# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Nov 2022

## 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
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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 treatement 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, Bhobatian 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**

NOOS Questioire

**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**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
District Headquarter Hospital Faisalabad
**Full name of responsible person**
shaista Bano
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Department of physical Therapy., District Headquarter Hospital Faisalabad
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
University of Lahore
**Full name of responsible person**
Dr. Ashfaq Ahmed
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One Km Defence Road, Bobatiyan Chowk, Lahore, Pakistan
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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
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Sahreen Anwar
**Position**
Assistant professor
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## Person responsible for scientific inquiries

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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