

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Kinetic Control Training on Clinical, Radiographic, and Electromyographic Findings among Taxi Drivers with Sacroiliac Joint Dysfunction: A Randomized Controlled Trial

Protocol summary

Study aim

To evaluate the effectiveness of Kinetic Control Training (KCT) compared with standard physiotherapy

Design

Randomized controlled trial (RCT)

Settings and conduct

Gilani Physio and Joint Care, Model Town, Lahore, Pakistan

Participants/Inclusion and exclusion criteria

Inclusion: 1. Male taxi drivers aged between 20 and 60 years. 2. Professional driving experience of at least one year. 3. Symptoms of sacroiliac joint dysfunction persisting for more than two months. 4. Diagnosis of SIJD confirmed by three or more positive sacroiliac joint provocative tests (e.g., Patrick's test, Thigh Thrust, Gaenslen's test, Sacral Thrust, Compression/Distraktion tests). 5. Pain intensity rated between 4 and 7 on the Visual Analogue Scale (VAS). 6. Willingness to participate in the study and provide written informed consent.

Exclusion: 1. Participants will be excluded from the study if they present with any of the following: 2. History of malignancy or systemic illness affecting musculoskeletal function. 3. Neurological disorders (e.g., multiple sclerosis, dementia). 4. Inflammatory conditions, including sacroiliitis, ankylosing spondylitis, rheumatoid arthritis, or fibromyalgia. 5. Disc herniation or lumbar radiculopathy confirmed by clinical and radiological assessment. 6. ly with the intervention protocol or follow-up assessments.

Intervention groups

Intervention Group (Group A): Kinetic Control Training (KCT) Control Group (Group B): Standard Physiotherapy Program

Main outcome variables

1. Pain Intensity 2. Functional Disability 3. Ultrasound-based contraction ratios

General information

Reason for update

Acronym

SIJ

IRCT registration information

IRCT registration number: **IRCT20200208046409N1**

Registration date: **2026-07-06, 1405/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-06, 1405/04/15**

Update count: **0**

Registration date

2026-07-06, 1405/04/15

Registrant information

Name

Syed Asadullah Arslan

Name of organization / entity

The University of Lahore-Pakistan

Country

Pakistan

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+92 42 35858446

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-30, 1405/04/09

Expected recruitment end date

2026-08-30, 1405/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Kinetic Control Training on Clinical, Radiographic, and Electromyographic Findings among Taxi Drivers with Sacroiliac Joint Dysfunction: A Randomized Controlled Trial

Public title

The Effect of a Movement Control Exercise Program on Pain, Function, and Joint Health in Taxi Drivers with Low Back and Pelvic Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

□ Male taxi drivers aged between 20 and 60 years. □ Professional driving experience of at least one year. □ Symptoms of sacroiliac joint dysfunction persist for more than two months. □ Diagnosis of SIJD confirmed by three or more positive sacroiliac joint provocative tests (e.g., Patrick's test, Thigh Thrust, Gaenslen's test, Sacral Thrust, Compression/Distract tests). □ Pain intensity was rated between 4 and 7 on the Visual Analogue Scale (VAS)—willingness to participate in the study and provide written informed consent.

Exclusion criteria:

□ Participants will be excluded from the study if they present with any of the following: □ History of malignancy or systemic illness affecting musculoskeletal function. □ Neurological disorders (e.g., multiple sclerosis, dementia). □ Inflammatory conditions including sacroiliitis, ankylosing spondylitis, rheumatoid arthritis, or fibromyalgia. □ Disc herniation or lumbar radiculopathy confirmed by clinical and radiological assessment. □ Pelvic inflammatory disease or other gynecological/urological conditions affecting the pelvic region. □ Previous spinal surgery within the past 12 months. □ Positive laboratory findings for inflammatory markers. □ Inability to comply with the intervention protocol or follow-up assessments.

