Original Article

Assessing the Quality of Life of Pregnant Women Using a New Pregnancy Belt: A Randomized Controlled Trial (RCT) Study

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ABSTRACT

Background: Quality of life (QOL) is a multidimensional concept encompassing physical, mental, emotional, and social functions. Lumbar pain (LP) experienced during pregnancy can have a negative impact on QOL, but the use of pregnancy belts has been known to improve it. Presently, these belts' most common design pattern involves an adjustable one-piece panel at the pelvic girdle (PG) but does not support the lumbar region. However, the new pregnancy belt evaluated in this study is designed to support the lumbar and pelvic girdles simultaneously. The primary objective of this study is to assess the QOL of pregnant females experiencing lumbar pain while using the new pregnancy belt compared to the current belt (CB).

Methods: In this randomized controlled trial study, a total of 48 pregnant females experiencing pregnancy-related lumbar pain (LP) participated. They were divided into three groups: the CB, new belt, and control groups. At the beginning of the study and after three weeks, all groups completed a demographic questionnaire and a Quality of Life (QOL) questionnaire using the SF36 tool.

Results: After three weeks, all eight health concepts of the SF36 questionnaire showed improvement in both the CB and new belt user groups. However, in the control group, there was a decrease in these health concepts during the same period. A significant difference was observed in the physical and mental health scales when comparing the new belt group to the CB group. However, the two variables had no significant difference, with p-values of 1.00 and 0.15, respectively.

Conclusion: Based on the study's findings, it can be inferred that the new pregnancy belt has a more significant impact on enhancing the Quality of Life (QOL) of pregnant females compared to the CB (current belt).

Introduction

Quality of life (QOL) is a comprehensive term encompassing an individual's perception of their socio-cultural living conditions, considering their expectations, goals, standards, and responsibilities [1]. It is a multidimensional concept that includes mental, physical, emotional, and social aspects [2]. This broad and complex concept can impact various aspects of an individual's life, including physical health, mental well-being, level of autonomy, social connections, and interaction with the environment. Furthermore, an individual's overall health

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status is crucial in determining their QOL, making it a significant concept component [3].

Pregnancy is generally considered a routine physiological condition, and pregnant women are expected to continue their normal daily living and work activities [4]. However, this period in a woman's life can bring about significant physical and emotional changes, which may influence her QOL [3, 5].

During the third trimester of pregnancy, physical changes become more pronounced, especially the increase in abdominal size. This change can result in reduced static stability and adaptive alterations in spinal curvature, leading to an anterior displacement of the center of gravity [6, 7]. Consequently, pregnant women may experience postural adaptations that can impact their musculoskeletal system and contribute to the development of lumbar pain (LP) [8-11].

Pregnant females experiencing lumbar pain (LP) often encounter difficulties performing their usual daily activities, with more than 80% reporting such challenges [12]. The pain tends to intensify in the evening, suggesting that activity may trigger or exacerbate it. As a result, standing, sitting, and engaging in routine tasks become limited. Pregnancy-related LP can lead to functional disability, sleep disturbances, work absenteeism, and an increased risk of experiencing stress and anxiety, all of which can negatively impact the Quality of Life (QOL) [4, 13-18]. Previous studies have also shown that the QOL of pregnant females with LP decreases as gestational age advances [1, 3, 4, 12, 19].

Using pregnancy belts has proven beneficial for pregnant females in reducing pregnancy-related discomfort and lumbar pain, subsequently leading to an improvement in their Quality of Life (QOL) [20, 21]. These belts can be incorporated into daily life, providing lumbar support and enhanced comfort during routine activities [22, 23]. Notably, three studies have demonstrated the positive impact of pregnancy pelvic belts in improving health-related QOL and alleviating sacroiliac joint pain [24-26].

The most common design of pregnancy belts includes an adjustable device encompassing the pelvic girdle (PG). However, most of these belts were primarily created to support the pelvic area at the symphysis pubis and upper anterior iliac spine level, lacking adequate support for the lumbar region. Consequently, these belts have a shorter lever arm.

