

RESEARCH ARTICLE

Immediate Effect of Smart Paraffin Bath Therapy on Leg Pain among Third-Trimester Pregnant Women: A Quasi-Experimental Study

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ABSTRACT

Introduction: Leg pain is a frequent musculoskeletal complaint among third-trimester pregnant women due to physiological and biomechanical changes during pregnancy. Non-pharmacological pain management approaches are needed during pregnancy because pharmacological options may be limited due to maternal and fetal safety considerations. This study aimed to examine the immediate effect of Smart Paraffin Bath therapy on leg pain intensity among third-trimester pregnant women.

Methods: A quasi-experimental study with a non-equivalent control group design was conducted among 28 third-trimester pregnant women with leg pain. Participants were allocated into an intervention group (n = 14) receiving one supervised session of Smart Paraffin Bath therapy and a control group (n = 14) receiving conventional care. Pain intensity was measured using a 0–10 pain rating scale before and immediately after the intervention. Data collection was conducted between May and November 2025. Data were analyzed using paired and independent t-tests.

Results: In the intervention group, the mean pain score decreased from 5.71 ± 0.96 to 4.02 ± 0.88 . In the control group, the mean score decreased from 5.91 ± 0.86 to 5.64 ± 0.88 , with a mean reduction of 0.27 points ($p < 0.001$). Pain reduction was greater in the intervention group than in the control group ($p < 0.001$).

Conclusion: Smart Paraffin Bath therapy was associated with an immediate reduction in leg pain intensity among third-trimester pregnant women. However, these findings should be interpreted as preliminary evidence due to small sample size, non-random group allocation, and absence of follow-up assessment.

Keywords: Antenatal Care; Leg Pain; Pregnant Women; Smart Paraffin Bath; Third Trimester.

INTRODUCTION

Leg pain is a common musculoskeletal complaint among pregnant women, particularly during the third trimester. This condition arises from physiological and biomechanical adaptations throughout pregnancy, including progressive weight gain, displacement of the center of gravity, fluid retention, and ligament laxity associated with increased relaxin levels, which promote connective tissue softening (1–5). These changes increase mechanical stress on the lower extremities, leading to muscle fatigue, joint discomfort, and pain (3,5,6). If not properly managed, leg pain may adversely affect maternal quality of life, limit daily functional activities, disrupt sleep patterns, and contribute to psychological discomfort.

Pharmacological pain management during pregnancy may be constrained by fetal safety considerations (7). Non-pharmacological strategies, including warm-water immersion and complementary pain-management education, have been explored in pregnancy and maternal care (8–10). Among complementary therapies, warm paraffin therapy has been used to relieve musculoskeletal pain through localized heat transfer. The thermal effect promotes vasodilation, enhances tissue elasticity, reduces muscle stiffness, and induces relaxation, thereby contributing to pain reduction (11). Previous studies have reported beneficial outcomes of paraffin therapy in several musculoskeletal conditions (12,13). However, conventional paraffin therapy devices may have practical limitations, including inconsistent temperature regulation, overheating risks, and limited usability.

Conventional paraffin therapy may present practical limitations, including inconsistent temperature control, potential overheating, and limited usability, which may affect comfort, safety, and consistency during application. Advances in embedded-system technology can support safety-oriented monitoring. Integrating digital temperature sensors such as the DS18B20 with Arduino Uno microcontrollers can support temperature monitoring, automated thermal control, and real-time system feedback (14–16). These technological features may support smart paraffin systems that maintain thermal exposure within a predetermined range while improving operational convenience (17–19). However, the present study did not independently validate temperature accuracy, calibration, or long-term thermal stability; therefore, the technological component is treated as a supportive feature of the intervention rather than as an independently validated device outcome.

