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# Effect of a Lumbopelvic Belt versus Pelvic Strengthening Exercise on the Level of Pregnancy-Related Low Back Pain

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***Abstract***
***Objective:*** *The current study aimed to compare the effect of a lumbopelvic belt versus pelvic strengthening exercise on the level of pregnancy-related low back pain.* ***Methods:*** *a non-randomized controlled trial was conducted at the Antenatal Outpatient Clinic of Mansoura University Hospitals, Egypt on a purposive sample of 126 pregnant women with pregnancy-related low back pain. The control group involved 42 clients who received usual prenatal instructions. Besides usual instructions, the belt group (n=42) wore a lumbopelvic belt, while the exercise group performed a 3-steps pelvic strengthening exercise. Data were collected using an assessment sheet for demographic characteristics, Numerical Rating Scale- Pain for pain intensity, Modified Oswestry Disability Index (MODI) to evaluate how the low back pain is affecting woman's ability in doing daily activities, while participant's adherence to wear the belt or perform exercise were recorded in daily diaries.* ***Results:*** *The mean difference in the pain scores during the preceding 24-hours and the previous week was significantly lower in the belt group subjects than exercise and control groups at 3 and 6 weeks. Pain scores during the previous week in belt group subjects compared to exercise and control groups were lower by a mean difference of 0.4 and 2.7 respectively at 3 weeks, while at 6 weeks mean differences were 1.5 and 4.8 respectively. Regarding MODI scores of the previous week, it was also significantly lower in belt group than exercise and control at 3 weeks by mean differences of 6.6 and 12.3 respectively; and by 7.8 and 19.6 at 6 weeks respectively.* ***Conclusion:*** *Existing study hypotheses were accepted. Using the pelvic support belt and exercise was effective in reducing pregnancy-related low back pain and MODI scores compared to usual prenatal care, and using the belt was more effective than the exercise performance .*

***Keywords:*** *Pelvic support belt, pregnancy-related low back pain, maternity support garment.*

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## 1. Introduction

Low back pain (LBP) is a common musculoskeletal ailment during pregnancy. It is defined as periodic or persistent pain around the lumbar spine for more than one week. Low back pain and pelvic girdle pain usually affect the pregnant women around the 17 and 19 weeks of gestation; reaching its peak between 24 and 36 weeks of gestation. Earlier studies cited a wide range of diversity in the incidence of pregnancy-related LBP between 30% and 78% in the United States of America, Europe, and certain African communities. This is higher than that of 20% to 25% in non-pregnant women [1-3]. A national study conducted in El-Menofia, Egypt revealed that 47.3% of pregnant women had low back pain in their pregnancy [4].

There is no definite cause for the pregnancy-related LBP. It is a multifactorial caused ailment that is attributed to different theoretical etiologies. Among these etiologies are anatomical, inflammatory, vascular and hormonal changes of pregnancy. Relaxin hormone secretion in pregnancy causing softening of the sacroiliac and symphysis pubis joints; resulting in pelvic instability which in turn intensifying back discomfort. However, a history of chronic LBP, multiparity, LBP in a previous pregnancy, pelvic injury, or young age are recognized as risk factors to the pregnancy-related LBP [5, 6].

Among reported cases of the pregnancy-related LBP, one-third rate their pain intensity as severe. A severe pain limiting pregnant mother's ability in performing daily living activities; such as walking, sitting, standing, and may disturb women's sleeping patterns, thus leading to higher absenteeism, ineffective working, and less work production [7]. The majority of pregnant women receive little or even no care for lumbopelvic pain. Given alarms about medications prescription during pregnancy, European guidelines suggested several non-pharmacological options for management of pregnancy-related low back pain and pelvic girdle pain [8]. Teaching pregnant women about ergonomic concerns and proper body mechanics is one of the recommended therapies for the pregnancy-related low back pain. Besides, various types of physical exercise and the use of pelvic support belts are prescribed for management [9-12].

Up to now, there is little evidence and heterogeneity of results concerning the impact of performing an exercise or using pelvic support belts on modulating pregnancy-related low back pain and its influence on daily living activities. A Cochrane review revealed that using pelvic support belts or pillow, acupuncture, physiotherapy, and performing exercise appeared to reduce pregnancy-related low back pain in comparison to usual prenatal care [13]. But, there is no definite consensus about the best choice for the management of pregnancy-related low back pain due to methodological concerns such as the inadequate absence of randomization, sample size, or un-blinding assessment. Therefore, the current clinical trial aimed to compare the effect of a lumbopelvic belt versus pelvic strengthening exercise on the level of pregnancy-related low back pain.

### 1.1 Significance of the study

Low back pain is a serious problem in 25% of the affected pregnant women; with an incidence of 8% are severely disabled to perform daily living activities [14]. It results in a reduction of pregnant women's quality of life and contributes to an increase in pregnant women's reports of sick leave; so it reduced nationwide productivity. In spite of that, pregnancy-related LBP is rarely treated. Managing the LBP could carry extensive implications for a community and increasing productivity [15]. In this instance, there is an urgent need to search for management options for this problem. Therefore, the current study conducted to compare the effect of a lumbopelvic belt versus pelvic strengthening exercise on the level of pregnancy-related low back pain.

### 1.2 Definition of terms

#### *1.2.1 Pregnancy-related low back pain*

It is a musculoskeletal pain arising from the lumbar spine area and/or posterior pelvic pain which involves one or two sided sacroiliac joints; with or without radiation to the sciatic distribution [16].

#### *1.2. 2 Pelvic support belt*

Pelvic support belt is defined as an elastic adjustable sheet to be enfolded around the pelvic girdle under the abdominal level. Commercially available in various designs. Certain types are attached with a wide supporting piece at the back. It is used for correcting pelvic instability, alleviating or managing the LBP, or lifting the weight of the pregnant uterus [17].

#### *1.2.3 Pelvic strengthening exercise*

This type of exercise proposes to strengthen the muscles of the back, pelvic floor, abdomen, buttocks, and those of the thighs; in order to reduce or even prevent the low back pain. It is carried out in a slow controlled manner. It is a 3-step easy exercise: 1) Pelvic tilts for abdominal muscles, 2) Arm and leg raise for back muscles and buttock muscles, and 3) Wall squats for abdominal muscles, buttock muscles, and thigh muscles.

### 1.3 Aim of the study

The current study aimed to compare the effect of a lumbopelvic belt versus pelvic strengthening exercise on the level of pregnancy-related low back pain.

### 1.4 Hypotheses of the study

To attain the aim of the current study, two hypotheses were tested:

***Hypothesis I.*** "Pregnant women who use the lumbopelvic belt experience lower pregnancy-related low back pain intensity compared to those who perform pelvic strengthening exercise".

