

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of instrument assisted soft tissue mobilization technique (IASTM) with dry needling (DN) in improving pain pressure threshold (PPT) , active cervical contra lateral flexion (ACCLF) , pain intensity (PI) and neck disability index (NDI) in patients with active trigger points of the upper trapezius muscle

Protocol summary

Study aim

Comparison of the effects of two manual treatments separately 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 fourth session and fourth week after the end of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Subjects between 18 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: Instrument assisted soft tissue mobilization technique , twice a week , For 2 weeks.

Intervention group 2: Dry needling , twice a week , For 2 weeks. Control group: There is no intervention.

Main outcome variables

Pain intensity at the visual scale of pain, Pressure pain threshold, Active cervical contra lateral flexion, Neck disability index,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180311039049N1**

Registration date: **2018-11-03, 1397/08/12**

Registration timing: **prospective**

Last update: **2018-12-24, 1397/10/03**

Update count: **1**

Registration date

2018-11-03, 1397/08/12

Registrant information

Name

Zeinab Ahmadpour emshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3331 2736

Email address

z.ahmadpour@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of instrument assisted soft tissue mobilization technique (IASTM) with dry needling (DN) in improving pain pressure threshold (PPT) , active cervical contra lateral flexion (ACCLF) , pain intensity (PI) and neck disability index (NDI) in patients with active trigger points of the upper trapezius muscle

Public title

Comparison of instrument assisted soft tissue mobilization technique (IASTM) with dry needling (DN) on the active trigger points of the upper trapezius muscle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Subjects between 18 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

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **75****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, a sample of 75 people, 25 cards for each intervention group and 25 cards for control 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

2017-08-13, 1396/05/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.278

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 fourth session and fourth week after the end of treatment

Method of measurement

Visual analogue scale

Secondary outcomes**1****Description**

Pain pressure threshold

Timepoint

Measurement at first session before and after intervention and the fourth session and fourth week after the end of treatment

Method of measurement

Digital algometer (Lutron FG-5020)

2

Description

Active cervical contra lateral flexion

Timepoint

Measurement at first session before and after intervention and the fourth session and fourth week after the end of treatment

Method of measurement

Goniometry

3

Description

Neck disability index

Timepoint

Measurement at first session before intervention and the fourth session and fourth week after the end of treatment

Method of measurement

Neck disability index- iranian version questionnaire

Intervention groups

1

Description

Intervention group: In this technique is first step to increase blood flow and muscle tissue temperature for 5 minutes, superficial heat will be used and then using the myo-release tool, muscle tissue will be massaged for 5 minutes. The soft tissue mobilization technique is carried out using the myo-release tool No. 1, made in Iran. The tool is made of stainless steel. Immediately after massage, the therapist applies 3 passive stretches for 30 seconds on the muscle and this phase is completed by the 2nd 12th active muscle stretches by the patient herself and in the final stage, the patient performs the shoulder elevation as 2 sets of 15. This technique is performed in 4 sessions and twice a week.

Category

Treatment - Other

2

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 4 sessions and twice a week.

Category

Treatment - Other

3

Description

Control group: There is no intervention.

Category

N/A

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

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1407

Fax

+98 21 7759 1807

Email

Tavan2020@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Fax

+98 21 2243 3455

Email

zarghi@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
Zeinab Ahmadpour Emshi
Position
MSC Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
SBMU School of Rehabilitation Sciences., Damavand Ave., Imam Hossein Square (AS).,Tehran., Iran
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1407
Fax
+98 21 7759 1807
Email
zeinab.ahmadpour1372@Gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
DR. Farshad Okhovatian
Position
Professor
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
SBMU School of Rehabilitation Sciences., Damavand Ave., Imam Hossein Square (AS).,Tehran., Iran
City

Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1407
Fax
+98 21 7759 1807
Email
Farshadokhovatian1965@Gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zeinab Ahmadpour Emshi
Position
MSC Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
SBMU School of Rehabilitation Sciences.,Damavand Ave., Imam Hossein Square (AS).,Tehran., Iran
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1407
Fax
+98 21 7759 1807
Email
zeinab.ahmadpour1372@Gmail.com

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