Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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 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

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Hafsa Chandio
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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 envelops 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 , Punjab , Pakistan
City
Lahore
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-betweens.

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

Contact
Name of organization / entity
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Position
Consultant
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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 confidentially
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 alsoapply 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