***Hypothesis II.*** "Pregnant women who use the lumbopelvic belt record lower disability score in performing daily activities; according to the Modified Oswestry Disability Index, compared to those who perform pelvic strengthening exercise".

## 2. Subjects And Methods

### 2.1 Research design

The current study was designed as a non-randomized controlled trial. It was unblinded; where the participant and investigator were aware of which group a participant belonged to.

### 2.2 Study setting

This study was carried out at the Antenatal Outpatient Clinic of Mansoura University Hospitals, Egypt. This clinic was reconstructed in 2012 to distinctively follow-up on the health status of pregnant women and their fetuses.

### 2.3 Sampling

A purposive sample of 126 pregnant women was recruited from the beginning of June 2018 to the end of May 2019. The healthy pregnant mother attended the study setting at gestation weeks of 26 to 28; since the peak of the LBP evident at ≥ 24 weeks of gestation, were invited to participate in the current study if they were fulfilled the following **inclusion criteria:**

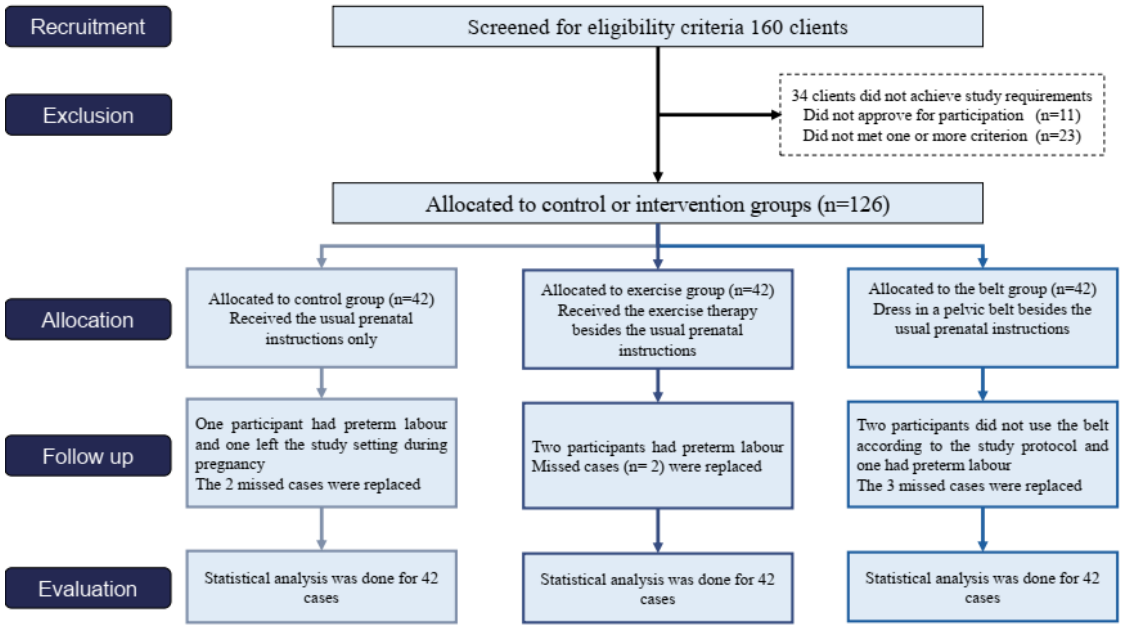
1. Had a singleton pregnancy.
2. Age between 20 to 35 years.
3. Had a pregnancy-related low back pain (i.e., pain arising from the lumbar spine area and/or posterior pelvic pain at one or two-sided sacroiliac joints). Those with pain at symphysis pubis joint without lumbar back pain or sacroiliac joint pain were excluded.
4. Free from a medical or obstetric condition that restricts the use of a pelvic belt or limit exercise performance. Such as, a woman with orthopedic or neurologic disorders and that is with a previous history of back or pelvic girdle injury and operations. As well as, not using pelvic belts or on an exercise regimen at recruitment time.

**2.3.1 Sample size calculation**

This non-randomized controlled trial proposes to compare the effect of a lumbopelvic belt versus pelvic strengthening exercise on the level of pregnancy-related low back pain. Based on data from a previous clinical trial [12], considering level of significance of 5% and power of study of 80%, the sample size can be calculated using the following formula: $n = [(Z_{\alpha/2} + Z_{\beta})^2 \times \{2(SD)^2\}]/$ (mean difference of pain scores between the two groups)$^2$ ,where $Z_{\alpha/2}$ depends on level of significance, for 5% this is 1.96, $Z_{\beta}$ depends on power, for 80% this is 0.84, and SD indicates to standard deviation. Therefore, $n= [(1.96 + 0.84)^2 \times \{2(2.6)^2\}]/ (6.1 - 4.5)^2=41.4$. Based on the above formula, the sample size required per group is 42, giving a total sample of 126 pregnant women with low back pain.

**2.3.2 Allocation into the groups**

Assignment of the groups was identified by selecting one closed envelope containing letters B, C, or E; where B refers to Belt group, C means Control group, while E indicates to Exercise group. The assignment was carried out at 1:1:1 ratio, where 1/3 of the envelopes (n=42) contained letter B, other 1/3 contained letter C, and remained 1/3 contained letter E. Envelopes were opened after diagnosis of the pregnancy-related low back pain, confirmation of eligibility, and taking informed written consents. Subjects' enrollment, exclusion, allocation, follow-up, and evaluation were presented in the study Flowchart.




**Flowchart of the study participants**

**2.4 Measures of data collection**

Four measures were used to gather the required data. Assessment sheet, Numerical Rating Scale- Pain, Modified Oswestry Disability Index, and daily diary for adherence to the interventions.

**2.4.1 Assessment sheet**

This sheet inquired about the demographic characteristics of the participant women. It included name, age, group, gestation age at enrolment and at pain feeling, occupation status, Body Mass Index (BMI) and parity.

**2.4.2 Numerical Rating Scale- Pain (NRS-Pain)**

The intensity of the low-back pain was evaluated by using the 0 to 10 NRS-Pain. It is a self-report scale. To describe pain intensity during the preceding 24 hours and previous week, respondents were instructed to choose a number represents pain intensity on a 0 to 10 scale. The 0 score represents no pain, while a score of 10 points to the worst pain. The NRS-Pain was validated earlier and its use for evaluating pain intensity had been anticipated [18].

***Scoring and interpretation***

The number given by the respondent represents the score of pain. Its intensity is categorized as mild, moderate, and severe. 1) A score of 0 to 4 lies in the mild category; which is minimal affects daily activities, 2) score of 5 or 6 specifies the moderate category; which interfere with certain functions such as sleep, mood, and socializing, while 3) scores of 7 to 10 reflects severe pain intensity. This category negatively affects a wide range of daily activities [19].

