

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness combination of myofascial release technique-dry needling and dry needling on the active trigger points of the upper trapezius muscle.

#### Protocol summary

##### Study aim

Comparison of the effects of two manual treatments separately and together in treating the active trigger points

##### Design

Clinical trial with control group, experimental-interventional, convenience sampling, random allocation.

##### Settings and conduct

The target community is selected from the students of the Rehabilitation School who have active trigger points in upper trapezius muscle. Sampling method is non-random and allocation of samples to groups will be random. Sampling will be done at the Biomechanics Laboratory of the Faculty of Rehabilitation. In this study data analyzer will be blind. The physiotherapist assesses the local pain intensity through (visual analog scale), active cervical contra lateral flexion using Goniometer and pressure pain threshold using algometer. Iranian version of neck disability index questionnaire will be used to determine the level of patient's ability. Variables will be assessed at the first session before and after the intervention and the third session and two weeks after the end of the treatment.

##### Participants/Inclusion and exclusion criteria

Subjects between 20 and 40 years, Presence of active trigger points, Pain at least 30 mm in visual analog scale, Exclusion criteria: History of whiplash injury, History of head , neck , cervical spine or shoulder surgery, History of cervical radiculopathy, Diagnosed fibromyalgia and myopathy, History of cancer, Pregnancy, History of treatment in a past month, Contraindication of dry needling technique,

##### Intervention groups

Intervention group 1: Dry needling , three times a week , For 1 week. Intervention group 2: Myofascial release+Dry needling+Myofascial release , three times a week , For 1 week..

#### Main outcome variables

Pain intensity at the visual scale of pain, Pressure pain threshold, Active cervical contra lateral flexion, Neck disability index Based on forward head posture.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191027045255N1**  
Registration date: **2019-11-09, 1398/08/18**  
Registration timing: **prospective**

Last update: **2019-11-13, 1398/08/22**

Update count: **1**

##### Registration date

2019-11-09, 1398/08/18

##### Registrant information

##### Name

maryam mobarakzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4466 0339

##### Email address

mobarakzadeh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effectiveness combination of myofascial release technique-dry needling and dry needling on the active trigger points of the upper trapezius muscle.

**Public title**  
Comparison of the combination of myofascial release technique-dry needling and dry needling on the active trigger points of the upper trapezius muscle.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Subjects between 20 and 40 years Presence of active trigger points in upper trapezius muscle Pain at least 30 mm in visual analog scale

**Exclusion criteria:**  
History of whiplash injury History of head , neck , cervical spine or shoulder surgery History of cervical radiculopathy Diagnosed fibromyalgia and myopathy History of cancer Pregnancy Myofascial therapy within the past month Contraindication of dry needling technique

**Age**  
From **20 years** old to **40 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, a sample of 60 people, 30 cards for each intervention group were considered and placed inside a sealed envelope that is non-transparent to draw then each patient takes one of the cards randomly and their group is identified and the generated sequence is recorded.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**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

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

##### Approval date

2019-05-05, 1398/02/15

##### Ethics committee reference number

IR.SBMU.RETECH.REC.1398.039

## Health conditions studied

### 1

#### Description of health condition studied

Myofascial Trigger Points of the Upper Trapezius Muscle

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain intensity in the visual scale of pain

#### Timepoint

Measure the severity of pain in the first session before and after the intervention and the third session and two weeks after the end of treatment

#### Method of measurement

Visual analogue scale

### 2

#### Description

Pain pressure threshold

#### Timepoint

Measurement at first session before and after intervention, the third session, and two weeks after the end of treatment

#### Method of measurement

Digital algometer (Lutron FG-5020)

### 3

#### Description

Active cervical contra lateral flexion

#### Timepoint

Measurement at first session before and after intervention and the third session and two weeks after

the end of treatment  
**Method of measurement**  
Goniometry

#### 4

##### **Description**

Neck disability index

##### **Timepoint**

Measurement at first session before intervention, the third session, and two weeks after the end of treatment

##### **Method of measurement**

Neck disability index- iranian version questionnaire

#### 5

##### **Description**

Forward head posture

##### **Timepoint**

Measurement at first session before intervention, and two weeks after the end of treatment

##### **Method of measurement**

Craniovertebral Angle

## **Secondary outcomes**

empty

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Dry needle technique is done using sterile needles and disposable Dong Bang with a length of 40 mm and a thickness of 0.25 mm. After the tight bundles are found in the upper trapezius muscle, the therapist inserts the needle at a 30-degree angle and inserts the needle out frequently and then again into another part of the trigger point, this procedure is repeated as long as no other local twitch response is felt. This technique is performed in 3 sessions and three times a week.

##### **Category**

Treatment - Devices

#### 2

##### **Description**

Intervention group: In this group, the tight bundles in the upper trapezius muscle were first released for 5 minutes, and the muscle response consisted of localized heat sensed by the patient indicating the correct technique. Then Dry needle technique is done using sterile needles and disposable Dong Bang with a length of 40 mm and a thickness of 0.25 mm. After the tight bundles are found in the upper trapezius muscle, the therapist inserts the needle at a 30-degree angle and inserts the needle out frequently and then again into another part of the trigger point, this procedure is repeated as long as no other local twitch response is felt. Then, again, the Myofascial release technique is performed for 5 minutes in the same manner as

described. This technique is performed in 3 sessions and three times a week.

##### **Category**

Treatment - Devices

## **Recruitment centers**

#### 1

##### **Recruitment center**

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

The School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences

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

Farshad Okhovatian

###### **Street address**

SBMU School of Rehabilitation Sciences., Damavand Ave., Imam Hossein Square (AS), Tehran., Iran

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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

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

Afshin Zarghi

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##### **Grant name**

##### **Grant code / Reference number**

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

No

##### **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

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**Person responsible for general inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

DR. Farshad Okhovatian

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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Maryam Mobarakzadeh

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Bachelor

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**Latest degree**

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**Other areas of specialty/work**

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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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

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