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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

Registration date
10/08/2018

Overall study status
Completed

Last Edited
07/11/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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 measure
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)

Secondary outcome measures
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 incliometer

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)

Overall study start date
01/03/2018

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

Age group
Adult

Sex
Female

Target number of participants
30

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
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Sponsor information

Organisation
Riphah International University islamabad

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Sponsor type
University/education

ROR
https://ror.org/02kdm5630

Funder(s)

Funder type
Not defined

Funder Name
Riphah International University

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal

Intention to publish date
01/12/2018

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