

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Neck-stabilization exercises and Pilates exercise on pain, sleep disturbance, and kinesiophobia in Non-specific chronic neck pain

#### Protocol summary

##### Study aim

To evaluate if pilates exercises have significant effects than neck-stabilization exercises in treating chronic neck pain, sleep disturbance as well as decreasing kinesiophobia in non-specific chronic neck pain patients

##### Design

Sixty participants will be randomly allocated into 2 groups , thirty in each group via computerized random number generator. Group 1 will receive neck stabilization exercises and Group 2 will receive Pilates exercises . The interventions will be given for 8 weeks

##### Settings and conduct

Sample will be selected through Convenient sampling technique from physiotherapy department of Allied Hospital, Faisalabad, Physical therapy department of DHQ Faisalabad

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: • Both gender • Age 18-45 years . • Recurrent history of neck pain from 3 months. • Intensity of pain greater than or equal to 5/10 on numerical pain rating scale. Exclusion criteria: • History of cervical spine injury or surgery • History of neck trauma , spinal deformity . • History of specific neck pain such as fibromyalgia , Rheumatological diseases • History of neck-pain secondary to other conditions including neoplasm, any neurological or vascular disease • History of radiculopathy • History of Degenerative arthritis of cervical spine • History of osteoporosis • History of low back pain

##### Intervention groups

Sixty participants will be randomly allocated into 2 groups , thirty in each group via computerized random number generator. Group 1 will receive neck stabilization exercises and Group 2 will receive Pilates exercises . The interventions will be given for 8 weeks

##### Main outcome variables

Numerical pain rating scale, Insomnia severity index and Tampas scale of kinesiophobia will be used for pre and post assessment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220930056062N7**

Registration date: **2024-06-24, 1403/04/04**

Registration timing: **prospective**

Last update: **2024-06-24, 1403/04/04**

Update count: **0**

##### Registration date

2024-06-24, 1403/04/04

##### Registrant information

##### Name

Kaiynat Shafique

##### Name of organization / entity

The University of Faisalabad

##### Country

Pakistan

##### Phone

+92 334 6925051

##### Email address

kaiynatshafique@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-06-26, 1403/04/06

##### Expected recruitment end date

2024-08-01, 1403/05/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of Neck-stabilization exercises and Pilates exercise on pain, sleep disturbance, and kinesiophobia in Non-specific chronic neck pain

## Public title

Neck-stabilization exercises vs Pilates exercise in non-specific chronic neck pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Both gender Age 18-45 years Recurrent history of neck pain from 3 months Intensity of pain greater than or equal to 5/10 on numerical pain rating scale

### Exclusion criteria:

History of cervical spine injury or surgery History of neck trauma , spinal deformity History of specific neck pain such as fibromyalgia , Rheumatological diseases History of neck-pain secondary to other conditions including neoplasm, any neurological or vascular disease History of radiculopathy History of Degenerative arthritis of cervical spine History of osteoporosis History of low back pain

## Age

From **18 years** old to **45 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will be randomly allocated into 2 groups , thirty in each group via computerized random number generator.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patients will be blind in this clinical trial. In this single-blinded RCT study, participants will be unaware of which treatment they are receiving. To ensure blinding, the treatments will be somewhat similar. The allocation sequence will be concealed.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Government College University Faisalabad

#### Street address

Faisalabad

#### City

Faisalabad

#### Postal code

38000

### Approval date

2024-06-14, 1403/03/25

### Ethics committee reference number

GCUF/REF/26451

## Health conditions studied

## 1

### Description of health condition studied

Cervicalgia (Non-specific Neck pain)

### ICD-10 code

M54.2

### ICD-10 code description

Cervicalgia

## Primary outcomes

## 1

### Description

Pain

### Timepoint

The assessment will be made two times , before and after 8 weeks

### Method of measurement

Numerical pain rating scale (NPRS)

## 2

### Description

Sleep disturbance

### Timepoint

The assessment will be made two times , before and after 8 weeks

### Method of measurement

Insomnia severity index (ISI)

## 3

### Description

Kinesiophobia

### Timepoint

The assessment will be made two times , before and after 8 weeks

### Method of measurement

Tampas scale of kinesiophobia

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: neck stabilization exercises (The interventions will be given 2 times per week for 8 weeks, 5 -10 repetitions, 30 minutes per session. Following exercises will include 1.Neutral head position 2.Shoulder blade stabilization 3.Chin tuck in 4.Cranio-cervical flexion 5.Cervical flexion - extension 6.Shoulder shrugging. )

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: Pilates exercises (The interventions will be given 2 times per week for 8 weeks, 5 -10 repetitions, 30 minutes per session. Following exercises will include 1. Hip twist level 1, 2. Rolling like a ball, 3. Shoulder bridge level 1, 4. The hundred level 1, 5. Breast stroke level 1, 6. Breast stroke level 2)

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

DHQ Faisalabad

##### Full name of responsible person

Rafia Imtiaz

##### Street address

Faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 9210092

##### Email

rafiaimtiaz@gcuf.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Government College University Faisalabad

##### Full name of responsible person

Rafia Imtiaz

##### Street address

Faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 9210023

##### Email

rafiaimtiaz@gcuf.edu.pk

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

No

##### Title of funding source

It will be a self funded study

##### Proportion provided by this source

1

##### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Government College University Faisalabad

##### Full name of responsible person

Rafia Imtiaz

##### Position

Lecturer

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

Faisalabad

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##### Province

Punjab

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rafiaimtiaz@gcuf.edu.pk

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Government College University Faisalabad

##### Full name of responsible person

Rafia Imtiaz

##### Position

Punjab

##### Latest degree

Master

##### Other areas of specialty/work

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**Person responsible for updating data****Contact****Name of organization / entity**

Government College University

**Full name of responsible person**

Rafia Imtiaz

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Faisalabad

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No - There is not a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available