**2.4.3 Modified Oswestry Disability Index (MODI)**

This measure was designed to evaluate how is low back pain limits an individual's ability to achieve daily living activities [20]. It is a self-administered questionnaire comprised of ten items (i.e., pain intensity, personal care such as washing or dressing, lifting, walking, sitting, standing, sleeping, social life, traveling, and employment which replaced the sex life question in the original pre-modified Oswestry Disability Index). The respondent consumes around 5 minutes to fill in. For use in the current clinical trial, the English version of the MODI was translated into the Arabic language. The validity of the translated version confirmed by a panel of 5 experts in the Maternity Nursing department to assess if each translated item gave the meaning intended to or not.

***Scoring and interpretation***

Each item is evaluated by selecting one out of six options. The 1st option scored as 0 and means that an individual's ability to perform daily activities did not affected by the LBP, while the 6th option scored 5 and representing the greatest disability. If the ten items are completed, the total score calculated by dividing the total achieved score on the total possible score (50) and multiply by 100. For example: if the total achieved score was 16, it is divided on the total possible score (i.e., 16/ 50) X 100= 32%. If one item is missed, its highest score (i.e., 5) will be deducted from the total possible score to be 45; thus it will be 16/45X100= 35.5%. Level of disability identified according to the net achieved score as the following:

| ***Disability level*** | ***Score*** |
|---|---|
| *Minimal* | 0-20% |
| *Moderate* | 20-40% |
| *Severe* | 40-60% |
| *Crippled* | 60-80% |
| *Bed-bound* | 80-100% |

**2.4.4 Daily diary for adherence to the interventions**

Adherence of using the belt was determined by instructing each one in the belt group to daily record whether or not a pelvic belt was used. Additionally, the number of days the belt was used per week and the number of hours the belts were used per day were recorded. While adherence to performing the 3-steps pelvic strengthening exercise was identified by instructing each participant to weekly record whether or not performed the exercise and how times were performed per week.

**2.5 Ethical considerations**

Official acceptances were granted from Obstetrics and Gynecology Department board, Mansoura University Hospitals and from the Ethics Committee of the Nursing Faculty, Mansoura University to perform the current clinical trial. Moreover, the aim and approach of the study were clarified before getting the participant's informed written consent. Each participant is given the right to withdraw from the trial at any time without any influence on the provided prenatal care.

**2.6 Research process**

The current non-randomized controlled clinical trial was implemented in three phases. Phase 1 and 2 were preparation and implementation of the intervention, while the 3rd phase included evaluation of the outcomes.

**[1] Preparation phase**

Official approvals to conduct the current clinical trial were obtained from the concerned authorities. Before launching the current clinical trial, a pilot study was done on 10% of the pre-determined sample size. It was aimed to pick up a general idea on the feasibility of using the pelvic support belt or performing the exercise protocol, occurrence of any associated ailments, and clarity of the study measures. Results of the piloting indicated that using the pelvic support belt or performing the exercise was tolerable without associated ailments. As well, the pilot revealed clarity of the measures. Thus, no modification was done in the measures. Piloting sample did not include in the final statistical analysis.

**[2] Implementation phase**

This phase started by recruitment of the participant women, then assign each participant to one of three groups, and instruct each one about the intervention related to the assigned group. Subjects of the control group received the usual prenatal care. Meanwhile, besides the usual prenatal care subjects of the belt group were instructed on how to use the pelvic support belt and their mates in exercise group were taught how to perform the 3-steps pelvic strengthening exercise.

*Recruitment and groups' assignment*

Recruitment of the participants was done by explaining the aim and approach of the current study to the pregnant women who attended the study setting during the study period. Thereafter, screening for eligible cases with pregnancy-related low back pain was initiated. A case of low back pain was diagnosed by oral expression of "I feel back pain", and specifying pain site on a back chart at the lumbar vertebrae area or at one or both sacroiliac joints. A positive Menell's test besides oral expression and specifying site of the low back pain was a specific diagnostic test of a sacroiliac joint pain. Menell's test was performed by the following steps: 1. the client was instructed to lie on in a supine position, 2. move one leg into 30° abduction and 10° flexion at hip joint, and 3) push and pull the leg out from the pelvis, making a sagittal movement. The feeling of pain at a sacroiliac joint reflects a positive Menell's test [21].

Once the diagnosis of the pregnancy-related low back pain was confirmed, informed written consents were obtained from eligible ones. Demographic characteristics, 0-10 NRS-Pain scale, and MODI scale were completed as a baseline data. Then, participants were assigned randomly to the control, exercise, or belt groups and contact information was exchanged between participant women and a data collector researcher.

***Care of the control group***

This group received the usual prenatal instructions on how to reduce the intensity of the LBP; including 1) use of correct body mechanics in daily activities (e.g., walking or sitting), 2) make balance weight on both legs while standing, 3) be active with maintaining adequate rest, and 4) lying on a less painful side in sleeping. Simultaneously, participants were advised to avoid any activity that may worsen back pain (e.g., lifting heavy shopping, frequent going up and downstairs, crossing legs while sitting, long-standing or sitting, maintain one position more than 30 minutes).

***Care of the exercise group***

Besides the usual prenatal instructions, subjects of the exercise group were taught how to perform a 3-steps pelvic strengthening exercise. The pregnant women were taught to perform the exercise daily for a complete of 6 weeks; starting from the day of enrolment until 6 weeks thereafter.

*Step 1. Pelvic tilts*

The pelvic tilt is proposing to strengthen the abdominal muscles. This step is done when the woman lies on her back, bending her knees and flat feet on the floor. Compress the lower portion of the spine against the floor; leaving no space between the back and the floor. Relaxation of the buttocks was kept to isolate the abdominals. This position kept for 3-10 seconds and was repeated for 10-30 times. The pelvic tilt can be accomplished while lying on the back or sitting. It may take 30 seconds at least to be completed and a maximum time of 5 minutes is required to complete this step.

*Step 2. Arm and leg raise*

Step of arm and leg raises recommends to strengthen back and buttock muscles. The woman is going to assume the hands and knees position. Lift the right arm and left leg, making a straight line with the spine; for 3-10 seconds. Thereafter, lift the left arm and right leg in a straight line with the spine; for another 3-10 seconds. The woman asked to repeat both sides for 10-30 times. Both sides exercise took 1-10 minutes to be accomplished. The participant woman was instructed to modify this step by raise only leg or arm separately in case of feeling unbalance if raise both together.

*Step 3. Wall squat*

The wall squat step aims to reinforce the muscles of the abdomen, buttocks, and thighs. The woman stands with back against a wall and the feet are away from the wall by about 1-2 feet. The woman pressed the lower back against the wall and squat like going to sit down; making with the knees an angle of 90-degree. Then, raise up slowly keeping back and buttocks in touch with the wall. This step same as the first and second steps repeated 10-30 times. A woman may require 5 minutes to perform the wall squat step. Each participant was instructed to make the 3-steps of pelvic strengthening exercise daily. The number of sessions done was reported in a daily diary by all participants. Compliance with the intervention was attained by recording the performance of at least 4 sessions weekly; giving a total of 24 sessions during the 6 weeks study period.

