

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Additive Effects of Active Versus Sham Neuromuscular Electrical Stimulation Added to Core-Pelvic Stability Training in Women with Lumbar Hyperlordosis and Anterior Pelvic Tilt: A Randomized Controlled Trial

Protocol summary

Study aim

To investigate whether adding active neuromuscular electrical stimulation to core-pelvic stability training produces greater improvement in lumbar lordosis angle compared to exercise alone or exercise plus sham NMES.

Design

A three-arm parallel-group will randomize controlled trial with assessor blinding and a pretest-posttest design. Participants will be allocated in a 1:1:1 ratio to one of three groups (Exercise, Exercise + Sham NMES, Exercise + Active NMES). The randomization sequence will generate using permuted blocks of six by an independent biostatistician, and group allocation will be concealed using sequentially numbered opaque sealed envelopes (SNOSE). Outcome assessors and the statistician will be blinded to group allocation.

Settings and conduct

The study will be conducted in Isfahan, Iran. All intervention sessions (exercise and electrical stimulation) will be delivered in-person under direct supervision. Baseline and post-intervention assessments will also be performed at the same center by a trained examiner who will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Women aged 25–40 years Lumbar lordosis $>45^\circ$ (measured by flexible ruler) Anterior pelvic tilt $>12^\circ$ (measured by digital inclinometer) History of spinal surgery or fracture Acute or chronic low back pain requiring treatment within the past year Neurological or vestibular disorders affecting balance Pregnancy or delivery within the previous 12 months Musculoskeletal deformities (congenital or acquired) Participation in structured core stability training within the previous 6 months Contraindications to NMES (e.g., pacemaker, epilepsy, skin conditions at electrode sites) Inability to attend scheduled sessions

Intervention groups

3 groups: Exercise Sham NMES Active NMES

Main outcome variables

Lumbar Lordosis Angle

General information

Reason for update

Acronym

NMES-Lordosis Trial

IRCT registration information

IRCT registration number: **IRCT20211103052956N2**

Registration date: **2026-08-10, 1405/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2026-08-10, 1405/05/19**

Update count: **0**

Registration date

2026-08-10, 1405/05/19

Registrant information

Name

Saeid Rostami

Name of organization / entity

Ragheb Isfahani higher education institute

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01
Expected recruitment end date
 2026-05-10, 1405/02/20
Actual recruitment start date
 2026-04-21, 1405/02/01
Actual recruitment end date
 2026-08-11, 1405/05/20
Trial completion date
 2026-10-23, 1405/08/01

Scientific title
 Additive Effects of Active Versus Sham Neuromuscular Electrical Stimulation Added to Core-Pelvic Stability Training in Women with Lumbar Hyperlordosis and Anterior Pelvic Tilt: A Randomized Controlled Trial

Public title
 Effects of Electrical Stimulation on Lumbar Lordosis and Pelvic Tilt in Women

Purpose
 Other

Inclusion/Exclusion criteria
Inclusion criteria:
 Women aged 25–40 years Lumbar lordosis >45° (measured by flexible ruler) Anterior pelvic tilt >12° (measured by digital inclinometer)
Exclusion criteria:
 History of spinal surgery or fracture, Acute or chronic low back pain requiring treatment within the past year, Neurological or vestibular disorders affecting balance, Pregnancy or delivery within the previous 12 months, Musculoskeletal deformities (congenital or acquired), Participation in structured core stability training within the previous 6 months, Contraindications to NMES (e.g., pacemaker, epilepsy, skin conditions at electrode sites), Inability to attend scheduled sessions

Age
 From **25 years** old to **40 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **90**
 Actual sample size reached: **87**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization was performed using permuted blocks of six with a 1:1:1 allocation ratio. The random sequence was generated by an independent biostatistician, and group allocation was concealed using sequentially numbered opaque sealed envelopes (SNOSE).

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Outcome assessors and statisticians were blinded to group allocation. Participants and trainers could not be

blinded due to the exercise-based nature of the intervention, but participants were instructed not to disclose their group assignment during testing sessions.

Placebo
 Used

Assignment
 Factorial

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of reserches (Islamic Azad university, Isfahan branch)
Street address
 Arghavanie street
City
 isfahan
Province
 Isfahan
Postal code
 8316111258
Approval date
 2026-02-08, 1404/11/19
Ethics committee reference number
 IR.KHUISF.REC.1403.260

Health conditions studied

1

Description of health condition studied
 hyperlordosis
ICD-10 code
 M40.4
ICD-10 code description
 Postural lordosis

Primary outcomes

1

Description
 Variable name: Lumbar Lordosis Angle, Unit of measurement: Degrees (°)
Timepoint
 The mean of three consecutive measurements will recorded. Timing of measurement: Before the start of the intervention (baseline) and immediately after the 8-week intervention period (post-intervention)
Method of measurement
 Measurement method: Measured using a flexible ruler (non-elastic tape) will place along the spinous processes from T12 to S2 in a relaxed standing position. The lordotic angle will calculate using the formula: angle

(degrees) = $4 \times (\text{arc height} / \text{chord length}) \times 57.3$.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: exercise

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ragheb Isfahani higher education institute

Full name of responsible person

Saeid Rostami

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Sponsors / Funding sources

1

Sponsor

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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

Ragheb Isfahani higher education institute

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

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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

De-identified individual participant data (IPD): Includes demographic data (age, height, weight, BMI), primary outcome data (lumbar lordosis angle at two time points), secondary outcome data (anterior pelvic tilt angle and plank endurance time at two time points), and group allocation data. All data will be shared after removing identifiable information (names, surnames, contact

numbers, and addresses).

When the data will become available and for how long

Access Start: 6 months after publication of the study results in a peer-reviewed scientific journal. Access End: Up to 5 years after publication of results (in accordance with ICMJE standards). Estimated Publication Date: Within 12 months after study completion (study completion: 8 weeks after last participant enrollment).

To whom data/document is available

Researchers affiliated with academic and scientific institutions who submit a written request and obtain approval from their institutional ethics committee. Also, researchers intending to conduct secondary analyses or meta-analyses for scientific and non-commercial purposes. Additional conditions: Priority will be given to researchers who have an approved research proposal from their institutional ethics committee and sign a non-disclosure agreement committing to use the data solely for scientific purposes.

Under which criteria data/document could be used

Data and documents may be used exclusively for scientific and research purposes. Permitted uses include: Secondary analyses for research purposes Meta-analyses and systematic reviews Validation of the original study results Education and research methodology training Conditions of use: Proper citation of the original article is mandatory Commercial or for-profit use is prohibited Any new publication of results must be coordinated with the responsible authors Data must not be transferred to third parties

From where data/document is obtainable

Name: Dr. Saeid Rostami (Corresponding Author and General Public Contact Person) Email: srostami.20@gmail.com Phone: 00989131088601 Postal Address: Department of Sport Sciences, Faculty of Human Sciences, Ragheb Isfahani Higher Education Institute, Isfahan, Iran. Postal Code: 81551-39998 Initial Contact Method: Submit a written request via email, including the study title, IRCT registration code, and proposed research plan for data analysis.

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

Request Process Steps: Submit a written request via email to the corresponding author (including: study title, IRCT code, requester's full details, institutional affiliation, and purpose of data use) Initial review by the research team (maximum 2 weeks) If approved: Send the non-disclosure agreement and data use agreement form for signature Receive signed form and final approval from the requester's institutional ethics committee Send data/documents via email or secure download link (maximum 4 weeks after final approval) Total Process Time: Approximately 4 to 6 weeks from receipt of a complete request

Comments