

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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+92 334 6925051

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Full name of responsible person

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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