

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effects of breathing Reeducation on clinical outcomes in non specific chronic neck pain.

Protocol summary

Study aim

To compare the effects of breathing reeducation on clinical outcomes in non specific chronic neck pain.

Design

A Randomised controlled trial, Double blinded, sample size of 80 patients single centre

Settings and conduct

Trial will be conducted at district Headquarter Hospital Faisalabad, patient and therapist are blinded by sealed envelop method

Participants/Inclusion and exclusion criteria

Inclusion criteria • Patients having non specific neck pain for more than 3 months • Patients having no history of respiratory disease • Patients having FEV1/FVC ratio=0.7 or 70% of the predicted • Age between 25-50 years
Exclusion criteria • Smokers • Patients with upper cervical signs and symptoms • Prolong sitting

Intervention groups

Intervention group will receive supervised breathing exercises focusing on proper inhalation, exhalation and chest expansion for 15 minutes in addition to routine physical therapy treatment. Patients will undergo the intervention twice a week for consecutive 8 weeks.

Main outcome variables

Pain, ROM, Disability, Strength of neck muscles, Endurance, Quality of life, Vital capacity FET values

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200226046623N1**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

sahreen Anwar

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 41 8750106

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-27, 1398/12/08

Expected recruitment end date

2021-06-30, 1400/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of breathing Reeducation on clinical outcomes in non specific chronic neck pain.

Public title

Breathing reeducation in neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients having non specific neck pain for more than 3 months • Patients having no history of respiratory

disease• Patients having FEV1/FVC ratio=0.7 or 70% of the predicted value• Patients having no history of antidepressant drug treatment• Both genders Age between 25-50 years

Exclusion criteria:

Smokers• Known history of depression• Patients having any sort of Asthma• Patients with upper cervical signs and symptoms• Prolong sitting.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization by sealed envelop method

Blinding (investigator's opinion)

Double blinded

Blinding description

participants in the study are blind to the treatment to which they are exposed to.The assessor who is measuring the outcome measures is unaware of the treatment the patient has gone through

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of university of Lahore

Street address

1km, Defence Road, Bhotatian chowk Lahore
Pakistan

City

Lahore

Postal code

54000

Approval date

2019-12-16, 1398/09/25

Ethics committee reference number

697

Health conditions studied

1

Description of health condition studied

Non specific Neck pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and at 4th ,8th week

Method of measurement

Visual Analogue scale (VAS)

2

Description

Range of motion neck

Timepoint

Before intervention,at 4th and 8th week

Method of measurement

CROM device

3

Description

Cervical muscle strength

Timepoint

Before intervention,and at 4th week and 8th week

Method of measurement

Dynamometer

4

Description

Neck muscles endurance

Timepoint

Before intervention,4th week and 8th week

Method of measurement

Craniocervical Flexion test, Biopressure feedback

5

Description

Neck disability

Timepoint

Before intervention,at 4th and 8th week

Method of measurement

Neck disability index questionire

6

Description

Quality of life

Timepoint

Before intervention and at 4th and 6th week

Method of measurement

7**Description**

Pulmonary Function Test

Timepoint

Before intervention, at 4th and 6th week

Method of measurement

Spirometry

Secondary outcomes

empty

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

Intervention group: Group will receive supervised breathing exercises focusing on proper inhalation, exhalation and chest expansion for 15 minutes with routine physical therapy treatment in form of infrared for 10 minutes, isometric exercises for flexor, extensor and side flexor of cervical spine in supine lying 20 repetitions with 10 seconds hold. Patients will undergo the intervention twice a week for consecutive 8 weeks. Outcome measures will be taken for musculoskeletal and respiratory elements on baseline and at 4th and 8th week respectively. For musculoskeletal element Pain and ROM will be assessed by using visual Analogue scale and CROM (deluxe), Functional disability will be measured through Neck disability index. Cervical muscle strength and endurance will be measured through isometric neck dynamometer and craniocervical flexion test respectively. For respiratory element Spirometer will be used for assessing pulmonary volumes, flows and maximal voluntary ventilation.

Category

Treatment - Other

2**Description**

Control group: Control group will receive routine physical therapy treatment in form of infrared for 10 minutes, isometric exercises for flexor, extensor and side flexor of cervical spine in supine lying 20 repetitions with 10 seconds hold. Patients will undergo the intervention twice a week for consecutive 8 weeks. Outcome measures will be taken for musculoskeletal and respiratory elements on baseline and at 4th and 8th week respectively. For musculoskeletal element Pain and ROM will be assessed by using visual Analogue scale and CROM (deluxe), Functional disability will be measured through Neck disability index. Cervical muscle strength and endurance will be measured through isometric neck dynamometer and craniocervical flexion test respectively. For respiratory element Spirometer will be used for assessing pulmonary volumes, flows and maximal voluntary ventilation.

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

District Headquarter Hospital Faisalabad

Full name of responsible person

shaista Bano

Street address

Department of physical Therapy., District Headquarter Hospital Faisalabad

City

Faisalabad

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shaistaphysio@hotmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of Lahore

Full name of responsible person

Dr. Ashfaq Ahmed

Street address

One Km Defence Road, Bobatiyan Chowk, Lahore, Pakistan

City

Lahore

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51000

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+92 42 35321456

Email

Ashfaaqpt@gmail.com

Web page address<https://www.Uol.edu.pk>**Grant name****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

The University of Lahore

Full name of responsible person

Sahreen Anwar

Position

Assistant professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Province

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Position

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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

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

IPD collected for primary outcome measures only

When the data will become available and for how long

june 2022 till june 2023

To whom data/document is available

people working in academics as well as in business

Under which criteria data/document could be used

type of analyses and criterias will be available

From where data/document is obtainable

data will be available on request through email

id...Sahreenanwar@yahoo.com

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

Just send an email with purpose of acquiring data and within a week data will be provided

Comments

N/A