In contrast, the new pregnancy belt extends below the scapula, simultaneously supporting the lumbar area and the pelvic girdle. This design covers a larger torso area and creates a bigger lever arm. As a result, the forces applied to the spine are distributed over a wider surface, leading to reduced pressure. Therefore, the new pregnancy belt is expected to provide greater improvement in pelvic stability and lumbar pain (LP) compared to the current belt (CB) in pregnant females [27].

Given the previous evidence showing the efficacy of the new belt in reducing pain [27], this study aims to evaluate the Quality of Life (QOL) in pregnant females with LP using the new pregnancy belt compared to the CB. The hypothesis is that the new belt, with its simultaneous lumbar and pelvic girdle coverage, can enhance the QOL of pregnant females experiencing LP.

Materials and Methods

Participants

The randomized controlled trial (RCT) study was conducted at the Kowsar specialized and sub-specialized clinic in Iran for six months, from January to July 2021. All pregnant females who participated in the study provided informed consent. The study was approved by the ethics committee of the University of Social Welfare and Rehabilitation Sciences (USWR), Iran, with reference number IR.USWR.REC.1399.161. Additionally, the study was registered with the Iranian Registry of Clinical Trials (IRRCT) under the code IRCT20200925048833N1.

The sample size for this study consisted of 48 pregnant females experiencing pregnancy-related lumbar pain (LP). Initially, 62 pregnant females with LP were assessed for eligibility, but 14 did not meet the inclusion criteria and were excluded from the study, resulting in a final sample size of 48 participants (as shown in Figure 1).

These 48 participants were then randomly divided into three groups: group 1 (users of the current belt, CB), group 2 (users of the new belt), and group 3 (control group, without any belt). Simple randomization was used to allocate the participants into the intervention and control groups.

The inclusion criteria for this study were as follows:

1. Pregnant females at or beyond the 20th week of pregnancy.

2. Age under 40 years.

3. Pregnant females experiencing mild to extreme pain.

4. Pregnant with a single pregnancy (not twins or multiple pregnancies).

5. Clinical diagnosis of lumbar pain (LP) based on the individual's self-report and the doctor's opinion [14, 25].

The exclusion criteria for this study were as follows:

1. Pregnant females with a history of surgery on the spine.

2. Pregnant females with a history of lumbar pain (LP) before the current pregnancy.

3. Pregnant females with systemic illnesses that could potentially interfere with the study.

4. Any signs of high-risk pregnancy that could pose a risk to the participants' health or affect the study outcomes.

5. Lack of proper patient collaboration, meaning participants who were unable or unwilling to participate in the study actively.

