Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
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The University of Lahore
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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
Street address
Department of physical Therapy., District Headquarter Hospital Faisalabad
City
Faisalabad
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38000
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+92 41 8750106
Email
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
Postal code
51000
Phone
+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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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