Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effect of six Weeks of Dynamic Neuromuscular Stabilization (DNS) Exercise with and without the Use of Virtual Reality (VR) on pain, Balance, Proprioception, Range of Motion and Lumbar Arch Degree in Middle-aged Women with Hyperlordosis with nonspecific chronic low back pain: A randomized clinical trial

Protocol summary

Study aim

Comparison of the effects of a six-week Dynamic Neuromuscular Stabilization (DNS) exercise program—with and without Virtual Reality (VR)—on pain intensity, balance, proprioception, range of motion, and lumbar curvature in middle-aged women with lumbar hyperlordosis and chronic nonspecific low back pain.

Design

Randomized, parallel, three-arm, open-label clinical trial (Phase: Not Applicable / Rehabilitation) with a sample size of 50. Randomization was done by lot drawing in blocks of three, and allocation was concealed using sealed opaque envelopes.

Settings and conduct

The study was conducted at Shahid Beheshti University in Tehran on women aged 30–50 with hyperlordosis and chronic low back pain. Exercise interventions were delivered over six weeks at the university rehabilitation gym. Pre- and post-intervention assessments, six weeks apart, were performed to measure pain (VAS), lumbar lordosis, balance, proprioception, and range of motion. No blinding was implemented.

Participants/Inclusion and exclusion criteria

1.Women aged 30 – 50 years 2.No history of spinal fracture,or joint disease 3.Lumbar lordosis greater than 40 degrees 4.Body-mass index (BMI) between 18.5 and 27 5.No use of orthotic insoles, a cane, some drugs 6.Pain intensity between 3-7 on the Visual Analogue Scale (VAS) 7.No related pathological signs 8.No orthopedic deformities or neurosurgical disorders 10.No surgery or pregnancy in the past 30 days

Intervention groups

1.Group receiving Dynamic Neuromuscular Stabilization (DNS) exercises with a virtual-reality device (DNS + VR).
2.Group receiving Dynamic Neuromuscular Stabilization (DNS) exercises without a virtual-reality device (DNS-only).

Main outcome variables

Change in low-back pain intensity and in lumbar lordosis angle by the end of the 6-week intervention.

General information

Reason for update

Acronym

Dynamic neuromuscular exercise(DNS)

IRCT registration information

IRCT registration number: **IRCT20250801066719N1**
Registration date: **2025-08-19, 1404/05/28**
Registration timing: **prospective**

Last update: **2025-08-19, 1404/05/28**
Update count: **0**

Registration date

2025-08-19, 1404/05/28

Registrant information

Name

Niusha Tashakori Arani

Name of organization / entity

The University of Shahid Beheshti

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-08-25, 1404/06/03
Expected recruitment end date
2025-10-27, 1404/08/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of six Weeks of Dynamic Neuromuscular Stabilization (DNS) Exercise with and without the Use of Virtual Reality (VR) on pain, Balance, Proprioception, Range of Motion and Lumbar Arch Degree in Middle-aged Women with Hyperlordosis with nonspecific chronic low back pain: A randomized clinical trial

Public title
comparison the effect of DNS exercise with and without the use of VR on Hyperlordosis with nonspecific chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women between 30-50 years of age Lumbar lordosis greater than 40 degrees Body-mass index (BMI) between 18.5 and 27 Pain intensity between 3 and 7 on the Visual Analogue Scale (VAS)
Exclusion criteria:
history of spinal fractures, surgery, or joint disease Use of orthotic insoles, a cane, antidepressant or narcotic medications, or muscle relaxants within 30 days prior to the study, and no significant visual impairment or motor disorders that would prevent the use of virtual-reality equipment Presence of pathological signs related to the condition, such as heart disease, cancer, tumors, previous surgery, etc. Presence of orthopedic deformities or neurosurgical diseases Presence of disc degeneration or other conditions that could influence the interpretation of the results (e.g., severe fibromyalgia or rheumatoid arthritis in combination with other treatments) Surgery or pregnancy within the past 30 days Use of devices or apparatuses for treating hyper-lordosis Presence of any other postural abnormalities
Age
From **30 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Sequence Generation To keep an equal 1 : 1 : 1 allocation across the three study arms— Group A = DNS exercise only Group B = DNS + virtual-reality (VR) exercise Group C = no-treatment control I first divide the total sample size n into three equal parts (n / 3 per group). Then I prepare n / 3 identical paper slips marked “A”, n / 3 slips marked “B”, and n / 3 slips marked “C.” All slips are folded twice so the label cannot be seen, placed together in a single opaque, non-transparent container, and thoroughly mixed before recruitment begins. For each eligible participant I (or an independent staff member) draw one slip blindly from the container. The letter on the slip immediately determines that participant’s assignment. After a slip is drawn it is removed from the pool and stored separately, so the remaining probabilities stay constant (sampling without replacement).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shaid Beheshti University
Street address
Shahid Shahriari Square, Evin, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2025-05-24, 1404/03/03
Ethics committee reference number
IR.SBU.REC.1404.042

Health conditions studied

1

Description of health condition studied
هایپرلوردوزیس همراه با کمردرد مزمن غیراختصاصي
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Hyperlordosis
Timepoint
Outcome assessments will be conducted at baseline and after the completion of the 6-week intervention period.
Method of measurement
Hyperlordosis will be assessed using the Spinal Mouse device.

