Kurdistan Regional Government-Iraq
Presidency of Ministerial Council
Ministry of Higher Education and Scientific Research
University of Raparin
Collage of Nursing

حکومەتی هەرێمی کوردستان-عێراق
سەرۆکایەتی ئەنجومەنی وەزیران
وەزارەتی خوێندنی باڵا و توێژینەوەی زانستی
زانکۆی ڕاپەڕین
کۆلیجی پەستاری

Postgraduate Research Protocol

Ph.D. [X]

MSc. [ ]

Researcher Name:

Begard Othman Muhammad

First Supervisor:

Prof Dr. Hmdia Mirkhan Ahmad Pirany

Second supervisor:

Dr. Shwan Qader Muhammad

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This protocol is from the department of Maternity and Pediatric Nursing to the deanery of the College of Nursing. Our department informs you the sent research plan of a PhD. Students Begard Othman Muhammad for the purpose of enhancement.

1.0. Title:

Impact of therapeutic exercise and instruction on pregnancy-related lumbopelvic pain in health sectors of Sulaymaniyah City (An evaluative study)

1.1. The type of research:

A. Scientific ○
B. Applicable ○
C. Scientific and applicable ●

1.2. Equipment and tests required for carrying out the work:

A. In the University ○
B. Outside the University ○
C. In Kurdistan Region ●
D. Outside Kurdistan Region ○

1.3. Aim of the study:

To evaluate the impact of therapeutic exercise and education on pregnancy-related lumbopelvic pain who attend health sectors in Slimani city.

1.4. Specific objectives of the study

1. To find out the characteristics of lumbopelvic pain among pregnant women.
2. To assess pain intensity before and after therapeutic exercise intervention.
3. To measure the level of effort/difficulties in performing daily activities before and after therapeutic exercise intervention.
4. To assess the level of knowledge associated with the practice regarding body mechanics before intervention in both groups.

5. To assess the level of knowledge associated with the practice regarding body mechanics after receiving therapeutic exercise among the intervention group only.
6. To find out the most effective therapeutic exercise for lumbopelvic pain.

1.5. Introduction:

Lumbopelvic pain during pregnancy, defined as pregnancy-related low back pain (LBP) and/or pelvic girdle pain (PGP), is a complex problem with both a physical and psychological burden (Vleeming et al., 2008). The reported prevalence ranges from 24% to 90%, mainly due to the lack of a clear definition and classification of the condition (Vleeming et al., 2008; Vermani, FRCA*, Mittal and Weeks, 2010) .

Pregnancy causes physiological and anatomical changes in the woman's body and can affect several systems (such as cardiovascular, respiratory, endocrine, and renal, among others) and the musculoskeletal system. In some pregnant women, the musculoskeletal system changes will cause lower back or pelvic pain that prevents the normal movement of these structures and causes suffering. Therefore, this lumbopelvic pain during pregnancy has gained importance in recent years due to the impact it has on the pregnant woman's life and the costs involved (Aragão, 2019)

Despite its prevalence, LBP or PGP during pregnancy is often considered normal, and not enough emphasis is placed on its management. This benign neglect can contribute to physical inactivity during pregnancy, resulting in a higher incidence of obstetric complications (Sabino and Grauer 2008) and cesarean sections (Price et al., 2012; Domenjoz et al., 2014) .

Considering each woman's personality and pregnancy situation with early detection and treatment will lead to the best possible results. Thus, Conservative management, such as physical therapy, has been pointed out in the literature as a therapeutic resource for resolving this problem. Muscle strengthening, breathing and relaxation exercises, stretching, and flexibility are among various techniques. Even though therapeutic exercises are provided muscle strength and improve body posture, it supplies positive psychological effects while also helping to develop the ability to concentrate and relax (Garashabi and Zadeh, 2005; Elden et al., 2008; Bandpei et al., 2010; Dumas et al., 2010; Klugue et al., 2011; Kordi et al., 2013; Clinton et al., 2017).

