Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of adding kegel exercises to DNS exercises on pain, electrical muscle activity, lumbopelvic rhythm, pelvic floor function, disability and quality of life with lumbopelvic pain in postpartum women

Protocol summary

Study aim
The effect of adding Kegel exercises to Dynamic Neuromuscular Stabilization (DNS) training on pain, muscle electrical activity, lumbopelvic rhythm, pelvic floor function, disability, and quality of life in women with postpartum lumbopelvic pain.

Design
"This will be a single-blinded, randomized controlled clinical trial consisting of one control group and two exercise groups, will be conducted on 42 participants."

Settings and conduct
This trial will be conducted at a university-affiliated rehabilitation center in Iran. The facility is equipped with private treatment rooms and standardized exercise equipment. All interventions will be delivered by trained therapists in a controlled clinical environment. Outcome assessments will be performed by an independent and trained assessor.Therefore, the study has been designed as a single-blind randomized controlled trial.Outcome assessors, who will conduct pre- and post-intervention evaluations.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 20–40 years who had a vaginal delivery within the previous 3–12 months, with pregnancy- or postpartum-related low back pain and/or pelvic girdle pain, a positive ASLR test, at least three positive sacroiliac joint provocation tests, and a pain intensity score of 3–7 on the Visual Analog Scale (VAS). Exclusion criteria: Spinal disorders or abnormalities, major neurological or systemic diseases, a history of lumbopelvic surgery, postpartum urinary disorders, urogenital prolapse greater than grade 3.

Intervention groups
Group 1: Dynamic Neuromuscular Stabilization (DNS) training program. Group 2: Dynamic Neuromuscular Stabilization (DNS) training combined with Kegel exercises.Control Group: No specific exercise intervention

Main outcome variables
Pain intensity: Visual Analog Scale (VAS), Disability)Oswestry Disability Index (ODI) Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260421069124N1**
Registration date: **2026-06-08, 1405/03/18**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **0**

Registration date
2026-06-08, 1405/03/18

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-10, 1405/03/20

Expected recruitment end date
2026-08-10, 1405/05/19

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

Scientific title
The effect of adding kegel exercises to DNS exercises on pain, electrical muscle activity, lumbopelvic rhythm, pelvic floor function, disability and quality of life with lumbopelvic pain in postpartum women

Public title
The Effect of Combined Kegel and DNS Exercises on Pain and Functional in Postpartum Women"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 20–40 years with a history of singleton vaginal delivery in the past 3 to 12 months. Diagnosis of non-specific low back pain, pelvic girdle pain, or a combination of both, with onset during pregnancy or at least 3 weeks postpartum, confirmed by a specialist physician. Positive Active Straight Leg Raise (ASLR) test and positive results in at least three out of the following six sacroiliac joint provocation tests: distraction test, compression test, posterior shear test (thigh thrust), Gaenslen's test (right), Gaenslen's test (left), and sacral thrust test. Pain intensity between 3 and 7 (on a 0–10 Visual Analog Scale – VAS) at the time of assessment or during the past two weeks. ody Mass Index (BMI) less than 30 kg/m²
Exclusion criteria:
Spinal abnormalities or pathological conditions of the spine (such as spinal stenosis, scoliosis, spondylolisthesis, fracture, tumors of the spine or pelvis, etc.). History of neurological, cardiovascular, respiratory, renal diseases, or rheumatoid arthritis. History of surgical intervention in the lumbopelvic region. Postpartum urinary disorders (including urinary incontinence and/or urinary retention). Urogenital prolapse greater than grade 3. History of cesarean section or more than two vaginal deliveries. Failure to complete at least 90% of the study sessions. Use of any concurrent medications or physiotherapy interventions during the study period.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated to the three study groups (Control group, Exercise Group 1, and Exercise Group 2) in a 1:1:1 ratio. Block randomization with varying block sizes of 3 and 6 will be performed using Random Allocation Software (version 2.0). Allocation concealment will be ensured by using sequentially numbered, opaque, and sealed envelopes. These envelopes will be prepared in advance by an independent individual not involved in the study team. The envelopes will be opened sequentially according to the order of participant enrollment.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the exercise interventions, it is not possible to blind the participants or the exercise instructors. This study is therefore designed as a single-blind randomized controlled trial. Outcome assessors (who perform the pre- and post-intervention evaluations including pain intensity, ASLR test, sacroiliac joint provocation tests, and questionnaires) will be blinded to group allocation. To maintain blinding, assessors will not be involved in the randomization process, exercise training sessions, or data analysis. Participants will be instructed not to disclose their group assignment or type of exercises to the assessors during assessments.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Kharazmi University.
Street address
Biomechanics and Corrective Exercise Laboratory, Faculty of Physical Education and Sport sciences, Kharazmi University, Mirdamad Blvd., Hesari St
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Approval date
2026-04-19, 1405/01/30
Ethics committee reference number
IR.KHU.RCT.1405.012

Health conditions studied

1

Description of health condition studied

lumbopelvic pain in postpartum women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Baseline (T0), post-intervention (T1, Afer 8 weeks)

Method of measurement

The Visual Analog Scale (VAS) is the most common scale for reporting pain. The patient will select a number corresponding to a pain ruler from 0 to 10 that best represents the intensity of their pain. Zero indicates no pain, and 10 indicates the worst imaginable pain. This scale is often categorized as follows: no pain (0), mild pain (1-3), moderate pain (4-6), severe pain (7-10). The reported reliability of the Visual Analog Scale is 0.91.

