Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of adding an individualized staged corrective-exercise program to a foundational active intervention on the postural profile of adults meeting prespecified postural criteria for upper crossed syndrome: a randomized controlled trial

Protocol summary

Study aim
To compare the added effect of 12-week individualized corrective exercise versus an active intervention on posture; EMG, range of motion, and balance are secondary, and EEG is exploratory.

Design
Two-arm parallel trial, 36 participants, 1:1 allocation, blocks of four and six, stratified by sex; assessors, signal processors, and statistician blinded.

Settings and conduct
Assessments occur at Arak University, EEG at Valiasr Hospital, and training at Diaphragm Clinic. Assessments are at baseline, week 12, and four-week follow-up; EMG and EEG have no follow-up.

Participants/Inclusion and exclusion criteria
Inclusion: women and men aged 18–40 years, BMI 18.5–24.9, residing in Arak, with head ≥44°, shoulder ≥49°, and kyphosis ≥42°; consent and ability to attend. Exclusion: relevant surgery/fracture; neurological, psychiatric, musculoskeletal, or cardiopulmonary disease; CNS medication; acute pain; pregnancy; trunk rotation >5°; balance disorder; or recent regular exercise.

Intervention groups
Intervention: 36 sessions of 60–80 minutes; active foundational intervention plus individualized staged exercise. Comparator: 36 sessions of 20–30 minutes including cycling, stretching, mobilization, and education.

Main outcome variables
Primary outcome: head, shoulder, and kyphosis angle profile at week 12. EMG, range of motion, and balance are secondary; EEG is exploratory.

General information

Reason for update
Due to the armed conflict and its consequences, including disrupted access to the study sites, restrictions on the operation of collaborating centers, and the absence of safe conditions for participant recruitment and assessment, the study could not begin as originally scheduled. Consequently, study implementation was postponed, and the study timeline and protocol details were reviewed and updated before the enrollment and randomization of the first participant. At the time of this update, no participant had been randomized and no outcome data had been collected or analyzed.

Acronym
ISCEP

IRCT registration information
IRCT registration number: **IRCT20250921067305N1**
Registration date: **2025-11-12, 1404/08/21**
Registration timing: **prospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **1**

Registration date
2025-11-12, 1404/08/21

Registrant information
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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01
Expected recruitment end date
2026-12-22, 1405/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of adding an individualized staged corrective-exercise program to a foundational active intervention on the postural profile of adults meeting prespecified postural criteria for upper crossed syndrome: a randomized controlled trial

Public title
Individualized staged corrective exercise in adults with an upper crossed syndrome postural phenotype
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Female or male, aged 18–40 years, and residing in Arak Concurrent presence of a forward-head angle of at least 44 degrees, a forward-shoulder angle of at least 49 degrees, and thoracic kyphosis of at least 42 degrees Body mass index of 18.5–24.9 kg/m² Ability to complete the assessments and exercise program safely Willingness to maintain the usual pattern of physical activity and refrain from beginning a new structured exercise program outside the study Ability to attend intervention sessions and study assessments Provision of written informed consent before formal assessment
Exclusion criteria:
History of surgery or fracture affecting the spine, shoulder girdle, or pelvis A diagnosed neurological, psychiatric, or musculoskeletal condition that could compromise safety or confound the outcomes Use of medication affecting the central nervous system Acute pain or uncontrolled cardiopulmonary disease Pregnancy An angle of trunk rotation greater than five degrees during the forward-bending test A lower-limb or pelvic disorder that precludes valid balance testing Regular participation in corrective exercise, resistance training, or manual therapy during the preceding three months
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized
Randomization description
After completion of baseline assessment, an independent statistician will generate the allocation sequence using randomly permuted blocks of four and six, with a 1:1 allocation ratio and stratification by sex. Block sizes and the allocation sequence will remain concealed from personnel involved in recruitment and assessment. Allocation will be concealed using sequentially numbered, opaque, tamper-evident, sealed envelopes. The next envelope will be opened only after eligibility has been confirmed, baseline assessment completed, and the participant irreversibly enrolled, by a person who has no access to the allocation sequence.
Blinding (investigator's opinion)
Single blinded
Blinding description
Because of the nature of the intervention, participants and the intervention provider cannot be blinded. Outcome assessors, EMG and EEG processors, and the statistician will remain blinded to group allocation until completion of the primary analysis. Images, Formetric outputs, and signal files will be coded without group or time-point information and presented in random order. The code key will be held by an independent person, and any inadvertent unblinding will be documented.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
research Ethics Committees of University of Isfahan
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Approval date
2025-05-31, 1404/03/10
Ethics committee reference number
IR.UI.REC.1404.053

Health conditions studied

1

Description of health condition studied

Upper Crossed Syndrome

ICD-10 code

R29.3

ICD-10 code description

Abnormal posture

Primary outcomes

1

Description

Forward-head angle; the first component of the multivariate primary postural outcome. A lower angle is favorable.

Timepoint

Baseline, week 12, and four-week follow-up; the primary comparison is at week 12.

Method of measurement

Mean of three lateral photographs; C7–tragus angle relative to the vertical, calculated using AutoCAD 2025.

2

Description

Forward-shoulder angle; the second component of the multivariate primary postural outcome. A lower angle is favorable.

Timepoint

Baseline, week 12, and four-week follow-up; the primary comparison is at week 12

Method of measurement

Mean of three lateral photographs; C7–acromion angle relative to the vertical, calculated using AutoCAD 2025.