Exercise-based treatment is the most common component in managing pregnancy-related lumbosacral pain (PRLSP). Stabilization exercises are the most commonly used techniques, followed by pelvic floor exercises, strengthening exercises, and repeated directional exercises (Bishop et al., 2016). In a Cochrane review of 2015 that evaluated the effects of any intervention to prevent or treat LBP, PP, or the association of both in women at any stage of pregnancy, soil exercises in their various formats reduced the pain scores and the functional impairment in pregnant women with LBP, with an additional improvement when information on pain management is provided to the pregnant woman (Liddle and Pennick 2015).
Elden et al., (2008) and Kordi et al., (2013) showed that exercises performed during six weeks reduced pelvic pain, and according to Kluge et al., (2011), an exercise program that lasted ten weeks reduced the intensity of pregnancy low back pain and increased the functional capacity of the participants. Garashabi and Zadeh (2005) and Schim et al., (2007) concluded a reduction in

low back pain intensity. While Liddle and Pennick (2015), in a systematic review that included 23 studies with 4093 pregnant women, found evidence that the practice of specific exercises was able to relieve lumbopelvic pain during pregnancy .

European guideline (2017) recommends that PLBP and PGP are managed by providing information, and patients are advised to maintain a positive attitude, continue their normal daily activities and work as much as possible, and give appropriate individual exercises as appropriate (Katonis et al., 2011).

1.6. Importance of the research:

According to the World Health Organization, *maternal morbidity* is "*any health condition attributed to and/or complicating pregnancy and childbirth that has a negative impact on the woman's wellbeing and/or functioning"* (Chou et al., 2016). Globally and locally, maternal health and wellbeing have priority. Therefore, disorders like pelvic girdle pain (PGP), low back pain (LBP), hip pain, and sacroiliac pain can impact women's wellbeing, therefore should not be considered in isolation, but needs to take account of women's life context (Wadephul et al., 2021).

Internationally, many studies have been done on the LBP and PGP during pregnancy. However, it is often overlooked and considered just another part of the painful process of pregnancy (Mota et al., 2015; Bishop et al., 20016) because patients and clinicians have inadequate information about treatment options and fear of possible harmful effects of treatment on the developing fetus (Vermani, FRCA*, Mittal and Weeks, 2010; Liddle & Pennick, 2015, Mota et al., 2015). Lack of awareness of the impairment caused by pregnancy-related musculoskeletal disorders can cause poor management. Most studies on pregnancy-related LBP and PGP have been conducted in developed countries (Van De Pol et al., 2007; Robinson et al., 2010; Kovacs et al., 2012).

In Kurdistan region/Iraq, according to the researcher experiences, low back and pelvic girdle pain during pregnancy have not been investigated, while there is a noticeable number of complaints, according to what the researcher observed during her visit to antenatal care units within primary health centers. There is a lack of information on the prevalence, risk factor, diagnosis, prevention and management of PRLPP.

The modern concept of being pregnant in our culture means less mobility, limited activities, and more bed rest. Furthermore, Kurdish women have special behavioral habits in relation to posture when standing, sitting, and doing activities, as well as using traditional squat toilets and taking improper care during pregnancy. Therefore, pregnant women might be more susceptible to get LBP and PGP. When pregnant women experience any kind of musculoskeletal pain, they endure this pain without complaint to their health workers. Because of the common belief that this pain is a normal side effect of pregnancy. On another hand, even if they reach out to their health workers, they are usually told to “take bed rest” or they are provided with supplementary vitamins and/or painkillers when the pain is severe. Quite a few clinicians are helpless to give a “watch and wait” approach as the best solution for those women.