2

Description

Disability

Timepoint

Baseline (T0), post-intervention (T1, Afer 8 weeks)

Method of measurement

Disability will be assessed using the Oswestry Disability Index (ODI). The ODI is a 10-item self-administered questionnaire designed to assess pain-related disability in individuals with low back pain. Each item is scored on a scale of 0 to 5, with 0 indicating no disability and 5 indicating the highest level of disability. The total score ranges from 0% to 100%, with higher scores indicating greater disability. The Persian version of the ODI, which has demonstrated reliability and validity characteristics in individuals with low back pain, will be used in this study.

Secondary outcomes

1

Description

Lumbopelvic rhythm

Timepoint

At baseline and at the end of the intervention (after 8 weeks).

Method of measurement

Shimmer3 IMU sensors (100 Hz frequency) will be used to record the movement angles of the lumbar spine and pelvis. The IMUs will be placed on the S1 vertebra (lower back) and T12 vertebra (mid-back), and on the femur to measure the flexion/extension angle and the lumbopelvic rhythm (the ratio of pelvic to lumbar movement).

2

Description

Muscle activity

Timepoint

At baseline and at the end of the intervention (after 8 weeks).

Method of measurement

Surface electromyography (sEMG) data from the transversus abdominis (TrA), multifidus (MF), and rectus abdominis (RA) muscles on both dominant and non-dominant sides will be recorded using a six-channel Noraxon (USA) wireless FREEEMG system (sampling frequency 2000 Hz). Surface electrodes (Ag/AgCl, 12 mm diameter) will be placed along the muscle fibers of each muscle by a trained researcher, following SENIAM guidelines. Before electrode placement, the skin will be cleaned with isopropyl alcohol and abraded to reduce inter-electrode resistance. The electrodes will be placed on the TrA (4 cm below and medial to the anterior superior iliac spine), MF (at the L4-L5 vertebral level, 2 cm lateral to the midline), and RA (2 cm lateral to the umbilicus, 1 cm above and 1 cm below, parallel to the RA muscle fibers). The signals will be processed with a band-pass filter (20-450 Hz) and normalized based on maximum voluntary contraction (MVC).
Electromyography data will be recorded during a box-lifting movement (lifting a box from the floor and standing up). RMS will be used after data recording and filtering to quantify muscle electrical activity.

3

Description

Pelvic floor function

Timepoint

At baseline and at the end of the intervention (after 8 weeks).

Method of measurement

The Pelvic Floor Distress Inventory (PFDI-20) is a standardized and valid instrument designed to assess the severity of symptoms related to pelvic floor disorders in women. This questionnaire is specifically used to evaluate the impact of pelvic floor problems on quality of life and daily functioning, and it is applied in areas such as urinary incontinence, fecal incontinence, and pelvic organ prolapse. The internal consistency reliability of the total questionnaire was 0.89, indicating high internal reliability, and the test-retest reliability, measured by the intraclass correlation coefficient (ICC), was 0.92 for the total questionnaire, indicating excellent temporal reliability.

4

Description

Quality of Life

Timepoint

At baseline and at the end of the intervention (after 8 weeks).

Method of measurement

Quality of life will be assessed using the 36-item Short Form Health Survey (SF-36). This questionnaire consists of 36 questions and is comprised of 8 subscales, with each subscale containing 2 to 10 items. The eight subscales of this questionnaire are: physical functioning, role limitations due to physical health, role limitations

due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health. Additionally, by combining subscales, two overall scales named physical health (which measures the physical aspect of health) and mental health (which evaluates the psychosocial aspect of health) are derived. A subject's score for each question in this questionnaire ranges from 0 to 100, with a higher score indicating better quality of life.

Intervention groups

1

Description
First Intervention group: Dns exercises
Category
Rehabilitation

2

Description
Second intervention group: DNS exercises combined with Kegel exercises.
Category
Rehabilitation

3

Description
Control group:
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharazmi University
Full name of responsible person
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Sponsors / Funding sources

1

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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
Kharazmi 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
Kharazmi Univercity
Full name of responsible person
Akram keikha hosseinpoor
Position
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Latest degree
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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
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
Only the primary findings will be shared

When the data will become available and for how long
“Access will commence one year after the publication of the results

To whom data/document is available
“Researchers employed at academic and scientific institutions

Under which criteria data/document could be used
“Data and documentation will be provided exclusively for research and scientific purposes to qualified researchers. Commercial use or use outside the approved research framework is prohibited. Access is contingent upon a written request and ethics committee approval.”

From where data/document is obtainable
“To access data/documentation, applicants should submit their request to the Principal Investigator or Research Lead via email or formal correspondence. Requests will be processed and provided to applicants upon review and approval by the Research Ethics Committee, contingent upon meeting all requirements.”

What processes are involved for a request to access data/document
Data/Documentation Access Procedure: 1. Submit a formal written request. 2. Verification of applicant’s identity and alignment with research ethics guidelines. 3. Signing of a Data Use Agreement (DUA) followed by data/documentation provision. Approximate timeframe: 2-4 weeks.**

Comments