

# 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**

Goniometer

## 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

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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 scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Ph.D. student

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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](mailto: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**