6. Fatigue or any condition that hindered the ability to continue with the required actions [14, 25].

Intervention

This study utilized two types of belts: the current belt (CB) and the new belt. The CB is made of fabrics containing anti-allergy fibers, ensuring it is safe for pregnant females. It is designed to be flexible and soft, providing comfort during wear. The CB is positioned at the level of the anterior iliac spine (ASIS) [24, 25] (as shown in Figure 2).
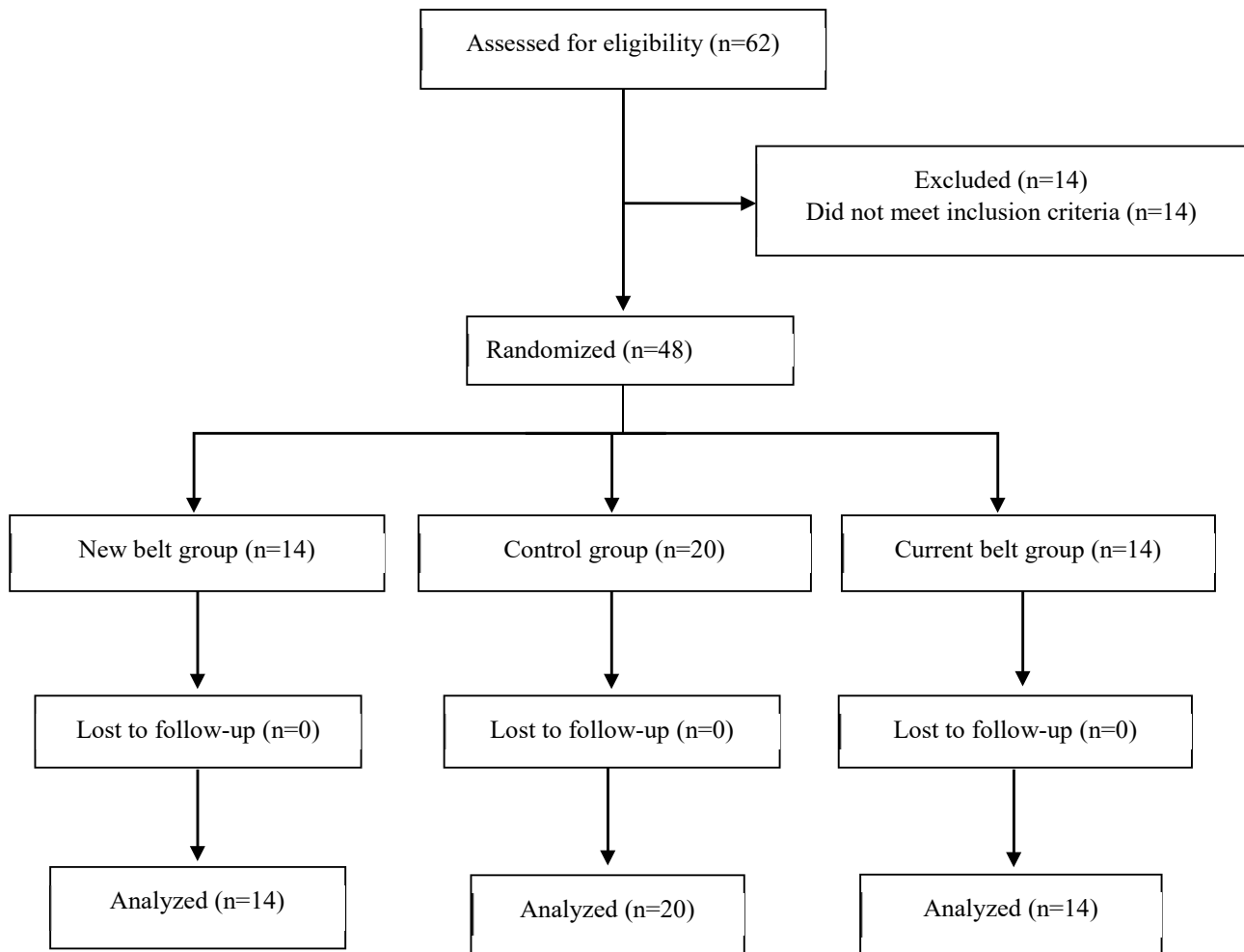
Figure 1: Flow chart diagram of the study

The research team designed the new belt, which includes several components to provide comprehensive support. The new belt consists of an abdominal part, lumbar part, and pelvic part, along with a coccygeal pad and shoulder straps. It is made from anti-allergy fibers that offer strength and elasticity, ensuring a proper and comfortable fit for the users.

The lumbar part of the new belt covers the lumbar region from below the scapula to the gluteal area, providing support along the entire lumbar region. The abdominal component is positioned inside the abdomen to support the weight of the fetus specifically. The pelvic part is placed around the pelvic girdle (PG) and includes a coccygeal pad for additional support and comfort. Shoulder straps

help suspend the belt in place (as shown in Figure 3).

The new belt was designed in three different sizes to cater to the varying needs of pregnant females. The materials used in the belt's construction are elastic, allowing the device to stretch and accommodate the enlargement of the abdomen as the pregnancy progresses. This flexibility ensures that pregnant females can comfortably use the belt throughout their pregnancy without discomfort or issues [27].

Procedure

The researchers used the 36-item Short Form Survey (SF-36) questionnaire to assess the Quality of Life (QOL) of pregnant females in this study [28]. SF-36 is a self-reported health measure widely used to measure various

Figure 2: The current belt(CB)

Figure 3: The new pregnancy belt

QOL aspects. It consists of 36 questions, which cover eight domains related to physical and mental health: Physical functioning, Physical role, Emotional role, Social functioning, Vitality (Energy/fatigue), Mental health, Pain, and General health [29].

These eight domains provide information for two summary scales: physical and mental health. Physical health includes the domains of physical functioning, physical role, pain, and general health. On the other hand, mental health encompasses vitality, social functioning, emotional role, and mental health [29].