***Care of the pelvic support belt group***

Participants of this group dress in a pelvic support belt beside the usual prenatal instructions. The data collector researcher provided each participant with a belt (3M Nexcare™ Maternity support). The data collector researcher explained to each one how to use the belt; how to adjust its size according to pelvic size, so belt was well fitted around the pelvis and be comfortable (i.e., neither loose nor restrictive). Participants were taught to wear the belt from enrolment day until six weeks. It was dress in as tolerated during day waking hours and un-dress during sleeping hours. The number of hours the woman dress in the belt were recorded in a daily diary.

**[3] Phase of the outcomes evaluation**

The 0-10 NRS-Pain scale and MODI scale were completed at baseline, at the 3rd and 6th weeks from enrolment. Respectively, to evaluate back pain intensity during the preceding 24 hours and the previous week and effect of pain on performing daily living activities. At the end of the study period, adherence to the interventions was determined; by reviewing the daily recording diaries for both belt and exercise groups.

**2.7 Statistical analysis**

Statistical calculations of data were performed using SPSS for windows version 20 (SPSS, Chicago, IL). Continuous variables were normally distributed and were presented in Mean ± Standard Deviation (SD), while categorical variables were presented in number and percent. At each time point evaluation, the comparisons between every two groups were determined using Student's t-test, while one-way analysis of variance (ANOVA) test was used for comparison across the 2 groups. Repeated measures ANOVA test was used for comparison of pain and MODI scores in each group at different time points of evaluation. A chi-square test was used for comparison of variables with categorical data. The 95% Confidence Interval (CI) for a difference of means was calculated. Statistical significance cutoff was set at $p<0.05$.

## 3. Results

**3.1 Demographic characteristics**

**Table 1** exhibits the homogeneity of the participants. The three groups were matched regarding the age, gestation weeks at enrollment in the study, gestation weeks at pain feeling, parity, occupational status and body mass index.

**3.2 Pain intensity of the groups before and after the interventions**

The pain score of the pregnant women was recorded and compared among the three groups during the preceding 24 hours and during the previous week at baseline and at 3 and 6 weeks. As presents in **Table 2 and Figures 1a&b**, during the preceding 24 hours, the pain scores did not show a significant difference in the baseline evaluation among the groups. However, at the 3 and 6 weeks evaluation, differences in the recorded average pain scores were significant ($p<0.001$). In comparing between every two groups, the pain score in the exercise group was significantly lower than that of the control group at 3 and 6 weeks by a mean difference of 1.2 and 2.5 points respectively; $p<0.001$. Meanwhile, the pain score of the belt group was significantly lower than that of the exercise group by a mean difference of 0.5, $p=0.003$ at 3 weeks and by 1.5, $p <0.001$ at 6 weeks.

Further lower pain score was reported in the belt group than the control group at 3 and 6 weeks (mean difference = 1.7 and 4 respectively; p<0.001). Moreover, the change in pain score in the control group from baseline to 3-weeks and 6-weeks evaluations was insignificant meanwhile the decrease of pain score in the exercise group and belt group from baseline to 3-weeks and 6-weeks evaluations was significant (p<0.001).

Differences in the pain scores of the three groups during the previous week were insignificant at baseline. Yet, at the 3 and 6 weeks evaluations, differences were significant (p<0.001). The comparison of the average pain score between each two groups revealed that the pain score in the exercise group was significantly lower than the control group at 3 and 6 weeks (mean difference = 2.3, 3.3 points respectively; p<0.001), while pain score of the belt group was significantly lower than the exercise group (mean difference = 0.4, 1.5 points respectively; p=0.011) and further lower than control group (mean difference = 2.7, 4.8 points respectively; p<0.001). Moreover, the change in pain score during the previous week in the control group from baseline to 3-weeks and 6-weeks evaluations was insignificant meanwhile the decrease of pain score in the exercise group and belt group from baseline to 3-weeks and 6-weeks evaluations was significant (p<0.001).

**3.3 The MODI scores of the three groups before and after the interventions**

**Table 3 and Figure 2** demonstrate the MODI scores of the three groups at baseline and at 3 and 6 weeks follow-ups. MODI scores did not differ significantly among the groups at baseline. However, at 3 and 6 weeks, differences in the average MODI score were significant (p<0.001). Comparing the MODI scores by individual groups found the MODI score reduction achieved in the belt group subjects was more than that of control group subjects at 3 and 6 weeks by mean differences of 12.3 and 19.6 respectively, while a lower reduction observed between exercise and control group subjects at the 3 and 6 weeks (mean differences 5.7, p= 0.031 and 11.8, p <0.001). Moreover, the MODI score of the belt group is lower than that of the exercise group (mean difference 6.6, p =0.006 and 7.8, p=0.002 respectively) at 3 and 6 weeks follow-ups.

**3.4 The intervention groups adherence to the interventions**

**Figure 3a** showed that the participants complied with belt wearing for 7-9 hours, 35.7% (n=15) of the belt group subjects wore the belt for 8 hours, while 38.1% (n= 16) wore the belt for 9 hours. The remaining 26.2% (n=11) of the belt group subjects wore the pelvic belt for 4 hours. Furthermore, **Figure 3b** illustrated that slightly more than three-quarters of the exercise group subjects (76.2%) were keen to perform at least 4 exercise sessions or more per week.