Age

From **20 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

The unit of randomization will be the individual participant. After confirming eligibility criteria and obtaining written informed consent, each participant will be assigned a unique study identification number. A computer-generated randomization sequence will be created by an independent researcher who is not

involved in participant recruitment, assessment, treatment administration, or data analysis. The random sequence will be generated using randomization software (e.g., Random Allocation Software version 2.0 or the randomization function in SPSS). Variable block sizes of 4 and 6 will be used to reduce the predictability of treatment assignment while maintaining balanced group allocation. No stratification factors will be used because the study population is relatively homogeneous (male taxi drivers aged 20-60 years with sacroiliac joint dysfunction). Therefore, stratified randomization is not planned. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope will contain the treatment assignment according to the computer-generated randomization sequence. The envelopes will be prepared by the independent researcher and stored in a secure location. After completion of baseline assessments, the next envelope in sequence will be opened by a study coordinator not involved in outcome assessment. Outcome assessors responsible for clinical, ultrasonographic, and electromyographic measurements will remain blinded to group allocation throughout the study. Participants will be instructed not to disclose their treatment allocation to the assessors. Thus, the study will employ computer-generated block randomization, individual participant allocation, concealed assignment through sequentially numbered opaque sealed envelopes, and blinded outcome assessment to minimize selection and assessment bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

All clinical outcome assessments, including pain intensity (VAS), disability measures (ODI and RMDQ), muscle strength assessments, ultrasound imaging, and surface electromyography evaluations, will be conducted by independent assessors who are blinded to treatment allocation. Outcome assessors will have no involvement in participant recruitment, randomization, or intervention delivery. Ultrasound sonographers and electromyography assessors will be blinded to group allocation. Image files and EMG recordings will be anonymized and coded before analysis. Assessors will evaluate recordings using participant identification numbers only and will have no access to treatment information.

Placebo

Not used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee

Street address

17Km- Raiwind Road Lahore

City

Lahore

Postal code

55150

Approval date

2026-01-15, 1404/10/25

Ethics committee reference number

Ref: JRB/FAHS/DEAN/2025/MBS-53/285

Health conditions studied

1

Description of health condition studied

Sacroiliac Joint Dysfunction

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Pain Intensity

Timepoint

Before and after the intervention

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Functional Disability

Timepoint

before and after the intervention

Method of measurement

Roland-Morris Disability Questionnaire (RMDQ)

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

2

Description

Control group:

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Gillani Physio and Joint Care

Full name of responsible person

Dr. Muhammad ilyas

Street address

Model Town Link Road Lahore

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54000

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+92 332 1483575

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asadshahgilani@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Superior University Lahore

Full name of responsible person

Prof. Dr. Muhammad Naveed Babur

Street address

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Superior University 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**

Superior University Lahore
Full name of responsible person
Dr. syed asadullah arslan
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

De-identified Individual Participant Dataset (IPD) Study Protocol Statistical Analysis Plan (SAP) Data Dictionary and Codebook Informed Consent Form Template Case Report Forms (CRFs)

When the data will become available and for how long

Individual participant data (IPD), the study protocol, statistical analysis plan, informed consent form, and anonymized dataset will be made available upon reasonable request to the corresponding investigator. Data will become available beginning 6 months after publication of the primary study results in a peer-reviewed journal and will remain available for a period of 5 years thereafter. Researchers requesting access must provide a methodologically sound proposal and obtain approval from the principal investigator and the relevant institutional ethics committee. Data will be shared in a de-identified format to protect participant confidentiality and privacy.

To whom data/document is available

De-identified Individual Participant Data (IPD) underlying the published results, including demographic data, outcome measures, and statistical analysis datasets, will be made available upon reasonable request after publication of the primary study findings. Access may be

granted to qualified researchers from academic institutions, healthcare organizations, governmental agencies, and private-sector research organizations who provide a methodologically sound research proposal and obtain any required ethical approvals. Requests will be reviewed by the Principal Investigator and the study supervisory committee to ensure that the proposed use is scientifically valid and consistent with participant consent and data protection regulations. Additional supporting documents, including the study protocol, statistical analysis plan, informed consent form, data dictionary, and analytic code, may also be made available upon request. Data will be shared in a de-identified format to protect participant confidentiality. Commercial organizations may apply for access under the same review process; however, data will not be used for purposes that could compromise participant privacy or conflict with the original consent provided by participants. Data will be available beginning six months after publication of the primary study results and for up to five years thereafter. Requests should be directed to the Principal Investigator via the contact information provided in the trial registration.