Preliminary observations at PMB Ronni Siregar found that a considerable proportion of third-trimester pregnant women reported persistent leg and calf pain, with management primarily limited to warm water immersion. Despite this intervention, symptoms often persisted, indicating the need for a more structured and controlled non-pharmacological approach. Existing studies on paraffin therapy in maternal populations remain limited, and there is still insufficient evidence regarding the immediate effect of a smart temperature-controlled paraffin bath on leg pain among third-trimester pregnant women. This gap is important because the clinical outcome of interest in maternal care is not only the availability of therapeutic device, but also whether its use is associated with measurable short-term pain reduction.

Therefore, this study aimed to examine the immediate effect of one supervised session of Smart Paraffin Bath therapy on leg pain intensity among third-trimester pregnant women within antenatal supportive care. The Arduino Uno and DS18B20 components supported temperature monitoring; device engineering performance was not an independent outcome. No separate health-promotion outcome is reported in the available study materials.

METHODS

Study Design

This study employed an exploratory quasi-experimental design with a non-equivalent control group approach to examine the immediate effect of Smart Paraffin Bath therapy on leg pain intensity among third-trimester pregnant women. Participants were allocated to an intervention group receiving Smart Paraffin Bath therapy and a control group receiving conventional care. Pain intensity was measured before and immediately after the intervention in both groups.

Because the intervention was delivered in a single session and the outcome was assessed immediately after therapy, the findings were interpreted as short-term self-reported pain outcomes rather than sustained clinical effects.

Study Setting and Period

The study was conducted at PMB Ronni Siregar, a maternal health clinic providing complementary midwifery services. Data collection was carried out between May and November 2025.

Participants, Eligibility Criteria, and Sampling

The study population consisted of all third-trimester pregnant women presenting with complaints of leg pain at the study site during the data collection period. A total sampling technique was applied, resulting in 28 eligible participants who met the study criteria. The inclusion criteria were third-trimester pregnant women with leg pain, gestational age between 28 and 36 weeks, willingness to participate, and ability to communicate pain intensity using the study's 0–10 pain rating scale. The exclusion criteria were high-risk pregnancy, skin lesions or infection on the lower extremities, peripheral vascular disorders, severe edema, fever, hypersensitivity to paraffin, current use of analgesic medication, and participation in other pain management interventions during the study period.

Allocation Procedure

Participants were assigned to the intervention and control groups using a non-random allocation procedure based on recruitment order and clinic service scheduling until each group included 14 participants.

Smart Paraffin Bath Device

The Smart Paraffin Bath device used an Arduino Uno microcontroller and a DS18B20 digital temperature sensor to support temperature monitoring and automated thermal control during treatment.

In this study, the technological component was used as a supportive feature of the intervention. Separate laboratory-based validation of device performance, such as long-term temperature stability, calibration accuracy, and sensor precision testing, was not conducted. Therefore, the clinical outcome of this study focused on changes in pain intensity rather than independent validation of device performance.

Intervention Protocol

Participants in the intervention group received one supervised session of Smart Paraffin Bath therapy. Before treatment, the skin of the lower extremities was inspected for wounds, irritation, infection, or contraindications to heat exposure. The affected lower extremity was immersed in warm paraffin for approximately 20 minutes under direct supervision.

The temperature was monitored during the procedure using the Smart Paraffin Bath system. Participants were observed for discomfort, excessive heat sensation, skin redness, dizziness, or other adverse responses. Treatment was to be stopped if a participant reported discomfort or if an abnormal skin response was observed. The same intervention procedure was applied to all participants in the intervention group to maintain protocol consistency.

Comparator Condition

Participants in the control group received conventional supportive care consisting of education on rest, leg positioning, light stretching, and warm-water immersion. They did not receive Smart Paraffin Bath therapy.

Outcome Measures

The main outcome was leg pain intensity, recorded on a 0–10 pain rating scale from 0 (no pain) to 10 (the worst pain imaginable) before and immediately after the intervention.