**Table 1.** Demographic characteristics of the participants **(n=126)**

| | **Groups** | | | **Test of significance** | | | |
|---|---|---|---|---|---|---|---|
| **Items** | **Control** | **Exercise** | **Belt** | **Control vs. Exercise** | **Control vs. Belt** | **Exercise vs. Belt** | For groups |
| | **(n=42)** | **(n=42)** | **(n=42)** | | | | |
| **Age (years)** | | | | | | | |
| <25 | 13 (31.0%) | 11 (26.2%) | 12 (28.6%) | | | | |
| 25 – 30 | 14 (33.3%) | 12 (28.6%) | 11 (13.0%) | $X^2$=0.79 | $X^2$=0.20 | $X^2$=0.20 | $X^2$=0.79 |
| >30 | 15 (35.7%) | 19 (45.2%) | 17 (40.5%) | P=0.673 | P=0.904 | P=0.907 | P=0.940 |
| **RANGE** | 20 – 35 | 20 – 35 | 20 – 35 | t=0.40 | t=0.02 | t=0.39 | F=0.10 |
| **MEAN ±SD** | 27.9 ±5.0 | 28.4 ±4.7 | 28.0 ±4.9 | P=0.687 | P=0.982 | P=0.700 | P=0.902 |
| **Gestation weeks at enrolment** | | | | | | | |
| **RANGE** | 26 – 28 | 26 – 28 | 26 – 28 | t=0.662 | t=0.410 | t=0.26 | F=0.23 |
| **MEAN ±SD** | 27.0 ±0.8 | 26.8 ±0.9 | 26.9 ±0.8 | P=0.510 | P=0.683 | P=0.793 | P=0.798 |
| **Gestation weeks at pain feeling** | | | | | | | |
| **RANGE** | 24 – 26 | 24 – 26 | 24 – 26 | t=0.916 | t=0.256 | t=0.68 | F=0.45 |
| **MEAN ±SD** | 25.0 ±0.9 | 24.8 ±0.9 | 24.9 ±0.8 | P=0.362 | P=0.798 | P=0.498 | P=0.639 |
| **Parity (N, %)** | | | | | | | |
| 2 | 18, 42.9% | 20, 47.6% | 17 (40.5%) | | | | |
| 3 | 10, 23.8% | 11, 26.2% | 12 (28.6%) | $X^2$=0.513 | $X^2$=0.247 | $X^2$=0.45 | $X^2$=0.81 |
| 4 | 14, 33.3% | 11, 26.2% | 13 (31.0%) | P=0.774 | P=0.884 | P=0.797 | P=0.938 |
| **Occupation status (n, %)** | | | | | | | |
| Housewife | 18 (42.9%) | 19 (45.2%) | 17 (40.5%) | $X^2$=0.05 | $X^2$=0.05 | $X^2$=0.20 | $X^2$=0.20 |
| Working | 24 (57.1%) | 23 (54.8%) | 25 (59.5%) | P=0.826 | P=0.825 | P=0.659 | P=0.907 |

| **Body mass index (kg/m²)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **RANGE** | 20.3 – 34.9 | 19.5 – 34.2 | 20.1 – 34.2 | t=0.83 | t=0.47 | t=1.28 | F=0.86 |
| **MEAN ±SD** | 27.2 ±3.5 | 27.8 ±3.8 | 26.9 ±3.8 | P=0.411 | P=0.643 | P=0.205 | P=0.426 |

**Table 2.** Pain intensity of the control and intervention groups during the preceding 24 hours and the previous week at different follow-ups **(n= 126)**

| | **Groups** | | | | **Comparisons** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Time | **Control (n=42)** | **Exercise (n=42)** | **Belt (n=42)** | **In groups** | **Control vs. exercise** | | **Control vs. belt** | | **Exercise vs. belt** | |
| | Mean ±SD | Mean ±SD | Mean ±SD | ANOVA* | t-test | | t-test | | t-test | |
| | | | | | Mean difference [95CI] | | Mean difference [95% CI] | | Mean difference [95% CI] | |
| **During the preceding 24 hours** | | | | | | | | | | |
| Baseline | 6.0 ±0.8 | 6.1 ±0.8 | 6.2 ±0.9 | F=0.603 | t=0.56 | 0.1 | t=0.29 | 0.2 | t=0.54 | 0.1 |
| | | | | P=0.549 | P=0.574 | [-0.43,0.24] | P=1.076 | [-0.57,0.7] | P=0.592 | [-0.47,0.27] |
| 3rd weeks | 6.3 ±0.5 | 5.1 ±0.8 | 4.6 ±0.7 | F=69.70 | t=8.71 | 1.2 | t=12.81 | 1.7 | t=3.05 | 0.5 |
| | | | | P<0.001 | p<0.001 | [0.97,1.55] | P<0.001 | [1.45, 1.96] | P=0.003 | [0.17,0.83] |
| 6th weeks | 6.4 ±1.1 | 3.9 ±0.8 | 2.4 ±0.4 | F=255.970 | t=11.91 | 2.5 | t=22.15 | 4.0 | t=10.8 | 1.5 |
| | | | | P<0.001 | p<0.001 | [2.08,2.92] | P<0.001 | [3.64, 4.36] | P<0.001 | [1.23,1.78] |
| **ANOVA**** | | | | | | | | | | |
| F | 2.600 | 79.625 | 314.137 | | | | | | | |
| P | 0.078 | <0.001 | <0.001 | | | | | | | |
| **During the previous week** | | | | | | | | | | |
| Baseline | 5.8 ±1.0 | 5.9 ±1.4 | 6.0 ±1.2 | F=0.29 | t=0.54 | 0.1 | t=0.830 | 0.2 | t=0.35 | 0.1 |
| | | | | P=0.751 | p=0.590 | [-0.38,0.67] | p=0.41 | [-0.68,0.28] | p=0.726 | [-0.67-0.47] |
| 3rd weeks | 6.1 ±0.8 | 3.8 ±0.8 | 3.4 ±0.6 | F=163.13 | t=13.35 | 2.3 | t=17.50 | 2.7 | t=2.59 | 0.4 |
| | | | | P<0.001 | p<0.001 | [2.03, 2.74] | p<0.001 | [2.93, 3.01] | p=0.011 | [0.9, 0.71] |
| 6th weeks | 6.2 ±1.3 | 2.9 ±0.8 | 1.4 ±0.7 | F=269.426 | t=14.01 | 3.3 | t=21.06 | 4.8 | t=9.15 | 1.5 |
| | | | | P<0.001 | p<0.001 | [2.83, 3.77] | p<0.001 | [4.35, 5.25] | P<0.001 | [1.17, 1.83] |
| **ANOVA**** | | | | | | | | | | |
| F | 1.640 | 92.176 | 292.716 | | | | | | | |
| P | 0.198 | <0.001 | <0.001 | | | | | | | |

**Table 3.** Pain intensity of the control and intervention groups during the preceding 24 hours and the previous week at different follow-ups **(n= 126)**

| | Groups | | | | Comparison | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Time | **Control (n=42)** | **Exercise (n=42)** | **Belt (n=42)** | **In groups** | **Control vs. exercise** | | **Control vs. belt** | | **Exercise vs. belt** | |
| | **Mean ±SD** | **Mean ±SD** | **Mean ±SD** | **ANOVA*** | **t-test** | | **t-test** | | **t-test** | |
| | | | | | **Mean difference [95% CI]** | | **Mean difference [95% CI]** | | **Mean difference [95% CI]** | |
| **MODI score** | | | | | | | | | | |
| **Baseline** | 39.2 ±13.6 | 38.7±12.2 | 39.0 ±11.6 | F=0.017 | t=0.18 | 0.5 | t=0.83 | 0.2 | t=0.12 | 0.3 |
| | | | | P=0.983 | p=0.860 | [-5.11,6.11] | p=0.942 | [-5.29,5.69] | p=0.908 | [-5.47,4.87] |
| **3rd weeks** | 40.1±12.8 | 34.4±10.9 | 27.8 ±10.4 | F=12.216 | t=2.20 | 5.7 | t=4.83 | 12.3 | t=2.84 | 6.6 |
| | | | | P<0.001 | p=0.031 | [0.54, 10.86] | p<0.001 | [7.24, 17.36] | p=0.006 | [1.98, 11.22] |
| **6th weeks** | 41.9 ±10.7 | 30.1±11.1 | 22.3 ±11.2 | F=33.786 | t=4.960 | 11.8 | t=8.20 | 19.6 | t=3.21 | 7.8 |
| | | | | P<0.001 | P<0.001 | [7.07,11.80] | p<0.001 | [14.85, 24.36] | P=0.002 | [2.96,12.64] |
| **ANOVA**** | | | | | | | | | | |
| **F** | 0.514 | 5.961 | 24.789 | | | | | | | |
| **P** | 0.599 | 0.003 | <0.001 | | | | | | | |

