Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effects of Neuromuscular Electrical Stimulation and Core Training on Anabolic-Catabolic, Metabolic Hormones, and Sports Performance in Adult Man.

Protocol summary

Study aim

This study investigates the effects of core training and neuromuscular electrical stimulation (NMES) on anabolic and catabolic hormones, metabolic markers, and sports performance in adult men.

Design

This study is a randomized controlled clinical trial (RCT) with a parallel design and single-blind assessment, aiming to investigate the effects of core training and Neuromuscular Electrical Stimulation (NMES) on anabolic and catabolic hormones, metabolic markers, and sports performance in adult men. Participants will be randomly assigned to four groups: This study is in Phase 2 of the clinical trial, with steps including participant enrollment, randomization, intervention implementation, and pre- and post-assessments

Settings and conduct

This study will be conducted at the Specialized Health Promotion and Disease Prevention Clinic of Body House and at the Royal Arena Sports Club in Isfahan, Iran. All stages, including participant enrollment, interventions, and pre- and post-assessments, will take place at these centers. The randomization, evaluation, and follow-up procedures will be fully carried out at these locations.

Participants/Inclusion and exclusion criteria

Participants must be healthy men aged 35 to 55 years without serious medical conditions. Individuals with cardiovascular issues or those using hormone-affecting medications are excluded.

Intervention groups

The study includes 4 groups (control, core training, NMES, combined). The design is random, parallel, and single-blind

Main outcome variables

1. Anabolic Hormones: including testosterone, growth hormone, and IGF-1. 2. Catabolic Hormones: including cortisol. 3. Metabolic Variables: including insulin, liver enzymes (ALT, AST), and alkaline phosphatase. 4. Sports Performance: including evaluation of muscle strength and endurance, flexibility, stride length and time, symmetry, and dynamic stability in walking

General information

Reason for update

Acronym

NMES

IRCT registration information

IRCT registration number: **IRCT20250317065108N1**
Registration date: **2025-04-06, 1404/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-06, 1404/01/17**
Update count: **0**

Registration date

2025-04-06, 1404/01/17

Registrant information

Name

shokoofeh samouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date

2025-04-14, 1404/01/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Neuromuscular Electrical Stimulation and Core Training on Anabolic-Catabolic, Metabolic Hormones, and Sports Performance in Adult Man.

Public title
"Investigating the Effects of Neuromuscular Electrical Stimulation and Core Training on Hormones and Sports Performance in Men"
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gender: Male Age: 35 to 55 years Good general health (No chronic metabolic, cardiovascular, or neuromuscular diseases) No prior regular core training or NMES usage in the past six months No use of hormonal drugs or metabolism-affecting supplements Ability to attend study sessions and adhere to the research protocol No regular alcohol or tobacco consumption
Exclusion criteria:
Presence of metabolic, cardiovascular, or neuromuscular diseases (e.g., diabetes, heart disease, multiple sclerosis). Use of hormonal medications or supplements affecting metabolism (e.g., testosterone, steroids, insulin). History of NMES use in the past six months. Recent surgeries affecting physical activity or muscle function. Presence of implantable electronic devices (e.g., pacemakers) that may interfere with NMES.
Age
From **35 years** old to **55 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to one of the four groups (control, core training, neuromuscular electrical stimulation, or combined training and stimulation) using block randomization with equal block sizes. The allocation sequence is not predetermined and will be generated using random number software to ensure balance across groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, both the outcome assessor and data analyst are blinded to group allocation. While participants and intervention administrators are aware of the assigned groups, the outcome assessor collects performance and metabolic data without knowledge of group assignments. Additionally, the data analyst processes and analyzes the data after collection and coding, ensuring blinding to group allocation.
Placebo
Not used
Assignment
Parallel
Other design features
1. Simultaneous comparison of two distinct interventions: The study simultaneously compares two intervention methods (core training and NMES) and their combination with a control group. 2. Four-group design: The study employs a four-group design, including control, core training, neuromuscular electrical stimulation, and the combined group, allowing for a more detailed analysis of independent and combined effects. 3. 8-week intervention duration: The study spans an 8-week intervention period to examine the long-term effects of training and electrical stimulation. 4. Focus on anabolic and catabolic hormones: The study investigates the effects of training and NMES on anabolic and catabolic hormones, a less common focus in similar research. 5. Assessment of metabolism and physical performance: In addition to hormones, the study evaluates the impact of these interventions on physical performance and metabolic markers. 6. Body composition assessment with InBody 270: The use of the InBody 270 device for accurate body composition measurement is a unique feature of this study. 7. Utilization of advanced technology (TruSculpt Flex) for NMES: The use of the advanced TruSculpt Flex device for neuromuscular electrical

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee on Research Islamic Azad University, Isfahan Branch (Khorasgan)
Street address
Arghavanie blv., Khorasgan
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Province
Isfehan
Postal code
813895183
Approval date
2024-12-25, 1403/10/05
Ethics committee reference number
IR.IAU.KHUISF.REC.1403.470

Health conditions studied

1

Description of health condition studied
Prevention
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The primary outcome variables include changes in anabolic hormones (testosterone, IGF-1, growth hormone), catabolic hormones (cortisol), related metabolic markers (insulin, ALT, AST, alkaline phosphatase), and sports performance indices (muscle strength, endurance, flexibility, step length and time, symmetry, and dynamic stability in gait). These variables will be measured before and after the intervention
Timepoint
The outcome variables will be measured at two time points: before the intervention (Baseline) and after the intervention period (Post-intervention, week 8)
Method of measurement
Anabolic and catabolic hormones (testosterone, IGF-1, growth hormone, cortisol, insulin): Blood samples will be collected in a fasting state and analyzed using Chemiluminescent Immunoassay (CLIA). Liver enzymes (ALT, AST) and alkaline phosphatase: Measured using biochemical enzymatic methods، Sports performance: Muscle strength and endurance using a handheld dynamometer and standard endurance tests. Flexibility using the Sit and Reach Test. Step length, step time, symmetry, and dynamic stability in gait will be assessed using motion analysis and gait assessment systems، Quality of Life Questionnaire (English):To assess quality of life, the Short Form Health Survey (SF-36) will be used. This questionnaire consists of 36 questions evaluating various aspects of physical and mental health.

Secondary outcomes

empty

Intervention groups

1

Description
The core training group will perform core stability and strength exercises for 8 weeks, 3 sessions per week.
Category
Prevention

2

Description
Intervention group: The NMES group will receive neuromuscular electrical stimulation using the TruSculpt Flex device (2 sessions per week for 3 weeks, plus a reminder session in week 8).
Category
Prevention

3

Description
Intervention group: The combined group will receive only NMES in the first 3 weeks and will start core training from week 4.
Category
Prevention

4

Description
Control group: The control group will receive no intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Health Promotion and Disease Prevention Body House
Full name of responsible person
Shokoofeh Samouei
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Sponsors / Funding sources

1

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Islamic Azad University
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Khorasgan, Arghavanieh Blvd., Khorasgan Islamic Azad University
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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
Islamic Azad University
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
Other

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

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

Data Dictionary

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