Safety and Tolerability Monitoring

Safety and tolerability were monitored during the intervention session. Participants were asked to report any discomfort, excessive heat sensation, dizziness, or other complaints during therapy. Skin condition was observed before and after therapy to identify possible irritation, redness, or heat-related adverse reactions. Any adverse event during the intervention was recorded by the research team.

Data Analysis

Data were analyzed using SPSS software. Descriptive statistics were used to summarize participant characteristics and pain scores, including means, standard deviations, frequencies, and percentages. Baseline characteristics between the intervention and control groups were compared to assess group comparability. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate, whereas numerical variables were compared using an independent-samples t-test.

Before conducting parametric tests, the normality of numerical data was assessed using the Shapiro–Wilk test, and homogeneity of variance was assessed using Levene's test. A paired t-test was used to analyze within-group differences in pre-intervention and post-intervention pain scores. Pain reduction was calculated as the difference between pre-intervention and post-intervention scores. An independent-samples t-test was used to compare the mean pain reduction between the intervention and control groups because the groups were independent.

Statistical significance was set at $p < 0.05$. Effect sizes and 95% confidence intervals were reported where appropriate to support interpretation of the magnitude and precision of the findings. The between-group effect size for change scores was expressed as Cohen's d , calculated as the mean difference in change scores divided by the pooled standard deviation of the change scores. Because this study had a small sample size and used a non-randomized quasi-experimental design, adjusted analyses such as ANCOVA or multivariable regression were not used as the primary analytical approach; the findings were therefore interpreted cautiously.

RESULTS

Respondents' characteristics ($n=28$). A total of 28 third-trimester pregnant women with leg pain were included in this study, with 14 in the control group and 14 in the intervention group. Baseline characteristics were compared between groups to assess initial comparability. As shown in Table 1, the distributions of maternal age, gravidity status, and baseline pain intensity were comparable between the control and intervention groups. No participants in either group reported relevant comorbidities.

Table 1. Respondents' characteristics

Characteristics	Control (n=14)		Intervention (n=14)		n	%	p-value
Maternal age (years)							
20-35	11	78.6	8	57.1	19	67.9	0.420
<20	3	21.4	6	42.9	9	32.1	
Gravidity status							0.421
Primigravida	5	35.7	2	14.3	7	25	
Secondgravida	4	28.6	5	35.7	9	32.1	
Multigravida	5	35.7	7	50	12	42.9	
Baseline pain score, mean $\pm$ SD	5.91 $\pm$ 0.86		5.71 $\pm$ 0.96		-		0.567

Note. Values are n (%) unless otherwise stated. Maternal age: Fisher's exact test; gravidity status: Pearson chi-square test; baseline pain score: independent-samples t-test. SD = standard deviation. All displayed values are based on the final analysis dataset (n = 28).

The majority of participants were aged 20–35 years, with 11 participants (78.6%) in the control group and 8 participants (57.1%) in the intervention group. Multigravida status was more common in both groups, particularly in the intervention group. The baseline pain score was 5.91 $\pm$ 0.86 in the control group and 5.71 $\pm$ 0.96 in the intervention group, indicating comparable pain intensity before intervention.

Changes in Pain Intensity Within Groups

Analysis of changes in pain levels before and after intervention in each group is presented in Table 2. These changes were analyzed using a *paired t-test* to assess differences in pre-test and post-test pain scores between the control and intervention groups.

Table 2. Changes in Pain Intensity Before and After Intervention in Each Group

Group	Pre-test (Mean $\pm$ SD)	Post-test (Mean $\pm$ SD)	Mean Reduction	95% CI	p-value
Control (n=14)	5.91 $\pm$ 0.86	5.64 $\pm$ 0.88	0.27 $\pm$ 0.18	0.17-0.37	<0.001
Intervention (n=14)	5.71 $\pm$ 0.96	4.02 $\pm$ 0.88	1.69 $\pm$ 0.60	1.34-2.04	<0.001

