Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 41 9210023
Email
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
Physiotherapy

Street address
Faisalabad
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 41 9200876
Email
rafiaimtiaz@gcuf.edu.pk

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
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 41 9200876
Email
rafiaimtiaz@gcuf.edu.pk

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