Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rashid latif medical college
Full name of responsible person
Ifra Zulqarnain Awan
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35-km ferozepur road lahore
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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
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Person responsible for updating data

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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