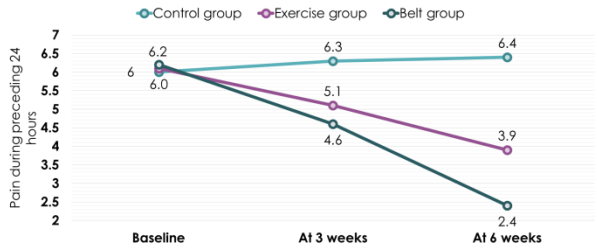



**Figure 1a.** Comparison of the pain intensity in control and intervention groups during the preceding 24 hours

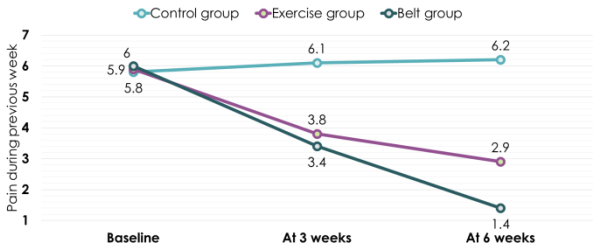



**Figure 1b.** Comparison of the pain intensity in control and intervention groups during the previous week

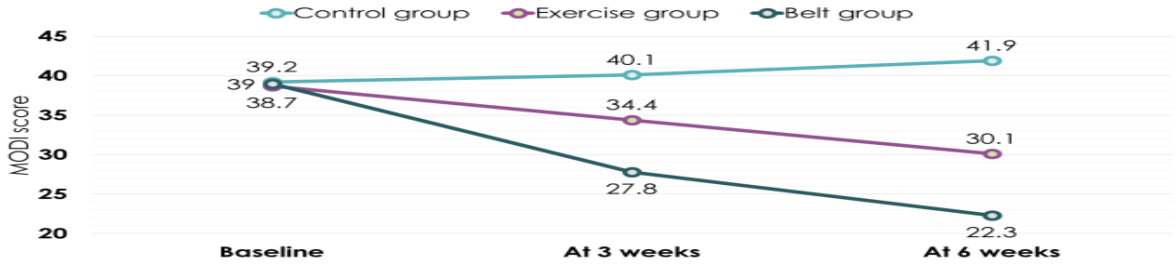



**Figure 2.** Comparison of the MODI scores in control and intervention groups during the previous week

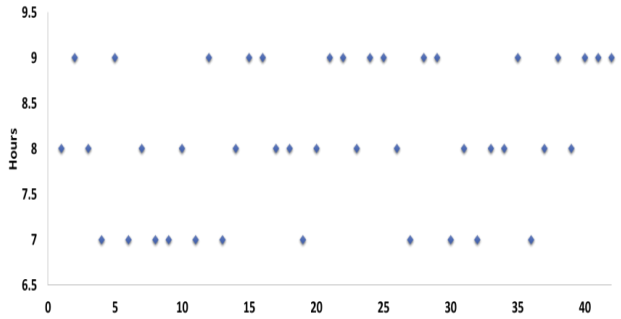



**Figure 3a.** Number of hours the belt group subjects used the belt daily

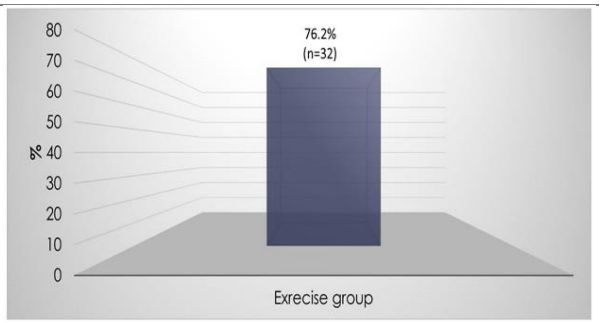



**Figure 3b.** Percent of the subjects in exercise group attained four exercise sessions or more weekly

## 4. Discussion

The current study aimed to compare the effect of a lumbopelvic belt versus pelvic strengthening exercise on the level of pregnancy-related low back pain. This aim was achieved through the present study finding. The principal finding of the current study is that pain intensity and its effect on daily living activities were significantly reduced among the exercise and belt groups compared with the control group at follow-ups. In comparison to the exercise group, the lumbopelvic belt group showed more reduction in VAS- pain and MODI scores at follow-ups.

Congruently, Kordi and colleagues noted that using non-rigid lumbopelvic belt; as an adjunct to applying ergonomic advice in performing daily activities, was most effective in reducing low back pain and pelvic girdle pain compared with implementing exercise with ergonomic advice or application of ergonomic advice alone in **Iranian** randomized controlled trial [22].Consistently, Flack and coauthors (2015) in a pilot randomized clinical trial in **New Zealand** demonstrated that using a pelvic support belt was an effective tool to decrease the severity of the pregnancy-related pelvic pain and added that using flexible pelvic support belt was more effective than the rigid one [23]. There is a notion that pregnancy is associated with abdominal enlargement due to fetal growth; resulting in an alteration in the pelvic alignment of pregnant women [24]. Pelvic instability negatively

impacts on body's mechanics and putting additional strain on different body parts contributing to musculoskeletal pain. It was evidenced that wearing a pelvic support belt is associated with the modification of the pelvic instability [25]. This may explain the alleviation of the pregnancy-related LBP evidenced in pelvic support belt subjects of the current study.

Kokic and colleagues 2017, found a beneficial effect of reducing pregnancy-related low back pain intensity after performing the exercise for at least 6 weeks [26]. Meanwhile, Wikmar and coauthors [27] did not find a significant effect of exercise performance on decreasing the pregnancy-related low back pain. Regarding the role of the exercise in evidenced low back pain reduction, authors of the existing study in agreement with others [28] found no certain consensus on explaining its role.

