

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ferozepur 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 ferozepur road lahore

City

lahore

Postal code

54600

Phone

+92 333 4975431

Email

ifra.awan@rlmc.edu.pk

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 ferozepur 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**

ifra.awan@rlmc.edu.pk

Person responsible for updating data

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**

ifra.awan@rlmc.edu.pk

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