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A study to investigate the effects of an exercise program focusing on core body muscles in patients with low back pain after a C-section

Submission date
03/07/2018

Recruitment status
No longer recruiting

Registration date
31/07/2018

Overall study status
Completed

Last Edited
06/12/2019

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. Some females who have given birth by C-section may have low back pain for a long time afterwards or on a regular basis. Exercise and physical activity are some of the ways in which patients can relieve their low back pain, and this can sometimes be supervised by a physical therapist.
This study aims to look at the difference between a core stability exercise program for women with post-C-section low back pain, either supervised by a physical therapist or unsupervised at home.

Who can participate?
Women who have had low back pain as a result of a C-section for at least 2 months

What does the study involve?
Participants will be randomised into 2 groups. Both groups will receive the same core stability exercise training for a period of 6 weeks; however, Group I will undergo a supervised program, whereas Group II will undergo an unsupervised program. Both groups will also receive a hot pack to use.
Group I will receive supervised training, with 3 sessions per week for 6 weeks. Every 2 weeks, participants will progress to the next level of the exercises. Group I will also receive TENS treatment.
Group II will have 1 training session and will be provided with written materials explaining how to complete the exercises at home, and will be provided with a hot pack to use at home.

What are the possible benefits and risks of participating?
The possible benefits of taking part for participants is that they may have relief from low back pain and their core muscle strength will improve. There are no known risks to participants taking part in this study.

Where is the study run from?
Helping Hand for Relief and Development (HHRD) Comprehensive Rehabilitation Centre
Chakwal, Pakistan

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

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NA

Study information

Scientific Title
Effects of supervised versus unsupervised home-based core stability exercise programs in post C-section low back pain

Study objectives
There is a difference between supervised versus unsupervised home-based core stability exercise program in patients with post C-section 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, Pakistan, 20/03/2018, Riphah/RCRS/REC/00345

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post C-section low back pain

Interventions
Informed consent will be taken from all the study participants. The participants will then be asked to complete Oswestry Disability Index and a questionnaire of open-ended questions. 40 participants will be assessed relating to low back pain associated with having had a C-section. 31 of these participants will be selected by convenient sampling. Following this, participants will be randomly assigned into either group I (14 participants) or II (17 participants) using the see through envelope method. Both groups will receive the same core stability exercise program; however, group I will be treated with a supervised version, whereas group II will be provided with an unsupervised, home-based core stability exercise program. Both the supervised and unsupervised programs have a duration of 6 weeks.

The core stability program consists of the following exercises:
1. Level I: weeks 1-2 - easy strengthening exercises:
1.1. Supine abdominal draw-in with single knee to chest, with heel slide and with double knee to chest:
1.1.1. Supine twist
1.1.2. Prone bridging on elbow
1.1.3. Side bridging on elbow
1.1.4. Prone cobra
1.2. Supine glute lift with arm at side, across chest and with single leg lift
2. Level II: weeks 2-4 - medium strengthening exercises:
2.1. Abdominal draw-in with feet on medicine ball and with feet on ball with movement added:
2.1.1. Supine dead bugs
2.1.2. Rolling like a ball
2.1.3. Prone bridging on elbows with single leg hip extension
2.1.4. Side bridging on elbows with single leg hip abduction
2.1.5. Quadruped opposite arm/leg raise (can add weight or dumbbell)
2.1.6. Abdominal crunches on physioball
2.1.7. Abdominal crunches on physioball with rotation
2.1.8 Bridging with head on physioball
3. Level III: weeks 4-6 - difficult strengthening exercises:
3.1. Prone bridging "around the world"
3.2. Side bridging - hip abduction, followed by flexion, followed by extension movements
3.3. Seated Russian twist with medicine ball

The supervised program (Group I) consists of three levels, each of which is 2 weeks of selected exercises, and after completion, participants proceed to the next level. Each level involves 3 sessions per week with 2 sets of 10 repetitions and 10 seconds hold. Additionally, at the beginning of each session, participants will receive conventional low back pain treatment - hot packs and TENS.

Group II will receive one training session and be provided with written materials to enable them to complete the core stability exercises at home. They will be provided with a hot pack and will be guided to use a hot water bottle at home before the session. Group II participants will be called for further assessment after 4 weeks and after completion of the 6 week program.

Intervention Type
Behavioural

Primary outcome(s)
The following were assessed at the baseline and 6 weeks (end of the intervention):
1. Low back pain measured using Oswestry Disability Index (ODI) and Numeric Pain Rating Scale (NPRS)
2. Core stability assessed using the Core Stability Assessment Scale

Key secondary outcome(s))
Current secondary outcome measures as of 26/09/2018:
Range of motion, assessed using an incliometer at the baseline and 6 weeks (end of the intervention)

Previous secondary outcome measures:
Goniometry of lumbar spine, assessed using goniometer at the baseline and 6 weeks (end of the intervention)

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Post C-section low back pain for a minimum of 2 months and maximum of 2 years
2. Aged 25-40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Participants with other systemic, bone and soft tissue diseases including:
1. Lumbar spinal stenosis
2. Spondylosis
3. Spondylolisthesis
4. Lumbar radiculopathy
5. Spinal cord injury
6. Paraplegia
7. Fractures
8. Herniated lumbar disc
9. Scheuermann's disease
10. Ankylosing spondylitis
11. Rheumatoid arthritis
12. Osteoporosis etc.

Date of first enrolment
01/08/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
Pakistan

Study participating centre
Helping Hand for Relief and Development (HHRD) Comprehensive Rehabilitation Centre Chakwal
Govt. College Road
Chakwal
Pakistan
48800

Sponsor information

Organisation
Riphah International University

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 Syed ShakeelurRehman (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	Participant information sheet	11/11/2025	11/11/2025	No	Yes