All three groups, including the users of the current belt, the new belt, and the control group without any belt, completed demographic and QOL questionnaires at the beginning of the study and then again three weeks after the belts were applied.

Statistical Analyzing

In this study, the normality of the data was checked using the Kolmogorov-Smirnov test. Each group's mean and standard deviation were calculated to describe the data. For comparing the post-test scores within the three groups (test of between-subject effects), analysis of covariance (ANCOVA) was applied.

The statistical analysis was performed using SPSS 26 software (IBM SPSS Statistics 26.0, 2019). A significance level of $P<0.05$ was considered to determine the statistical significance of the study.

Results

The total number of 48 pregnant females with LP was divided into three groups CB (N=14), new belt (N=14), and control (N=20) in the study.

Bases on SF36 results in Cameron's study [24], the estimated parameter was as follows:

$$z_{1-\frac{\alpha}{2}} = 1.96;$$

$$z_{1-\beta} = 0.84;$$

$$s^2 = 55.95;$$

$$\Delta = 6.99$$

$$n_c = \frac{2s^2\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2}{\Delta^2} \cong 20; \quad n_{I1} = n_{I2} = \frac{20}{\sqrt{2}} \cong 14;$$

Table 1 presents the mean±SD (mean plus or minus standard deviation) values for the study samples' age, BMI, and other characteristics.

Table 2 displays the mean and standard deviation of the eight concepts measured by the SF36 questionnaire at the baseline (basic time) and after three weeks for all three groups: CB (current belt group), new belt group, and control group.

According to the results in Table 2, all aspects of Quality of Life (QOL) showed an increase in both the CB and new belt groups after three weeks of using the belts. In contrast, the control group, without any belts, experienced a decrease in these aspects over the same period.

Specifically, the physical and mental health of the participants using the belts improved, while the control group's physical and mental health scores declined.

Table 1: The features of the study samplings

Groups	Number	Age (years)	BMI	Time of start of pain (weeks)	First pregnancy	Second pregnancy
Current belt	14	28.86±2.71	27.07±1.70	21.36±1.15	16.7%	12.5%
New belt	14	29.64±2.56	27.48±1.10	22.14±1.40	22.9%	6.3%
Control	20	29.60±2.41	27.83±1.20	21.95±1.27	27.1%	14.6%

SD: Standard deviation, BMI: Body Mass Index

Table 2: Defining variables of the study samplings

	Current belt	New belt	Control
Physical functioning T1	29.64±8.87	33.57±8.41	41.75±12.16
Physical functioning T2	54.64±13.07	70.35±8.87	15.75±6.74
Physical role T1	23.21±22.92	23.21±15.39	58.75±21.87
Physical role T2	66.07±21.04	89.28±12.83	10.00±14.95
Emotional role T1	35.71±24.33	35.71±20.52	55.00±22.36
Emotional role T2	78.57±24.83	78.57±16.57	26.66±20.51
Vitality T1	44.28±9.57	38.92±10.22	57.50±11.06
Vitality T2	52.50±6.72	69.28±8.05	19.00±6.60
Mental health T1	63.14±7.22	61.14±6.54	74.00±6.80
Mental health T2	73.42±6.39	82.85±4.27	47.40±5.69
Social functioning T1	32.57±12.98	30.57±9.35	49.37±13.73
Social functioning T2	53.57±11.42	67.85±10.64	16.85±8.01
Pain T1	28.78±15.23	21.96±13.27	45.37±14.74
Pain T2	50.17±13.91	60.71±9.92	11.72±10.60
General health T1	39.64±9.70	48.92±7.38	57.25±9.10
General health T2	57.85±8.48	66.07±7.38	37.50±5.00
PCS T1	30.32±12.46	31.92±8.31	50.78±11.59
PCS T1	57.19±10.66	71.61±5.74	18.74±7.22
MCS T1	43.93±7.80	41.59±6.53	58.97±10.40
MCS T1	64.52±8.51	74.64±6.85	27.48±6.28

T1: at the basic time, T2: after three weeks, PCS: Physical component scale, MCS: Mental component scale

Table 3 presents the results of the ANCOVA test for the eight concepts of the SF36 questionnaire, comparing the three groups (CB, new belt, and control) after three weeks of using the belts. According to the outcomes in Table 3, there were significant differences observed in all variables (the eight concepts of QOL) between the three groups after three weeks of the intervention (P<0.001).