The low back pain adversely impacts pregnant women's performance of the daily living activities and comprise a leading reason for a large proportion of prenatal sick-leave [29-31]. Thus, the extent to which low back pain affects mothers' ability to achieve daily living activities was evaluated in the current study; by using the measure of MODI. Using pelvic support belt or implementing pelvic exercise as an adjunct to applying ergonomic advice, were associated with a reduction in the MODI scores compared with that of the control group. In comparing belt and exercise groups, subjects of the belt group recorded lower MODI scores than their mates of the exercise group in the 3$^{rd}$ and 6$^{th}$ weeks from intervention.

In a secondary analysis of a randomized controlled trial, Kokic and coauthors [26] investigated the effect of individualized structured exercise programs on the physical activities of the pregnant women. The structured exercise performed twice weekly for at least 6 weeks. It comprised 50-55 minutes of aerobic exercise, resistance exercises, and pelvic floor exercises, and 30 minutes daily walking. Kokic found a significant reduction in the Roland-Morris Disability scores; indicating better physical performance, among the exercise group compared with the standard obstetric care group. As in the current study, Kordi and colleagues [22] worked on three groups. Kordi's finding revealed that using a pelvic support belt besides applying ergonomic advice was the most effective option; compared to implementing exercise with ergonomic advice or application of ergonomic advice alone, in reducing the associated physical disabilities. One rationale may explain the evidenced improvement of physical activities. The belt contributes to modifying the pelvic alignment; which reduces pressure on different body parts, giving the woman a chance for moving and accomplishing daily activities. Unlike the current finding, Flack and coauthors found an insignificant decrease in the Oswestry Disability Index scores among users of the non-rigid pelvic support belt; but of clinical importance [23]. The absence of a statistically significant difference in Flack's findings may be related to the lower sample size.

Levels of adherence to both interventions were assessed in the current pelvic support belt group and exercise group. Concerning the number of hours the participants tolerated the use of the pelvic belt, it was evinced to range between 7 to 9 hours in current study subjects. However, Flack and colleagues [23], found a lower average of daily tolerance hours; with an average of 5.0 hours. Flack and colleagues, attributed lower tolerance hours of using the belt to that they did not direct the subjects to a specific duration of wearing the belt depending on lack of specific guidelines identifying the duration of effective use. Furthermore, Depledge and coauthors in an earlier study [32], found an average of 6.1 hours of using the flexible belt. Depledge related the short duration to that the participants tend to use the belt only on pain feeling. Authors of the current study attributed the evidenced higher tolerance hours to that the participants were taught to use the belt as long as tolerated; rather restricted to times of pain feeling or any specific time.

As regards adherence to the exercise protocol, participant women were instructed to record times of exercise per week and record any adverse events related to exercise performance. Current study findings revealed that slightly more than three-quarters of the participant women were keen to perform at least a lower number of exercise sessions and no one reported adverse events during exercise or even after. This may be related to the home-based nature of the exercise; hence increasing its adherence. Approved this finding, Kokic and coauthors [26], found a high adherence to the exercise protocol and nobody discontinued its performance due to a risky effect. Kokic endorsed such findings to that day and time of attendance the exercise sessions were optional. As each one was offered a chance of selecting a schedule matched their free time.

**4.1 Strengths and limitations of the study**

Adequate sample size, and the relatively low number lost in follow-ups increase the weight of this clinical trial and the possibility of generalizing its findings. On the other hand, implementing the intervention during limited gestation weeks may miss evaluation of its influence on the entire pregnancy or even during postpartum. Despite the declared limitation, findings precision is not affected.

**4.2 Clinical implications**

The use of the pelvic support belt along with keep on ergonomic advice in performing daily activities is an effective nonpharmacological tool in reducing the intensity of the pregnancy-related LBP and enhance the performance ability of the daily activities. It is a safe, useful, inexpensive, and easily accessible tool to cope with the pregnancy-related LBP and its use can be recommended for pregnant women.

## 5. Conclusion and recommendations

Based on the current study results, the tested hypotheses were accepted. As an adjunct with applying ergonomic advice in daily activities, using a pelvic support belt was more effective in reducing LBP intensity and improving women's ability to perform daily activities compared to exercise with applying ergonomic advice or applying ergonomic advice alone. Hence, the following can be recommended:

1. The use of the pelvic support belt is recommended during pregnancy.
2. Future researches that evaluate the effect of using different types of pelvic support belts and different exercise regimens are suggested. A longer follow-up period is also recommended in future researches.

## REFERENCES


[1]. Mota M, Sá-couto P, Demain S. Women's experiences of low back pain during pregnancy. *Journal of Back and Musculoskeletal Rehabilitation*. 2015; 28(2):351-357. doi: 10.3233/BMR-140527.

[2]. Abebe E, Singh K, Adefires M, Abraha M. History of Low Back Pain during Previous Pregnancy Had an Effect on Development of Low Back Pain in Current Pregnancy attending antenatal care clinic of the University of Gondar Hospital, Northwest Ethiopia. *Journal of Medical Science and Technology*. 2014; 3(3). 37-44.

[3]. Carvalho ME, Lima LC, de Lira Terceiro CA, Pinto DR, Silva MN[1], Cozer GA, Couceiro TC. Low back pain during pregnancy. *Revista Brasileira De Anestesiologia*. 2017 May - Jun; 67(3):266-270. doi: 10.1016/j.bjan.2016.03.002. Epub 2016 May 21

[4]. Gamila GA, Howida AA. Comparative study between primigravida and multigravida regarding women's self-care practices for management of selected minor discomforts. Madridge J Case Rep Stud. 2 (1): 41-49. ISSN: 2639-4553

[5]. Katonis P, Kampouroglou A, Aggelopoulos A, Kakavelakis K, Lykoudis S, Makrigiannakis A, Alpantaki K. Pregnancy-related low back pain .*Hippokratia*. 2011 Jul; 15(3):205-10.

[6]. Colleen M. Fitzgerald and Neil A. Segal, *Musculoskeletal Health in Pregnancy and Postpartum: An Evidence-Based Guide for Clinicians*, Eds., Springer Book, Cham, Switzerland, 2015.

[7]. Liddle SD, Pennick V. "Interventions for preventing and treating low-back and pelvic pain during pregnancy," *Cochrane Database of Systematic Reviews*, 2015 Sep 30; (9):CD001139. doi: 10.1002/14651858.CD001139.pub4. Review. PMID: 26422811

[8]. Vleeming A, Albert HB, Ostgaard HC, Sturesson B, Stuge B. "European guidelines for the diagnosis and treatment of pelvic girdle pain" *European Spine Journal*. 2008; 17 (6): 794-819.

