Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 conducted in Isfahan, Iran. All intervention sessions (exercise and electrical stimulation) will delivered in-person under direct supervision. Baseline and post-intervention assessments will be also will perform 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° (measured by flexible ruler) Anterior pelvic tilt >12° (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
3gruops: 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)

Phone
+98 31 3368 9040

Email address
srostami.20@gmail.com

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 yearsLumbar 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

Isfehan

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 × (arc height / chord length) × 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
Street address
Basij
City
Isfahan
Province
Isfehan
Postal code
8116532574
Phone
+98 31 3368 7040
Email
srostami.20@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ragheb Isfahani higher education institute
Full name of responsible person
Saeid Rostami
Street address
Bassij
City
Isfahan
Province
Isfehan
Postal code
8116237458
Phone
+98 31 3368 7040
Email
srostami.20@gmail.com
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
Ragheb Isfahani higher education institute
Full name of responsible person
Saeid Rostami
Position
Assistan professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Bassij
City
Isfahan
Province
Isfehan
Postal code
8136478549
Phone
0098313687040
Email
srostami.20@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ragheb Isfahani higher education institute
Full name of responsible person
Saeid Rostami
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Bassij
City
isfahan
Province
Isfehan
Postal code

84164835498

Phone

0098313687040

Email

srostami.20@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ragheb Isfahani higher education institute

Full name of responsible person

Saeid Rostami

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Bassij

City

Isfahan

Province

Isfehan

Postal code

8136445698

Phone

000098313687040

Email

srostami.20@gmail.com

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