Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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
Randomized clinical trial with three 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, with multiparity, 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 1: Participants will undergo a structured diastasis recti rehabilitation program incorporating progressive core-trunk exercises. Exercise Group 2: A structured rehabilitation program incorporating progressive core-trunk exercises combined with release techniques for erector spinae muscles and TLF. 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, EMG-based core muscle activation patterns, EEG-based brain activity patterns

General information

Reason for update
Changes in study design and the number of groups to two experimental groups and one control group

Acronym

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

Last update: **2026-07-06, 1405/04/15**
Update count: **1**

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
2026-06-22, 1405/04/01

Expected recruitment end date

2026-12-21, 1405/09/30

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 and caesarean 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: **90**

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 three groups based on allocation concealment using the SNOSE method. Participants will be randomly assigned to one of the experimental groups (n=2 * 30) or the control group (n=30).

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

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

Diastasis recti abdominis

Timepoint

pre- and post-intervention

Method of measurement

Ultrasonography

2

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

3

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

4

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

5

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

6

Description
Postpartum Low Back Pain
Timepoint
pre- and post-intervention
Method of measurement
VAS scale

Intervention groups

1

Description
Intervention groups: 8-10 weeks of comprehensive rehabilitation exercises, including core strengthening exercises from beginner to advanced
Category
Rehabilitation

2

Description
Control group: No intervention
Category
Rehabilitation

3

Description
Intervention group: 8-10 weeks of comprehensive rehabilitation exercises, including core strengthening exercises from beginner to advanced, with release of TLF and Erector Spine.
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
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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
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Person responsible for updating data

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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