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The effect of exercise on lower back pain during pregnancy

Submission date
20/08/2022

Recruitment status
No longer recruiting

Registration date
15/09/2022

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aim
Lower back pain during pregnancy is a common problem that can affect women's day-to-day activities and may worsen as the pregnancy progresses. Some women ask for advice from their healthcare provider. Pregnant women may wish to avoid medication and seek other ways to manage their symptoms. This study looks at the effect of appropriate, personalized exercises on these women.

Who can participate?
Women aged 18 years or over who were between 14 and 30 weeks pregnant when they joined the study. They had to be experiencing lower back pain.

What does the study involve?
Women were assessed by a physiotherapist who asked them about their symptoms and physically examined them. The women answered questions used in previous scientific research into back pain during pregnancy. The women were then allocated to one of two groups. One group continued with routine antenatal care. The other group undertook 12 weeks of exercises. The women had a weekly one-to-one clinic appointment with the physiotherapist for the first four weeks. The exercise program was personalized to suit the needs of each individual and included appropriate stabilizing and stretching exercises. At the end of the first four weeks, the woman decided on a personal plan of exercises to carry out once a day at home for the following eight weeks.

What are the possible benefits and risks of participating?
Past research has shown that specific exercises can reduce symptoms for women experiencing lower back pain during pregnancy. The exercises in this study have been used safely (for both mother and baby) in previous research and clinical practice. In addition, women were advised against continuing any exercise that increased their symptoms as the aim of all the exercises was to reduce pain.

Where is the study run from?
This study is part of the principal investigator's PhD studies and is the property of the Nursing College, the University of Raparin in the Kurdistan region/north Iraq.

When is the study starting, and how long is it expected to run?
September 2020 to February 2022

Who is funding the study?
Investigator initiated and funded

Who is the primary contact?
Begard Othman Muhammad, begard.othman@uor.edu.krd

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
7/29/3634 - University of Raparin/ Vice-President for scientific Affairs and Higher Education Directorate of Higher Education and Continuing Education.

Study information

Scientific Title
Effect of therapeutic exercise on lumbopelvic pain among pregnant women.

Study objectives
Does therapeutic exercise reduce pregnancy-related lumbopelvic pain and improve functional capability in performing daily activities?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2020, University of Raparin Scientific and Ethical Committee (Humanities Building, 3rd Floor, Main Street, Rania City, 46012, Iraq; +964 772208398; dr.sanaa@uor.edu.krd), ref: 7/29/3634

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a (Kurdish language) participant information sheet.

Health condition(s) or problem(s) studied
Lumbopelvic pain during pregnancy

Interventions
A quasi-experimental study involving 110 pregnant women with lumbopelvic pain, recruited from six primary healthcare clinics in Slemani city, Kurdistan region of Iraq.

Stability exercises to strengthen muscles around the lumbar and pelvic region and focused stretching exercises to increase flexibility at the lumbar spine, hip, knee, and ankle joints. The course of the study comprised:
- Clinic-based exercise program (CBEP), once a week for 4 weeks.
- Home-based exercise program (HBEP), one session of personalized exercises per day for 8 weeks.
At recruitment, women are allocated a number in sequential order (1,2,3 etc.) All who obtain odd numbers are assigned to the intervention group, and all with even numbers are assigned to the control group

Intervention Type
Behavioural

Primary outcome measure
Pain intensity measured using the Numeric Rating Scale (NRS) at baseline and follow up (12 weeks)

Secondary outcome measures
Functional ability measured using modified pregnancy mobility index, incorporating the Oswestry disability index (ODI), pregnancy mobility index (PMI) and pelvic girdle questionnaire (PGQ) at at baseline and follow up (12 weeks)

Overall study start date
20/09/2020

Completion date
28/02/2022

Eligibility

Key inclusion criteria

1. Pregnant women complaining of lower back pain (LBP) between the costal margin and inferior gluteal folds, with or without leg pain
2. Singleton pregnancy
3. Gestational stage 14 - 30 weeks
4. No previous treatment for current symptoms

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
In non-probability convenient sampling, the target number was 140 subjects (n=70 therapeutic and n=70 control) groups. But at the end of the study, the analyzed subjects were n=60 in the therapeutic and n=50 in the control group.

Total final enrolment
110

Key exclusion criteria
1. With reference to the American College of Obstetricians and Gynecologists (ACOG) guidelines on exercise during pregnancy, any woman for whom exercise is contraindicated.
2. Indications for high-risk pregnancy, e.g., placenta previa, pre-eclampsia.
3. History of disc prolapse, spine or pelvic trauma, or spinal surgery.
4. Body Mass Index greater than 40 kg/m²
5. Unexplained weight loss

Date of first enrolment
16/01/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
Iraq

Study participating centre
Private Physical Therapy Clinic
2nd floor, Poly-Clinic Asuda / ToyMalic Street
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Sponsor information

Organisation
University of Raparin

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Sponsor type
University/education

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ROR
https://ror.org/00fs9wb06

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/09/2022	No	No
Basic results	version 22	08/11/2022	08/11/2022	No	No