[9]. Reyhan CA, Dereli EE, Kuru CT. Low back pain during pregnancy and Kinesio tape application. Journal of Back and Musculoskeletal Rehabilitation. 2017; 30(3):609-613. doi: 10.3233/BMR-160584. Review. PMID: 28035911

[10]. Kokic IS, Ivanisevic M, Uremovic M, Kokic T, Pisot R, & Simunic B. Effect of Therapeutic Exercises on Pregnancy-Related Low Back Pain and Pelvic Girdle Pain: Secondary Analysis of a Randomized Controlled Trial. Journal of Rehabilitation Medicine. 2017; 49: 251-257.2017 Mar 6; 49(3):251-257. doi: 10.2340/16501977-2196.

[11]. Haakstad, L, Bø K. Effect of a regular exercise programme on pelvic girdle and low back pain in previously inactive pregnant women: A randomized controlled trial. J Rehabil Med 2015; 47: 229–234.

[12]. Kalus SM[1], Kornman LH, Quinlivan JA. "Managing back pain in pregnancy using a support garment: a randomized trial," *BJOG: An International Journal of Obstetrics.*2008 Jan; 115 (1):68-75. Epub 2007 Nov 12.

[13]. Pennick V, Liddle SD. Interventions for preventing and treating pelvic and back pain in pregnancy. Cochrane Database syst. Rev 2013; 8: CD001139.

[14]. Wu WH, Meijer OG, Uegaki K, Mens JM, van Dieen JH, Wuisman PI, Ostgaard HC. Pregnancy-related pelvic girdle pain (PPP), I: terminology, clinical presentation, and prevalence. Eur Spine J. 2004 Nov; 13(7):575-89. Epub 2004 Aug 27.

[15]. Assis RGd, Tibúrcio RES. Prevalência e características da lombalgia na gestação: um estudo entre gestantes assistidas no programa de pré-natal da maternidade Dona Íris em Goiânia. Goiânia: Universidade Católica de Goiás, 2004.

[16]. Albert HB, Godskesen M, Westergaard JG. Incidence of four syndromes of pregnancy-related pelvic joint pain. Spine (Phila Pa 1976). 2002 Dec 15;27(24):2831-4.PMID:12486356

[17]. Yip J, and Yu, W. Innovation and Technology of Women's Intimate Apparel, Woodhead Publishing Limited, Cambridge, UK, 2006.

[18]. Jensen MB. Hypnosis for Chronic Pain Management: Self-Report Measures Assessing Pain, Pain-Related Beliefs and Coping, and Clinical Success. Copyright © 2011 by Oxford University Press.

[19]. Serlin RC1, Mendoza TR, Nakamura Y, Edwards KR, Cleeland CS. When is cancer pain mild, moderate or severe? Grading pain severity by its interference with function. Pain. 1995 May; 61(2):277-84.

[20]. Fritz JM, Irrgang JJ. A comparison of a modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Physical Therapy*. 2001; 81:776-788. Modified by Fritz & Irrgang with permission of The Chartered Society of Physiotherapy, from Fairbanks JCT, Couper J, Davies JB, et al. The Oswestry Low Back Pain Disability Questionnaire. *Physiotherapy*. 1980; 66:271-273.

[21]. Albert H, Godskesen M, Westergaard J. Evaluation of clinical tests used in classification procedures in pregnancy-related pelvic joint pain. Eur Spine J. 2000 Apr; 9(2):161-6.

[22]. Kordi R. Abolhasani M. Rostami M. Hantoushzadeh S, Mansournia M, Vasheghani-Farahani F. "Comparison between the effect of pelvic belt and home based pelvic stabilizing exercise on pregnant mother with pelvic girdle pain; a randomized controlled trial," *Journal of Back and Musculoskeletal Rehabilitation*. 2013; 26 (2): 133–139.

[23]. Flack N, Hay-Smith E, Stringer M, Gray A, Woodley S. Adherence, tolerance and effectiveness of two different pelvic support belts as a treatment for pregnancy-related pain- a pilot randomized trial. BMC Pregnancy and childbirth. 2015; 15-36. DOI 10.1186/s12884-015-0468-5

[24]. Casagrande D, Gugala Z, Clark SM, Lindsey RW. Low Back pain and pelvic girdle pain in pregnancy. J Am Acad Orthop Surg. 2015;23(9):539–49

[25]. Morino S, Ishihara M, Umezaki F, Hatanaka H, Yamashita M, Kawabe R, Aoyama T. The effects of pelvic belt use on pelvic alignment during and after pregnancy: a prospective longitudinal cohort study. BMC Pregnancy and Childbirth. 2019; 19:305 https://doi.org/10.1186/s12884-019-2457-

[26]. Kokic IS, Ivanisevic M, Uremovic M, Kokic T, Pisot R, Simunic B. Effect of therapeutic exercises on pregnancy-related low back pain and pelvic girdle pain: Secondary analysis of a randomized controlled trial. J Rehabil Med 2017; 49: 251–257

[27]. Nilsson-Wikmar L, Holm K, Oijerstedt R, Harms-Ringdahl K: Effect of three different physical therapy treatments on pain and activity in pregnant women with pelvic girdle pain: a randomized clinical trial with 3, 6, and 12 months follow-up postpartum. *Spine* (*Phila Pa 1976*) 2005, 30(8): 850-856.
[28]. Elden H, Ladfors L, Olsen MF, Ostgaard HC, Hagberg H. Effects of acupuncture and stabilising exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomised single blind controlled trial. BMJ. 2005 Apr 2; 330(7494):761. Epub 2005 Mar 18.PMID: 15778231
[29]. Hughes CM, Liddle SD, Sinclair M, McCullough JEM. The use of complementary and alternative medicine (CAM) for pregnancy-related low back and pelvic girdle pain: an online survey. Complementary Therapies in Clinical Practice. 2018; 31:379–383 DOI 10.1016/j.ctcp.2018.01.015.
[30]. Clinton SC, Newell A, Downey PA, Ferreira K. 2017. Pelvic girdle pain in the antepartum population: physical therapy clinical practice guidelines linked to the international classification of functioning, disability, and health from the section on women's health and the orthopedic section of the American Physical Therapy Association. Journal of Women's Health Physical Therapy 41(2):102–125 DOI 10.1097/jwh.0000000000000081.
[31]. Backhausen M, Damm P, Bendix J, Tabor A, Hegaard H. The prevalence of sick leave: reasons and associated predictors—A survey among employed pregnant mother. Sexual & Reproductive Healthcare. 2018; 15:54–61 DOI 10.1016/j.srhc.2017.11.005.
[32]. Depledge J, McNair PJ, Keal-Smith C, Williams M. Management of symphysis pubis dysfunction during pregnancy using exercise and pelvic support belts. Phys Ther. 2005; 85: 1290-300

Tyseer Marzouk, Eman A. Fadel. "Effect of a Lumbopelvic Belt versus Pelvic Strengthening Exercise on the Level of Pregnancy-Related Low Back Pain ". *IOSR Journal of Nursing and Health Science (IOSR-JNHS)*, 9(1), 2020, pp. 01-12.