

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### COMBINED EFFECTS OF PELVIC FLOOR ACTIVATION EXERCISES AND BENSON RELAXATION TECHNIQUE ON PAIN, URINARY INCONTINENCE AND FUNCTIONAL ABILITY AMONG POST- CESAREAN PATIENTS

#### Protocol summary

##### Study aim

To determine the combined effects of pelvic floor activation exercises and Benson relaxation technique on pain, urinary incontinence and functional ability among postcesarean patients.

##### Design

It will Single blinded randomized clinical trial with parallel group design. 30 Participants will be allocated to two groups equally.

##### Settings and conduct

Arif Memorial Teaching Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria • Women aged 20 to 42 at 7 to 14 weeks after delivery or cesarean section Experiencing pain in the pelvic region post-cesarean section. • Patient's BMI did not surpass 30 kg/m2 primiparous and mild-degree SUI • Presented with symptoms of urinary incontinence. • Patients who were not currently undergoing any other specific pelvic floor rehabilitation program. Exclusion Criteria • Individuals with cognitive impairments or communication difficulties that may hinder participation in the study. • Patients with active infections or complications related to the cesarean section incision site. • Patients with severe medical conditions that may limit their ability to perform the prescribed exercises or relaxation techniques. Patients undergoing treatment for pelvic floor issues with interventions that may interfere with the study outcomes. presence of hypertension, diabetes, genital prolapse, and smoking.

##### Intervention groups

Group A will receive Pelvic floor activation exercises with Benson relaxation technique. Pelvic floor activation exercises will be performed for 4 weeks and five times in a week. Group B will receive Pelvic floor activation exercises only. Benson relaxation technique will be performed for 4 weeks and five times in a week.

#### Main outcome variables

Pain: Numeric pain rating scale Urinary incontinence: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form Functional ability: Functional Independence Measure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220701055331N5**  
Registration date: **2025-03-27, 1404/01/07**  
Registration timing: **registered\_while\_recruiting**

Last update: **2025-03-27, 1404/01/07**

Update count: **0**

##### Registration date

2025-03-27, 1404/01/07

##### Registrant information

##### Name

Ifra Zulqarnain Awan

##### Name of organization / entity

Rashid Latif Medical College

##### Country

Pakistan

##### Phone

+92 333 4975431

##### Email address

ifra.awan@rlmc.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-03-25, 1404/01/05

##### Expected recruitment end date

2025-07-25, 1404/05/03

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

COMBINED EFFECTS OF PELVIC FLOOR ACTIVATION EXERCISES AND BENSON RELAXATION TECHNIQUE ON PAIN, URINARY INCONTINENCE AND FUNCTIONAL ABILITY AMONG POST- CESAREAN PATIENTS

**Public title**

COMBINED EFFECTS OF PELVIC FLOOR ACTIVATION EXERCISESAND BENSON RELAXATION TECHNIQUE ON PAIN, URINARYINCONTINENCE AND FUNCTIONAL ABILITY AMONG POST-CESAREAN PATIENTS

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women aged 20 to 42 at 7 to 14 weeks after delivery or cesarean sectionExperiencing pain in the pelvic region post-cesarean section. Patient's BMI did not surpass 30 kg/m2 primiparous and mild-degree SUI Presented with symptoms of urinary incontinence Patients who were not currently undergoing any other specific pelvic floorrehabilitation program.

**Exclusion criteria:**

Individuals with cognitive impairments or communication difficulties that may hinderparticipation in the study. Patients with active infections or complications related to the cesarean section incisionsite. Patients with severe medical conditions that may limit their ability to perform theprescribed exercises or relaxation techniques. Patients undergoing treatment for pelvic floor issues with interventions that mayinterfere with the study outcomes. presence of hypertension, diabetes, genital prolapse,and smoking.

**Age**

From **20 years** old to **42 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random computer number generator will be used for randomization. Assign unique identification numbers to participants, then use a reliable software tool to generate a list of random numbers. Match these numbers to participant IDs and allocate individuals to different study groups based on the sorted random numbers. Ensure that the randomization process is concealed and

documented for transparency and integrity.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Single blinding in a study involves keeping the outcome assessor blind to the intervention received by the participants. This helps to minimize bias in assessing the study outcomes. To achieve single blinding, the outcome assessor is not informed about the treatment allocation of the participants and remains unaware of which group received the intervention being studied.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Institutional Review Board of Rashid Latif Medical College, Lahore.

**Street address**

35-KM Ferozepur Road Lahore

**City**

Lahore

**Postal code**

54600

**Approval date**

2024-09-26, 1403/07/05

**Ethics committee reference number**

IRB/2024/182

**Health conditions studied**

1

**Description of health condition studied**

Post-Cesarean Patients

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

Numeric pain rating scale to measure pain

## 2

### **Description**

Urinary incontinence

### **Timepoint**

Before intervention and 4 weeks after intervention

### **Method of measurement**

International Consultation on Incontinence  
Questionnaire-UrinaryIncontinence Short Form (ICIQ-UI  
SF)

## 3

### **Description**

Functional ability

### **Timepoint**

Before intervention and 4 weeks after intervention

### **Method of measurement**

Functional Independence Measure (FIM)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Pelvic floor activation exercises with  
Benson relaxation technique. It will be performed for 4  
weeks and five times in a week.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: Pelvic floor activation exercises. It  
will be performed for 4 weeks and five times in a week.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Arif Memorial Teaching Hospital

##### **Full name of responsible person**

Dr. Ifra Zulqarnain Awan

##### **Street address**

35-km ferozpur road Lahore

##### **City**

Lahore

##### **Postal code**

54600

##### **Phone**

+92 333 4975431

##### **Email**

ifra.awan@rlmc.edu.pk

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Rashid latif medical college

##### **Full name of responsible person**

Ifra Zulqarnain Awan

##### **Street address**

35-km ferozpur road lahore

##### **City**

lahore

##### **Postal code**

54600

##### **Phone**

+92 333 4975431

##### **Email**

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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**

Rashid Latif Medical College

#### **Proportion provided by this source**

100

#### **Public or private sector**

Private

#### **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**

Rashid latif medical college

##### **Full name of responsible person**

Malaika Sajid Sidhu

##### **Position**

Physiotherapist

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

35-km ferozpur road lahore

##### **City**

lahore

##### **Province**

punjab

##### **Postal code**

54600

##### **Phone**

+92 304 3044494

##### **Email**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rashid Latif Medical College

**Full name of responsible person**

Ifra Zulqarnain Awan

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Rashid Latif Medical College 35-km Ferozpur Road  
Lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54600

**Phone**

+92 333 4975431

**Fax**

**Email**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rashid Latif Medical College

**Full name of responsible person**

Ifra Zulqarnain Awan

**Position**

Physiotherapist

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Master

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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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable