

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Comprehensive corrective exercise program with and without soft tissue massage therapy on pain, functional mobility and quality of life among office syndrome patients

Protocol summary

Study aim

This study aimed to compare the effects of a comprehensive corrective exercise program with and without soft tissue massage therapy on pain, functional mobility, and quality of life in patients with office syndrome.

Design

Two arm parallel individual randomized trial with blinded outcome assessment

Settings and conduct

This randomized clinical trial (RCT) will be carried out in the Department of Physical Therapy and will be completed within nine months of receiving approval. Based on VAS outcomes, the computed sample size will be 34 participants per group (28 + a 20% dropout buffer), with a 95% significant level and 80% power

Participants/Inclusion and exclusion criteria

Participants of age 18-55, both male and female, with at least one myofascial trigger point on the trapezius muscle, and who had worked in an office or on a laptop for over a year and reported using a laptop for more than three hours daily will be selected. The study will be excluded patients with a history of motor vehicle accidents, inflammatory disorders such as rheumatoid arthritis, and cervical or lumbar radiculopathies with or without neurological deficits. Patients with spine degeneration, those who had undergone myofascial pain therapy within the previous month, individuals with recent fractures or dislocations and pregnancy will also be excluded.

Intervention groups

Those who met the eligibility criteria will be complete consent forms to participate. The lottery method will be used for randomization, with participants' names picked to determine whether they will be assigned to Group A (Comprehensive Corrective Exercise Program [CCEP] with Soft Tissue Massage [STM]) or Group B.

Main outcome variables

Pain using Visual Analogue Scale Functional Disability using Brief Inventory Pain Quality of life using WHOQOL-BREF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241119063780N1**

Registration date: **2024-11-29, 1403/09/09**

Registration timing: **retrospective**

Last update: **2024-11-29, 1403/09/09**

Update count: **0**

Registration date

2024-11-29, 1403/09/09

Registrant information

Name

Hafsa Chandio

Name of organization / entity

University of Lahore

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-30, 1402/11/10

Expected recruitment end date

2024-08-10, 1403/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comprehensive corrective exercise program with and without soft tissue massage therapy on pain, functional mobility and quality of life among office syndrome patients

Public title

A Comprehensive corrective exercise program with and without soft tissue massage therapy on pain, functional mobility and quality of life among office syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged between 18-55 years Both male and female
Participants diagnosed with having atleast one myofacial trigger point on trapezius muscle
Participants who reported using a laptop for more than three hours daily
Participants who have worked in an office setting or on a laptop for more than 1 year

Exclusion criteria:

Pregnancy
Patients with history of motor vehicle accident
Patients with Cervical & lumbar radiculopathies with or without neurological deficits
Patients with degeneration of spine
Patients with history of myofascial pain therapy within the mouth
Patients with recent fracture/dislocation

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

This is simple , individual randomization study. Non probability sampling technique will be used to select participants in which sealed envelopes will be used in randomization and allocation concealment will be carried out.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is single blinded study in which assessor will be kept blind who will unaware of the treatment being studied to which group's participants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of University of Lahore

Street address

University of Lahore Teaching Hospital Lahore ,
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Postal code

55150

Approval date

2024-05-22, 1403/03/02

Ethics committee reference number

REC-UOL-/184/08/24

Health conditions studied**1****Description of health condition studied**

Myalgia in office syndrome refers to muscle pain caused by prolonged sitting, poor posture, and repetitive movements. It commonly affects the neck, shoulders, and back, leading to discomfort and stiffness.

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes**1****Description**

The Numerical Pain Rating Scale (NPRS) is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0-10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line.

Timepoint

8th week

Method of measurement

The NPRS takes <1 minute to complete Scores range from 0-10 points, with higher scores indicating greater pain intensity. The NPRS can be administered verbally (therefore also by telephone) or graphically for self-completion.

2**Description**

The BPI-sf is a modification of the Brief Pain Inventory - Long Form, which includes additional questions on demographics (date of birth, marital status, education, employment), pain history, aggravating and easing factors, treatment and medication, pain quality, and response to treatment.

Timepoint

8th week

Method of measurement

The Brief Pain Inventory - Short Form (BPI-sf) is a 9 item self-administered questionnaire used to evaluate the severity of a patient's pain and the impact of this pain on the patient's daily functioning. The patient is asked to rate their worst, least, average, and current pain intensity, list current treatments and their perceived effectiveness, and rate the degree that pain interferes with general activity, mood, walking ability, normal work, relations with other persons, sleep, and enjoyment of life on a 10-point scale.

3**Description**

The WHOQOL-BREF is a shorter version of the WHOQOL. Both were developed by the World Health Organization (WHO) and published in 1995. It has been tested for reliability and validity. The WHOQOL-BREF is a self-administered questionnaire comprising 26 questions on the individual's perceptions of their health and well-being over the previous two weeks.

Timepoint

8th week

Method of measurement

Responses to questions are on a 1-5 Likert scale where 1 represents "disagree" or "not at all" and 5 represents "completely agree" or "extremely". The WHOQOL-BREF covers four domains each with specific facets. These domains are Physical health, psychological, social relationships and environment

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The study involves participants randomly assigned to Group A, who will be received the Comprehensive corrective exercise program. This massage regimen will be complemented by routine physical therapy, consisting of a 15-minute application of heat therapy. The Corrective comprehensive exercises will be designed in three phases, including initial, improvement, and maintenance. Exercises were progressed in frequency and intensity during these phases, as long as the movements will be performed in a good quality. The exercises in the initial phase will be characterized with a cognitive focus on scapular muscles (i.e., the internal focus of attention). Subjects will be instructed to contract underactive muscles isometric ally

and relax overactive muscles for normalization of scapular position and motion, after restoring the muscle balance in the static conditions, participants added upper extremity movements in various training positions . Once the participants could contract appropriate muscles in correct alignment during the movement pattern, the protocol will be focused on improving sustained postures. This goal will be addressed in the improvement phase when necessary tissue adaptations occurred by increasing the load of exercise. In the maintenance phase, the participant continued to do the exercises and maintain the training adaptations for two weeks". The exercises will be the same as the improvement phase without any progression in intensity and frequency three phases (concentric, isometric, and eccentric) lasting for 3s each. They had already been trained to achieved the reliable reproduction of the movement at the required velocity. They performed the movement five times, and the rest time lasted 3s in-between.

Category

Treatment - Other

2**Description**

Intervention group: The participants randomly allocated in Group B will be received passive Soft tissue therapy. Before Passive Soft Tissue Therapy routine physical therapy consist of electrical stimulation with heat therapy for 15 minutes will be applied. Participants will be encouraged to relax as much as possible before the pressure will be applied. After identifying and marking the most sensitive latent Trigger point(TP) in the area, the patient will be asked to lie in a supine or sitting position and the therapist stood over her at the end of the bed, putting her thumb on the area and applying pressure to the extent that the participant felt the pain; the contact with the TP will be maintained all through the treatment. Then the therapist will be passively moved in a position of comfort (5-8 degrees) so that participants will be report 75% reduction in pain. This condition will be maintained for 90 seconds and performed 3 times per session, with a 15-second rest interval

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources

1

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Grant name
None
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Lahore
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

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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

Demographic data and data related to final outcome will be shared by maintaining the confidentiality

When the data will become available and for how long

Data will be available after the publication of findings till six months

To whom data/document is available

For people working in academic institutions as well as people working in clinic can also apply to receive it

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding aithor of the study , Hafsa Chandio and can contact on +92 302 3159237, Hafsaphysiotherapist0@gmail.com

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

Open access and there is the traditional public data release where anyone can get access to the data

Comments