The Pairwise test was used to examine the results of the ANOVA further, as shown in Table 4.

According to the Pairwise Comparisons in all health concepts, both belt groups (CB and new belt) were significantly different from the control group (P<0.001). The control group experienced a significant decrease in physical and mental health after three weeks, indicating a decline in their Quality of Life (QOL).

When comparing the two belt groups (CB and new belt), significant differences were observed in several variables after three weeks, including Physical functioning, physical role, Social functioning, Vitality, Mental health, and Pain. However, there were no considerable differences in the variables of the Role of emotional and General health (P=1.00, P=0.15, respectively).

Notably, the new belt group showed significant improvements in items related to the QOL compared to the CB group. This finding suggests that the new belt had a more positive impact on the participants' QOL than the current belt.

Table 3: ANCOVA test results in three groups of the study

Variables		DF	Mean Square	F statistic	P value
Physical functioning T2	PFT1	1	1508.41	25.51	<0.001
	Group	2	13884.60	234.81	<0.001
	Error	44	59.13	-	
Physical role T2	RP T1	1	2677.94	12.43	0.001
	Group	2	23455.13	108.93	<0.001
	Error	44	215.31	-	
Emotional role T2	RE T1	1	6451.92	21.61	<0.001
	Group	2	18938.35	63.43	<0.001
	Error	44	298.53	-	
vitality T2	V T1	1	83.80	1.69	0.200
	Group	2	7515.62	151.93	<0.001
	Error	44	49.46	-	
mental health T2	MH T1	1	0.062	0.002	0.965
	Group	2	3296.94	104.67	<0.001
	Error	44	31.49	-	
Social functioning T2	SF T1	1	1120.27	15.07	<0.001
	Group	2	10495.46	141.24	<0.001
	Error	44	74.30	-	
Pain T2	Pain T1	1	1455.02	14.28	<0.001
	Group	2	10569.16	103.77	<0.001
	Error	44	101.84	-	
General health T2	GH T1	1	372.55	9.38	0.004
	Group	2	3576.45	90.07	<0.001
	Error	44	39.70	-	
PCS T2	PCS T1	1	1480.41	46.06	<0.001
	Group	2	10838.05	337.21	<0.001
	Error	44	32.14	-	
MCS T2	MCS T1	1	815.17	24.151	<0.001
	Group	2	7897.29	233.976	<0.001
	Error	44	33.75	-	

ANCOVA: Analysis of covariance, T1: at the basic time, T2: after three weeks, DF: Degree of freedom, F: F statistics, Statistically Significant (P<0.05), PCS: Physical component scale, MCS: Mental component scale

Table 4: Results of comparisons between three groups of the study

	Current belt VS new belt		Current belt VS control		New belt VS control	
	Mean Difference (95% Confidence)	P value	Mean Difference (95% Confidence)	P value	Mean Difference (95% Confidence)	P value
Physical functioning T2	-13.50±2.93	<0.001	45.71±3.00	<0.001	59.21±2.83	<0.001
Physical role T2	-23.21±5.54	<0.001	69.41±6.36	<0.001	92.62±6.36	<0.001
Emotional role T2	.000	1.00	62.19±6.41	<0.001	62.19±6.41	<0.001
Vitality T2	-17.48±2.71	<0.001	35.23±2.78	<0.001	52.72±3.08	<0.001
Mental health T2	-9.43±2.13	<0.001	26.08±2.36	<0.001	35.52±2.50	<0.001
Social functioning T2	-15.09±3.26	<0.001	43.48±3.47	<0.001	58.57±3.58	<0.001
Pain T2	-13.21±3.88	0.004	44.96±3.91	<0.001	58.18±4.27	<0.001
General health T2	-5.18±2.57	0.151	26.09±2.88	<0.001	31.28±2.36	<0.001
PCS T2	-13.58±2.14	<0.001	49.09±2.52	<0.001	62.67±2.44	<0.001
MCS T2	-11.27±2.20	<0.001	44.40±2.51	<0.001	55.66±2.66	<0.001

T1: at the basic time, T2: after three weeks, VS: Versus, PCS: Physical component scale, MCS: Mental component scale

Discussion

The new belt has shown positive effects on reducing lumbar pain (LP) in pregnant females [27]. Consequently, this study was conducted to evaluate the impact of the new belt on the Quality of Life (QOL) of pregnant females and compare it with the current belt (CB). The study involved 48 pregnant females with LP, and their QOL was assessed after using pregnancy belts for three weeks. Additionally, the QOL of the group that used the new belt was compared with two other groups: those who used the CB and those who did not use any belt. The average onset of LP was approximately 22 weeks in all three groups."

