Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity

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Iran (Islamic Republic of)

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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
Age
From **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.
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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
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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

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
MSC Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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