2

Description
pain intensity
Timepoint
Outcome assessment will be conducted at baseline and after the completion of the 6-week intervention period.
Method of measurement
Pain intensity will be measured using the Visual Analogue

Secondary outcomes

1

Description
static balance
Timepoint
Outcome assessment will be conducted at baseline and after the completion of the 6-week intervention period.
Method of measurement
static Balance will be assessed using the Biodex Balance System.

2

Description
Dynamic balance
Timepoint
Outcome assessment will be conducted at baseline and after the completion of the 6-week intervention period.
Method of measurement
Dynamic Balance will be assessed using the Biodex Balance System.

3

Description
lumbar proprioception
Timepoint
Outcome assessment will be conducted at baseline and after the completion of the 6-week intervention period.
Method of measurement
Lumbar Proprioception will be measured using a goniometer

4

Description
Range of motion
Timepoint
Outcome assessment will be conducted at baseline and after the completion of the 6-week intervention period.
Method of measurement
Range of motion will be measured using the MobeeMed device.

Intervention groups

1

Description
Intervention group 1: The group receiving dynamic neuromuscular training combined with virtual reality technology. Participants receive Dynamic Neuromuscular Stabilization exercises combined with virtual reality. The program lasts 6 weeks (18 sessions) with 3 sessions per week, and each session is 50 minutes. Training is conducted at the Fitness and Sports Rehabilitation Club, Faculty of Sport Sciences, Shahid Beheshti University. The VR device is the Meta Quest 3 headset and the selected game is Dodgeball, which is used to encourage controlled lumbar flexion. Each session includes 5 minutes of warm-up (light stretching, walking, simple mobility), 20 minutes of DNS, 20 minutes of VR-based training (Dodgeball tasks for balance, weight-shift, reaching, and trunk control), and 5 minutes of cool-down (gentle stretching and walking). DNS content covers diaphragmatic breathing and intra-abdominal pressure (IAP) work performed in developmental positions derived from infant motor patterns, including baby-rock/rolling, prone, side-lying, quadruped, bear position, tripod stance, and modified squat. The auxiliary equipment used during DNS consists of elastic resistance bands, light dumbbells, and a Pilates ball; the chosen VR game (Dodgeball) is selected based on prior literature for this population.
Category
Treatment - Other

2

Description
Intervention group 2:The group receiving dynamic neuromuscular training without the use of virtual reality technology. The program lasts 6 weeks (18 sessions) with 3 sessions per week. Each session is 50 minutes. Training is conducted at the Fitness and Sports Rehabilitation Club in the Faculty of Sport Sciences, Shahid Beheshti University. DNS exercises are performed for 40 minutes, with 5 minutes of warm-up at the beginning and 5 minutes of cool-down at the end, consisting of light stretching, walking, and simple mobility drills. The DNS component includes core patterns of diaphragmatic breathing and intra-abdominal pressure (IAP) in developmental positions derived from infant motor patterns, such as baby rock, prone, side-lying, quadruped, bear position, tripod stance, and modified squat. Auxiliary equipment during DNS includes elastic resistance bands, light dumbbells, and a Pilates ball.
Category

Treatment - Other

3

Description
Control group: The control group receiving no intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University
Full name of responsible person
Mehdi Gheitasi
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Shahid Shahriari Square, Evin, Tehran, Iran
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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?
No
Title of funding source
shahid Beheshti 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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Shahid Beheshti
Full name of responsible person
Niusha Tashakori
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Sport pathology and corrective movement science
Street address
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Person responsible for updating data

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Other areas of specialty/work
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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
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The shared data may include de-identified demographic variables, primary outcome data, and selected secondary outcomes. All shared datasets will be fully anonymized in accordance with confidentiality standards. Data will only be shared upon formal request and with approval by the ethics committee or relevant authorities. Public release of the full dataset is not planned at this stage, but specific outcome data may be included in future publications, following ethical guidelines.
When the data will become available and for how long
Access to aggregated, de-identified outcome data will begin approximately a few months after the publication of final results in a scientific article or thesis. Only summarized data will be publicly available through publications. No direct access to raw individual participant data is planned.
To whom data/document is available
Access to the study data and documents is limited to the principal investigator, research team members, academic supervisor, and, if necessary, the Ethics Committee of Shahid Beheshti University. Other individuals will only have access to aggregated and analyzed results published in the thesis or scientific articles. No direct access to raw data is planned for the public or external researchers.
Under which criteria data/document could be used
The data and documents from this study may only be used for research and educational purposes, in full compliance with ethical research principles, data confidentiality, and non-disclosure of participants' identities. Usage is limited to the results presented in the thesis or scientific publications. No access to raw data is permitted for third parties.
From where data/document is obtainable
Any requests for access to the data or documents related to this study must be formally submitted in writing to the principal investigator or the academic supervisor at the Faculty of Physical Education, Shahid Beheshti University. Approval from the university’s Research Ethics Committee may also be required, depending on the nature of the request.
What processes are involved for a request to access data/document
in the event of receiving a formal request for access to the study’s data or documents, the request will first be reviewed by the principal investigator or the academic supervisor. If the nature of the request involves access to unpublished or ethically sensitive information, it will be referred to the Research Ethics Committee of Shahid Beheshti University for final approval.
Comments