Pregnancy is a sensitive condition; therefore, excessive medication should be avoided. Being pregnant means overloading; besides occurring pain, it increases suffering. Pain is the chief complaint of anyone seeking health care; therefore, pregnant women may enjoy this period, not hurt. Until now, there is no consensus about treating pregnancy-related LPP, while this condition needs golden evidence regarding the management program. This study aimed to empower the approach of introducing specific exercises for reducing pain and promoting physical function among pregnant women who suffer from LPP. The musculoskeletal treatment based on essential physiotherapy for women's health problems during pregnancy is one of the significant interests of the researcher. Locally, there is a vast gap regarding managing musculoskeletal dysfunction during pregnancy.

1.7. Methodology of the research:

1.7.1. Design of the study:

A quantitative design-quasi-experimental study

1.7.2. Administrative Arrangement:

The study needs official permission from the Nursing College / University of Raparin to be conducted. In addition, an official request from Nursing College to the Director of Health in Sulaymaniyah for access and permission to enter the health facilities belonging to Sulaymaniyah DoH.

1.7.3. Ethical Consideration:

The study needs an official agreement from the scientific committee of the Nursing College in order to be conducted. The researcher will provide written informed consent from the subjects that will participate in this study and an agreement to protect their privacy.

1.7.4. Setting of the study:

Private physiotherapy clinic.

1.7.5. The sample of the study:

Non-probability purposive sample

- **Sampling:** Target population is pregnant women which will be divided into 2 groups (Intervention and control).
- **Sample size:**

70 pregnant women for each group

1.7.6. Samples criteria (inclusion and exclusion)

- **Criteria of inclusion:**

1. Age over 18years old
2. Gestation age been between 14 to 30 weeks.
3. Has lumbopelvic pain – means pain at lower back or pelvic region.
4. Without any co-morbidity
5. Singleton fetus confirmed by ultrasonography.
6. Not used treatment for the current low back and pelvic pain.

- **Criteria of exclusion**

1. Those who are contraindicated for exercises according to the American College of Obstetricians and Gynecologists (ACOG) guidelines (Artal, 2016) – any indications for high-risk pregnancy, e.g., placenta previa, pre-eclampsia, previous intrauterine death, previous miscarriage, Thrombophlebitis, decreased fetal movement, amniotic fluid leakage, severe anemia).
2. History of disc prolapse, spine or pelvic trauma, or operation.
3. Body Mass Index greater than 40 or unexplained weight loss

1.7.7. Techniques of data collections:

1. Health records revision (ultrasound, complete blood count, general urinary investigation)
2. Questionnaires

- Sociodemographic questionnaire includes (individual characteristics, obstetric profile, and past & present history of lower back pain) .
- Pain profile and Numerate Rating Score (NRS).
- Modified Mobility Pregnancy Index
- Body mechanic questionnaire that used for measuring Knowledge and practice.
- Questionnaire for measuring the effectiveness of therapeutic exercise program among the intervention group.
- Questionnaire for measuring the participant's satisfaction.

1.7.8. Intervention program

The intervention program is 12 weeks and going to be divided on two stations:

- **First station-four weeks: clinical based exercise program**

- Four weeks exercise at the private physical therapy clinic.
- Weekly one session.
- Each session 30 minutes, 5-6 exercise

- **Second station-eight weeks: home based exercise program**

- Eight weeks exercise at home.
- Repeat exercise daily
- Each participant has own program.

- **Materials of the therapeutic exercise program**

a. **Manual:** Content exercise and information
b. **Equipment:** the physical therapy clinic is occupied with what the program needs such as (mat, wall merroir, Swiss ball and pillow).

1.7.9. Validity of the study tools and Instruments:

The study's tools will present to 10 experts in the different fields that related to the study problem (obstetric, gynecologist, orthopedic, rehabilitation, professional nurse, and professional physical therapists).

1.7.10. Pilot study:

The intervention program will perform with ten pregnant women as a pilot project.

1.7.11. Reliability of the questionnaire:

Test-retest reliability use with pilot study sample, one-week interval.

1.7.12. Statistical analysis:

Use the SPSS program

1.7.13. References:

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