3

Description

Thoracic-kyphosis angle; the third component of the multivariate primary postural outcome. A lower angle is favorable.

Timepoint

Baseline, week 12, and four-week follow-up; the primary comparison is at week 12.

Method of measurement

Mean of six DIERS formetric 4D scans; ICT–ITL angle calculated using DICAM 3.

Secondary outcomes

1

Description

Normalized RMS amplitude of the dominant-side upper, middle, and lower trapezius and serratus anterior.

Timepoint

Baseline and week 12

Method of measurement

Eight-channel wireless Noraxon surface EMG; MVIC normalization and mean of three valid seven-second trials.

2

Description

Description: UT/MT, UT/LT, and UT/SA ratios based on normalized whole-task EMG amplitude.

Timepoint

Baseline and week 12

Method of measurement

Ratios calculated from the mean normalized RMS of three valid trials.

3

Description

Active flexion range of motion of the dominant shoulder.

Timepoint

Baseline, week 12, and four-week follow-up.

Method of measurement

Mean of three measurements using a 360-degree universal goniometer.

4

Description

Active external-rotation range of motion of the dominant shoulder.

Timepoint

Baseline, week 12, and four-week follow-up.

Method of measurement

Mean of three measurements using a 360-degree universal goniometer.

5

Description

Active cervical-flexion range of motion

Timepoint

Baseline, week 12, and four-week follow-up.

Method of measurement

Mean of three measurements using a 360-degree universal goniometer.

6

Description

Mean center-of-pressure velocity during eyes-open and eyes-closed Romberg tests.

Timepoint

Baseline, week 12, and four-week follow-up.

Method of measurement

Mean of three valid 30-second trials measured using DIERS Pedoscan.

7

Description

Lower Quarter Y-Balance composite score of the dominant limb.

Timepoint

Baseline, week 12, and four-week follow-up.

Method of measurement

Maximum reach in three directions normalized to limb length; three valid trials.

8

Description
Change in central relative alpha power, averaged across C3, Cz, and C4, during quiet standing with eyes open; exploratory EEG outcome.

Timepoint
Baseline and week 12

Method of measurement
Recorded using 24-channel EEG 3840 at 500 Hz; relative alpha power from 8 to <13 Hz calculated using EEGLAB 2026.0.0.

Intervention groups

1

Description
The intervention group will receive three sessions per week for 12 weeks, totaling 36 sessions. Each session will last approximately 60–80 minutes and comprise 10 minutes of stationary cycling, one to two minutes of transition and preparation, 40–55 minutes of main exercise, and 5–10 minutes of cool-down, stretching, or indication-based manual techniques. In addition to the components shared by both groups, the individualized staged program comprises overlapping stages addressing breathing and trunk control, restoration of mobility, retraining of muscle activation and coordination, basic movements, fundamental and functional movement patterns, and progression toward load tolerance and health-related physical fitness. Exercise selection, regression, and progression will follow prespecified criteria and individual response. Sessions will be delivered individually or to no more than three participants per provider.

Category
Lifestyle

2

Description
The active-comparator group will attend three sessions per week for 12 weeks, totaling 36 sessions. Each session will last approximately 20–30 minutes and comprise 10 minutes of stationary cycling, indication-based stretching of target muscles, prespecified mobilizations, and education on healthy movement habits. The type, sequence, and dose of the shared components will match the corresponding components in the intervention group. This group will not receive exercises based on the staged model, retraining of muscle activation and coordination, training of basic or complex movement patterns, individualized progression of load and task, or the specific transition toward health-related physical fitness. Participants will continue their usual activities and will not begin a new structured exercise program outside the study.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak university

Full name of responsible person
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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?
Yes

Title of funding source
The University of Isfahan

Proportion provided by this source
100

Public or private sector
Public

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 Isfahan
Full name of responsible person
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
The approved protocol, amendments, statistical analysis plan, data dictionary, analytic code, and the deidentified individual-level minimal dataset will be deposited in a stable public repository when the trial results are published. Coded assessment photographs and videos and raw biosignals that may carry a residual risk of re-identification will not be made publicly available and may be requested only through controlled-access procedures.
When the data will become available and for how long
Publicly shareable files will be deposited in a stable repository when the primary trial results are published and will remain available indefinitely or according to repository policy. Requests for controlled access to sensitive data may be considered after publication of the trial results.
To whom data/document is available
The deidentified minimal dataset, data dictionary, and

analytic code will be available to researchers through a public repository. Access to sensitive data will require a specific and justified scientific purpose, approval by the relevant institutional body or ethics committee, and execution of a data-use agreement. Access decisions will not be controlled by a single author.

Under which criteria data/document could be used

Performing statistical analyses within the scope of published articles related to the present research is permissible. However, the misuse of data to extract new findings is strictly prohibited.

From where data/document is obtainable

The public repository link will be added to the trial record and results article when available. Requests for controlled access to sensitive data should be submitted to the institutional email address m.khorami@spr.ui.ac.ir and should specify the research purpose, requested data, analysis plan, institutional or ethics approval, and data-protection plan. Requests will be reviewed by the relevant institutional body and research team; approved access will be provided under a data-use agreement.

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

The applicant must provide a compelling and specific justification for requesting the data. Upon receipt of the request, they will be notified that their application is under review. Following approval by the research team, the data will be made available to the applicant within one month from the start of the request review.

Comments