Under which criteria data/document could be used

De-identified individual participant data (IPD), including demographic characteristics, baseline and follow-up outcome measures (VAS, ODI, RMDQ, ultrasound contraction ratios, and surface EMG parameters), along with the study protocol, statistical analysis plan, informed consent template, and data dictionary, will be made available upon reasonable request. Requests for access must be submitted in writing to the Principal Investigator and should include a clear research proposal outlining the objectives, methodology, and planned analyses. Data will be shared only for scientifically sound research purposes, including secondary analyses, meta-analyses, systematic reviews, validation studies, or other non-commercial academic research. All requests will be reviewed by the Principal Investigator and supervisory research team to assess scientific merit, ethical compliance, participant confidentiality, and consistency with the original informed consent. Access will be granted only after approval of the request and completion of a data-sharing agreement. Data will be provided in a de-identified electronic format through secure file transfer or encrypted cloud-based storage. No information that could directly or indirectly identify participants will be disclosed. Data will be available beginning six months after publication of the primary study results and will remain accessible for a period of five years following publication.

From where data/document is obtainable

Researchers interested in obtaining study-related documents, including the full study protocol, statistical analysis plan, informed consent forms, and anonymized participant-level dataset, should contact the Principal Investigator. Preferred Method of Communication: Email correspondence is preferred for all initial requests.

Requests should clearly state the purpose of data use, research objectives, and institutional affiliation. Contact Information: Principal Investigator: Dr. Syed Asadullah Arslan, PhD (Physical Therapy) Institution: Gilani Physio and Medical Center Postal Address: Gilani Physio and Medical Center, Model Town, Lahore, Punjab, Pakistan

What processes are involved for a request to access data/document

Participants will be recruited from the outpatient department of Gilani Physio and Joint Care, Lahore, Pakistan. Individuals who express interest in participating will undergo an initial screening session to determine eligibility. Screening will include demographic information, occupational history, medical history review, and sacroiliac joint provocative tests. The screening process is expected to require approximately 30–45 minutes. Eligible participants will be invited to attend a baseline assessment session. During this visit, written informed consent will be obtained prior to data collection. Baseline assessments will include: • Pain assessment using the Visual Analogue Scale (VAS) (approximately 5 minutes). • Functional disability assessment using the Oswestry Disability Index (ODI) and Roland-Morris Disability Questionnaire (RMDQ) (approximately 15–20 minutes). • Muscle strength assessment using Manual Muscle Testing and/or Hand-Held Dynamometry (approximately 15 minutes). • Surface Electromyography (sEMG) assessment of trunk and pelvic stabilizing muscles during standardized tasks (approximately 30–40 minutes). • Ultrasound imaging for measurement of muscle thickness and contraction ratios of the Multifidus, Gluteus Maximus, Rectus Abdominis, and External Oblique muscles (approximately 20–30 minutes). The total baseline assessment session is expected to take approximately 90–120 minutes. Following baseline assessment, participants will be randomly allocated to either the Kinetic Control Training group or the Control group. Participants will attend supervised treatment sessions three times per week for eight weeks. Each treatment session will last approximately 45–60 minutes. At the completion of the 8-week intervention period, participants will undergo a post-intervention assessment involving the same clinical, ultrasound, and EMG measurements performed at baseline. This assessment is expected to take approximately 90–120 minutes. Participants will then return for a follow-up assessment three months after completion of the intervention. The follow-up assessment will again include all primary and secondary outcome measurements and will require approximately 90–120 minutes. Overall, each participant will be involved in the study for approximately five months, including screening, intervention, post-treatment assessment, and follow-up evaluation. The total direct participant commitment is estimated at 28–32 hours over the entire study period.

Comments