

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: hypertensive group with cervicocranium joint dysfunction which receives eye movement exercise therapy

##### Category

Treatment - Other

#### 2

##### Description

Control group: hypertensive group with cervicocranium joint dysfunction which receives placebo

##### Category

Placebo

### Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Physiotherapy research laboratory of university of social welfare and rehabilitation

**Full name of responsible person**

Pezhman Masoudi

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masoudip2002@yahoo.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

karimi nouredin

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Daneshyar alley , Daneshjoo Blv , Daneshjoo Square , Velenjak, Tehran

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karimi@uswr.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Nouredin karimi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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Ph.D. student

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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**

Part of data including interventional part of study would  
be available if asked .

**When the data will become available and for how long**

After 4 months if not required by journals or other  
organizations, data would be vanished

**To whom data/document is available**

Journals , Research committee

**Under which criteria data/document could be used**

Future related researches

**From where data/document is obtainable**

To first author

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

Asking by sending email to first author

**Comments**