

The effects of a static exercise program versus Swiss ball training for core muscles of the lower back and pelvic region in patients with low back pain after child delivery

Submission date 11/07/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/08/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/11/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Low back pain is a common cause of disability and can make daily functioning difficult. For some women, low back pain can last for a long time or return on a regular basis after giving birth. Exercise and physical activity are some of the ways in which patients can relieve their low back pain. This can be helped by a physical therapist, who can help these women improve their quality of life by relieving the pain.

This study aims to look at the difference between the effects of core stability exercises and Swiss ball exercises for the relief of low back pain in women after giving birth.

Who can participate?

Women with low back pain for over 2 months after giving birth

What does the study involve?

Participants will be randomised into 2 groups - Group I and II. Group I will receive static core strengthening training, involving various stabilisation and strength exercises. Group II will undertake Swiss ball exercises. Participants in both groups will be supervised for these exercises and will be provided with a hot pack to use before each session. For both groups, the exercises will be completed 3 days per week for 2 months and participants will be assessed before and 8 weeks after the start of the exercise program.

What are the possible benefits and risks of participating?

The possible benefit of taking part is relief from low back pain, which can improve their quality of life. There are no known risks to participants taking part in this study.

Where is the study run from?

Pakistan Railway General Hospital Rawalpindi, Pakistan

When is the study starting and how long is it expected to run for?
March 2018 to December 2018

Who is funding the study?
Riphah International University Islamabad (Pakistan)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of Static Core Muscles Stability Exercise versus Swiss ball training program in patients with post-partum low back pain

Study objectives
There will be a difference in the effects of the static exercise program and Swiss ball training in postpartum low back pain

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethical Committee, Riphah College of Rehabilitation Sciences Riphah International University, Islamabad, 20/03/2018, Riphah/RCRS/REC/00294

Study design

Interventional randomised parallel trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Postpartum low back pain

Interventions

Participants will be assessed in a physiotherapy OPD and will be randomly divided into 2 groups using the lottery method. One group will undertake static core muscle strengthening exercises, whilst the other will undertake Swiss ball exercises.

All participants will undergo an examination at the baseline (day 1) and after 8 weeks, which will assess pain, character of pain, nature of pain, aggravating factors, relieving factors and any ongoing treatment. Pain will be assessed using the NPRS, flexion and extension ranges will be measured using an inclinometer, core muscle strength will be assessed using the CSA scale and functional status will be assessed using the Oswestry disability scale.

Participants in both groups will apply a hot pack prior to taking part in the exercises.

Participants in the group undertaking static core muscle strengthening exercises will be asked to perform the following:

1. Bridging (stabilisation)
2. Plank (stabilisation and strength)
3. Side plank (integrated stabilisation)
4. Bird dog (integrated stabilisation)

These exercises will be completed 3 days per week for 2 months. For the stretching exercises, there will be 10 sets of 15 second holds. For the strengthening exercises, there will be 2 sets of 15 repetitions.

Participants in the group undertaking Swiss ball exercises will be asked to perform the following:

1. Stability-ball-elevated split squat
2. Stability ball hamstring curl
3. Dead bug
4. Stability ball Y-ups

These exercises will be completed 3 days per week for 2 months. For the stretching exercises, there will be 3 repetitions of 10 second holds. For the strengthening exercises, there will be 1 set of 10 repetitions.

Intervention Type

Behavioural

Primary outcome(s)

The following will be measured at the baseline (day 1) and after 8 weeks:

1. Pain assessed using the Numeric Pain Rating Scale (NPRS)
2. Functional status assessed using the Oswestry disability index (ODI)
3. Core muscle strength assessed using the Core Stability Assessment Scale (CSA)

Key secondary outcome(s)

Current secondary outcome measures as of 26/09/2018:

Flexion and extension range measured at the baseline (day 1) and after 8 weeks using an inclinometer

Previous secondary outcome measures

Flexion and extension range measured at the baseline (day 1) and after 8 weeks using a goniometer (goniometry of lumbar spine)

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Aged 25-35 years
2. Postpartum back pain for period of 2-8 months
3. Normal delivery during birth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Cesarean delivery
2. Systemic, bone and soft tissue diseases i.e. lumbar spinal stenosis, spondylosis, lumbar radiculopathy, spinal cord injury, herniated lumbar disc, ankylosing spondylitis, rheumatoid arthritis, osteoporosis

Date of first enrolment

15/08/2018

Date of final enrolment

31/10/2018

Locations

Countries of recruitment

Pakistan

Study participating centre

Pakistan Railway General Hospital

Pakistan Railway General Hospital Rawalpindi near Dhok Hassu, Railway workshop road scheme 7, Rawalpindi.

Rawalpindi

Pakistan

46000

Sponsor information

Organisation

Riphah International University islamabad

ROR

<https://ror.org/02kdm5630>

Funder(s)

Funder type

Not defined

Funder Name

Riphah International University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Shakeel ur Rehman (shakil.urrehman@riphah.edu.pk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