As mentioned earlier, the results of our study revealed a decline in all physical and mental aspects of Quality of Life (QOL) after three weeks in the control group (those who did not use pregnancy belts). These findings are consistent with previous studies examining the QOL of pregnant females with Lumbar Pain (LP), which also indicated a reduction in QOL with increasing gestational age [1, 3, 4, 12, 19].

The prevalence of LP in pregnant females was quite high, significantly impacting their QOL and limiting their daily activities and physical abilities [12]. Ibanez's study also concluded that LP adversely affects pregnant females' physical and mental health, exerting a strong influence on their overall QOL [19].

An analysis of the impact of Lumbar Pain (LP) and physical abilities on Quality of Life (QOL) in late pregnancy revealed that pregnant females generally had a lower QOL than publicly available data on healthy females. The authors noted that females with lumbar disorders experienced QOL issues primarily related to their physical abilities [4]. This finding highlights the significant impact that LP can have on pregnant females' overall well-being and QOL.

Similarly, another study conducted in 2017 also confirmed the adverse effects of LP on the QOL of pregnant females [1]. Additionally, a systematic review study conducted in 2018 found that pregnant females, particularly during the third trimester of pregnancy, experienced lower levels of physical activity and significantly inferior QOL compared to non-pregnant females [3].

The current study's results demonstrated that the use of pregnancy belts positively affected the Quality of Life (QOL) of pregnant females with lumbar pain. Specifically, all aspects of QOL showed improvement in both groups that used the pregnancy belts.

Indeed, it can be concluded that lumbar pain (LP) during pregnancy can give rise to various physical problems among pregnant females, impacting their overall Quality of Life (QOL). However, the use of pregnancy belts has been shown to positively influence the QOL of pregnant females by reducing LP and improving physical activity. Several studies have demonstrated the beneficial effects of pregnancy belts on the QOL of expectant mothers [21, 24-26].

For instance, Hammer's study in 2015 showed that pregnancy pelvic belts positively improved QOL and reduced sacroiliac joint pain [26]. Similarly, the outcomes of the Kordi study indicated that pelvic pain decreased in pregnant females who used pregnancy belts, and these females reported a higher QOL than other groups [25].

The current study revealed that using the new belt significantly improved six aspects of Quality of Life (QOL) in pregnant females with lumbar pain compared to the conventional belt (CB) group. The aspects of QOL that showed significant improvement in the new belt group were Physical functioning, Physical role, Social functioning, Vitality, and Mental health. However, Emotional role and General health aspects did not significantly increase in the new belt group.

The findings suggest that the new belt, which provides simultaneous support to the lumbar and pelvic regions, has a greater impact on improving the QOL of pregnant females with LP than the conventional belt and the group without a belt. Specifically, the new belt group experienced notable enhancements in physical and mental health, indicating a better overall QOL after three weeks of using the new belt.

The data collection for this study took place during the outbreak of the COVID-19 disease, which posed several challenges in obtaining sufficient participant cooperation, especially among pregnant females who may have been concerned about their health and safety during the pandemic. As a suggestion for future research, it would be beneficial to conduct similar studies with larger sample sizes to increase the statistical power and generalizability of the findings.

Conclusion

The study results suggest that the Quality of Life (QOL) of pregnant females with lumbar pain tends to decrease as their gestational age increases. Pregnancy belts, in general, have shown to have a positive effect on the QOL of pregnant females with lumbar pain, and the new pregnancy belt, which covers both the lumbar and pelvic regions simultaneously, appears to have an even greater impact on improving their QOL.

Acknowledgment

Conflict of Interest: None declared.

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