Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effects of Instrument-Assisted Soft Tissue Mobilization (IASTM) on trigger points of the cervical and lumbar region among sedentary individuals

Protocol summary

Study aim
To evaluate the effects of instrument-assisted soft tissue mobilization on trigger points of the cervical and lumbar region among sedentary individuals

Design
The research will use a prospective randomized control trial as a study design. a study design in which participants are randomly assigned to either an experimental or control group. A hypothesis may be tested to see which variables are most likely to be significant explanatory factors.

Settings and conduct
Data will be collected from department of Physical and Rehabilitative Medicine of Memon Medical Institute Hospital Karachi

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • 18 – 40 years of age male and female both • Cervical and lumbar pain more than 6 months • Pain intensity of at least 3 in the numeric pain scale Exclusion Criteria: • Any type of trauma related to pain area • Acute Fractures • Tuberculosis of spine • Who has history of whiplash injury • History of head, neck, cervical spinal surgery • History of cervical radiculopathy • Diagnosed fibromyalgia and myopathy • History of cancer in relevant area • Myofascial therapy within the past month • Who has taking any medicine for psychiatric disorder

Intervention groups
Intervention group: 25 participants will be received instrument-assisted soft tissue mobilization treatment technique using ergon tool. Along with ergon technique conventional treatment including hot pack 15 minutes, strengthening exercises of all weak cervical and lumbar muscles with 10-12 repetitions of each muscle would be performed. Stretching exercises of all tight cervical and lumbar muscles 3-6 repetition with 10 seconds hold Control Group: 25 participants will be received only conventional treatment same as included in intervention group

Main outcome variables
Neck Disability Index, Pain Sensitivity Questionnaire, Modified Somatic Perception Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220804055615N4**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date
2023-03-29, 1402/01/09

Registrant information

Name
Mohabbat Ali

Name of organization / entity
Memon Medical Intitute Hospital

Country
Pakistan

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+92 21 99261810

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ramal_209@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-15, 1401/12/24

Expected recruitment end date
2023-04-01, 1402/01/12

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Instrument-Assisted Soft Tissue Mobilization (IASTM) on trigger points of the cervical and lumbar region among sedentary individuals

Public title
Effects of Instrument-Assisted Soft Tissue Mobilization (IASTM) on trigger points versus manual Exercises
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 40 years are included Who having cervical and lumbar pain more than 6 months Patients diagnosed with at least active trigger points in cervical & lumbar region Patients having pain intensity of at least 3 in the numeric pain scale
Exclusion criteria:
If the pain is related to any trauma or fracture Patients with tuberculosis of spine Patients with any types of wounds History of infections or any other cause of back pain not due to muscles spasm or trigger point If the patients have a history of whiplash injury If the patients have history of head, neck and cervical spinal surgery If the patients have a history of cervical radiculopathy If the patients have diagnosed with fibromyalgia and myopathy If the patients have history of cancer at relevant area of body If the patients get the myofascial physical therapy treatment within the past one month If the patients are taking any anti-psychotic medicine
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used in this study. This method is used to ensure a balance in sample size across groups over time. Blocks are small and balanced with predetermined group assignments, which keeps the number of participants in each group similar at all times. The block size is determined with 2 treatment groups, a block size of 4. After block size has been determined, all possible balanced combinations of assignment within the block (ie, an equal number for all groups within the block) will be calculated. Blocks are then randomly chosen to determine the participants' assignment into the groups.
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
Institutional Review Board Memon Medical Institute Hospital
Street address
Safoora Goth Scheme 33
City
Karachi
Postal code
75270
Approval date
2022-07-14, 1401/04/23
Ethics committee reference number
IRB/MMIH/2022/03

Health conditions studied

1

Description of health condition studied
To treat the myofascial trigger points in cervical and lumbar region
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Instrumental versus manual exercises for trigger point release
Timepoint
The outcomes will be measured at the baseline and re-measured after the 18 sessions. The intervention protocol is based on three sessions per week for six weeks.
Method of measurement
Outcome will measure by numeric pain rating scale, neck disability index, pain sensitivity questionnaire and modified somatic perception questionnaire

Secondary outcomes

1

Description
Muscle power
Timepoint
Before and after 18 session of treatment
Method of measurement
Manual muscle power test

2

Description
To check range of motion before and after intervention
Timepoint
Before and after 18 session of treatment
Method of measurement
Range of motion will be check by inclinometer

3

Description
To check pain scale before an after the interventions
Timepoint
Before and after 18 session of treatment
Method of measurement
Pain will be check by numeric pain scale

Intervention groups

1

Description
Twenty five participants will be received instrument-assisted soft tissue mobilization treatment technique using ergon tool. The position of patients will be in prone lying. With the help of ergon tool, we give strokes (sweeping motion) proximal to distal or distal to proximal in both ways over the myofascial restrictions for 10 minutes. Along with ergon technique conventional treatment including hot pack 15 minutes, strengthening exercises of all weak cervical and lumbar muscles with 10-12 repetitions of each muscle would be performed. Stretching exercises of all tight cervical and lumbar muscles 3-6 repetition with 10 seconds hold. Every patient undergoes 45 minutes' treatment session, 3 sessions/ week for 6 weeks. Assessment will be performed at baseline and at the end of 6th week treatment protocol.
Category
Rehabilitation

2

Description
Twenty five participants will be received only conventional treatment including hot pack therapy for 15 minutes. Strengthening exercises of all weak cervical and lumbar muscles with 10-12 repetitions of each muscle would be performed. Stretching exercises of all tight cervical and lumbar muscles, 3-6 repetitions with 10 seconds hold. Every patient undergoes 45 minutes' treatment session, 3 sessions/ week for 6 weeks. Assessment will be performed at baseline and at the end of 6th week treatment protocol.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Memon Medical Institute Hospital
Full name of responsible person
Dr. Mohabbat Ali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Memon College of Physical and Rehasbilitaive Medicine
Full name of responsible person
Dr. Mohabbat Ali Principal of MCPRM
Street address
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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
Memon College of Physical and Rehasbilitaive Medicine
Proportion provided by this source
100
Public or private sector

Private

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

Memon Medical Institute Hospital

Full name of responsible person

Dr. Mohabbat Ali

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

analytical data will be avail in published article or can be request by email to get the data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available