Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of diastasis recti abdominis rehabilitation exercises on postpartum low back pain and inter-recti distance in affected women: A randomized controlled trial

Protocol summary

Study aim

This study aimed to investigate the effects of a comprehensive rehabilitation protocol for treating diastasis recti and improving postpartum low back pain, and to investigate the relationship of these changes with brain and muscle activity patterns in women with postpartum low back pain.

Design

Quasi-experimental, randomized clinical trial with two parallel arms and double-blinded.

Settings and conduct

Participants will be recruited from gynecology and obstetrics clinics, health centers, and social media platforms within Hamadan city. Initial evaluations will take place at the Sports Rehabilitation Laboratory of Bu-Ali Sina University. Before enrollment, all participants will receive clear and comprehensive information regarding the study's procedures, duration, objectives, potential benefits, and possible risks.

Participants/Inclusion and exclusion criteria

Inclusion: Women with postpartum LBP, aged 20-45 years, with multiparity, vaginal delivery, and diastasis recti greater than 2 cm above, below, and umbilicus. Exclusion: cardiac and respiratory diseases, acute LBP, rheumatic spinal diseases, CNS and PNS diseases, abdominal hernia, lumbar surgery, gestational diabetes, and sports activities.

Intervention groups

Exercise Group: Participants will undergo a structured diastasis recti rehabilitation program, incorporating progressive core trunk exercises, from beginner to advanced levels, and targeted release techniques for the erector spinae muscles. Control Group: Participants will maintain their usual daily routines throughout the study period.

Main outcome variables

Low back pain and disability, Inter-rectus distance, Core muscle thickness, Thoracolumbar fascia flexibility, lumbopelvic proprioception dysfunction, Lumbopelvic motor control, EMG-based core muscle activation patterns, EEG-based brain activity patterns in proprioceptive and pain receptors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250104064273N1**
Registration date: **2025-10-30, 1404/08/08**
Registration timing: **prospective**

Last update: **2025-10-30, 1404/08/08**
Update count: **0**

Registration date

2025-10-30, 1404/08/08

Registrant information

Name
Nahid Bigdeli
Name of organization / entity
Bu-Ali Sina University
Country
Iran (Islamic Republic of)
Phone
+98 61 3448 1616
Email address
nahid.bigdeli@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of diastasis recti abdominis rehabilitation exercises on postpartum low back pain and inter-recti distance in affected women: A randomized controlled trial

Public title
Effect of Core exercises on postpartum low back pain and DRA

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with postpartum low back pain Age range of 20-45 Having DRA above 2 cm in the 4.5 cm upper, below, and the umbilicus. The vaginal delivery
Exclusion criteria:
Cardiovascular diseases Acute low back pain (e.g., spondylolisthesis, herniation, etc.) Rheumatic diseases of the spine CNS and PNS diseases (Parkinson, MS, etc.) Abdominal herniation low back surgery Gestational diabetes Doing sports activities

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, subjects will be randomized based on the Random Number Generator software and then assigned to dual groups based on allocation concealment using the SNOSE method. Participants will be randomly assigned to one of the rehabilitation exercise groups (n=20) or the control group (n=20).

Blinding (investigator's opinion)
Double blinded

Blinding description
The assessors and study participants are blinded to the allocation and randomization of groups. Participants will be fully informed of the study’s purpose and inclusion rationale, while remaining blinded to group allocation to minimize bias and ensure methodological integrity.

Placebo
Not used

Assignment
Parallel

Other design features
Design of Comprehensive Exercises for Diastasis Recti

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of Bu Ali Sina University-Hamedan

Street address
Ahmadi Roshan Blvd., Bu Ali Sina University

City
Hamedan

Province
Hamadan

Postal code
65178-38695

Approval date
2025-10-05, 1404/07/13

Ethics committee reference number
IR.BASU.REC.1404.037

Health conditions studied

1

Description of health condition studied
Postpartum low back pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Diastasis recti abdominis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Postpartum low back pain

Timepoint
Pre- and Post-test of 8 weeks intervention

Method of measurement
VAS scale

Secondary outcomes

1

Description
Timepoint
Method of measurement

2

Description
Diastasis recti abdominis
Timepoint
pre- and post-intervention
Method of measurement
Ultrasonography

3

Description
thickness of core muscles
Timepoint
pre- and post-intervention
Method of measurement
Ultrasonography

4

Description
Brain activity patterns
Timepoint
pre- and post-intervention
Method of measurement
EEG

5

Description
Core muscle activity patterns
Timepoint
pre- and post-intervention
Method of measurement
EMG

6

Description
functional disability
Timepoint
pre- and post-intervention
Method of measurement
Oswestry Questionnaire

7

Description
lumbopelvic proprioception
Timepoint
pre- and post-intervention
Method of measurement
Goniameter

8

Description
lumbopelvic motor control
Timepoint
pre- and post-intervention
Method of measurement
pressure biofeedback

Intervention groups

1

Description
Intervention group: 8 weeks of comprehensive rehabilitation exercises including core strengthening exercises from beginner to advanced.
Category
Rehabilitation

2

Description
Control group: No intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nahid Bigdeli
Street address
Kermanshah Street, Fatemeh Hospital
City
Hamedan
Province
Hamadan
Postal code
3869565178
Phone
+98 81 3838 1423
Email
n.bigdeli@phe.basu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bu Ali Sina University
Full name of responsible person
Ali Yalfani
Street address
Ahmadi Roshan Blvd, Bu Ali Sina University
City
Hamedan
Province
Hamadan
Postal code
3869565178

Phone
+98 81 3838 1423
Email
yalfani@basu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bu Ali Sina 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
Bu Ali Sina University

Full name of responsible person
Nahid Bigdeli

Position
Ph.D. Student

Latest degree
Master

Other areas of specialty/work
Exercise rehabilitation and corrective exercise

Street address
Bu Ali Sina University, Ahmadi Roshan Blvd

City
Hamedan

Province
Hamadan

Postal code
3869565178

Phone
+98 81 3838 1423

Email
n.bigdeli@phe.basu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bu Ali Sina University

Full name of responsible person
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Position
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Email
n.bigdeli@phe.basu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Bu Ali Sina University

Full name of responsible person
Nahid Bigdeli

Position
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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
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 data related to demographic information and outcomes will be shared.

When the data will become available and for how

long

After publishing the article/articles extracted from the study

To whom data/document is available

The data can be displayed and shared upon reasonable request by the Iranian Clinical Trial Registry Center, journals, and individuals/academic researchers who are conducting research and scientific activities in this field.

Under which criteria data/document could be used

Data analysis and use of documentation can only be done on the condition that their results are stated in systematic review articles conducted by researchers and academic authors. Conditions for registering the submission of data and documentation include: 1. Sending an email (preferably with valid academic addresses) to one of the study researchers. 2. A brief and logical explanation regarding how the data or documentation will be used. 3. Ensuring the registration of the protocol of systematic review studies that have given access to the data or documentation.

From where data/document is obtainable

By requesting from the study researcher, Nahid Bigdeli, by email n.bigdeli@phe.basu.ac.ir

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

The applicant can request details from the researchers using an email message within 7 to 10 days.

Comments