Changes in pain intensity before and immediately after the intervention are presented in Table 2. In the control group, the mean pain score decreased from 5.91 $\pm$ 0.86 to 5.64 $\pm$ 0.88, with a mean reduction of 0.27 $\pm$ 0.18 points. Although this reduction was statistically significant, the magnitude of change was small. In the intervention group, the mean pain score decreased from 5.71 $\pm$ 0.96 to 4.02 $\pm$ 0.88, with a mean reduction of 1.69 $\pm$ 0.60 points. The 95% confidence interval indicated a greater and more precise reduction in pain intensity after Smart Paraffin Bath therapy.

Comparison of Pain Reduction Between Intervention and Control Groups

The comparison of the mean reduction in pain scores between the control group and the intervention group was analyzed using an independent t-test. The results of this analysis are presented in Table 3.

Table 3. Comparison of Mean Pain Reduction Between Control and Intervention Groups

Variable	Control (Mean $\pm$ SD)	Intervention (Mean $\pm$ SD)	Mean Difference	95% CI	p-value	Effect size
Pain reduction (Δ score)	0.27 $\pm$ 0.18	1.69 $\pm$ 0.60	1.42	1.06-1.78	<0.001	3.21

Note. Δ score = pre-intervention minus post-intervention pain score; CI = confidence interval; SD = standard deviation. Cohen's d was calculated using the pooled standard deviation of the change scores.

Based on Table 3, the mean reduction in pain intensity was greater in the intervention group than in the control group. The mean difference in pain reduction between groups was 1.42 points, with a 95% confidence interval of 1.06 to 1.78. The between-group effect size was Cohen's d = 3.21, indicating a large standardized difference in immediate pain reduction between groups.

During the intervention session, participants were monitored for discomfort, excessive heat sensation, dizziness, skin redness, irritation, or other adverse responses. No adverse events were reported, and the intervention was well tolerated under direct supervision.

DISCUSSION

Principal Findings

This study found that a single session of Smart Paraffin Bath therapy was associated with a greater immediate reduction in leg pain intensity than conventional supportive care among third-trimester pregnant women. The reduction in pain score was larger in the intervention group than in the control group, suggesting that paraffin-based heat therapy may provide short-term perceptual pain relief for lower extremity discomfort during late pregnancy. However, because pain intensity was measured only immediately after a single intervention session, the findings should be interpreted as immediate post-intervention outcomes rather than evidence of sustained clinical effectiveness.

Leg pain during the third trimester is closely related to physiological and biomechanical changes, including weight gain, changes in the center of gravity, fluid retention, and increased ligament elasticity (1–5). These changes may increase

mechanical loading on the lower extremities. The present finding is therefore clinically relevant because the intervention was applied to a symptom commonly experienced during late pregnancy.

Interpretation in Relation to Previous Evidence

Non-pharmacological approaches are important in pregnancy because the use of analgesic drugs may be limited by fetal safety considerations (7–9). Paraffin therapy has been reported to reduce pain in several musculoskeletal conditions through localized heat transfer, vasodilation, improved local circulation, increased tissue elasticity, and muscle relaxation (11–13,16). These mechanisms may explain the greater immediate reduction in pain intensity observed in the intervention group.

Nevertheless, the available evidence should be interpreted cautiously. Some previous studies on paraffin therapy were conducted in populations or clinical conditions different from third-trimester pregnant women. Therefore, such evidence provides indirect mechanistic and clinical support rather than direct confirmation of sustained benefit in this specific population. In the present study, the observed pain reduction reflects an immediate perceptual response after therapy, not long-term recovery or functional improvement.

The smaller reduction observed in the control group may reflect the limited short-term effect of routine supportive care, such as advice on rest, leg positioning, light stretching, or warm-water immersion. In contrast, Smart Paraffin Bath therapy provided direct localized heat exposure, which may have produced a more immediate analgesic response. Pain perception can also be influenced by central and peripheral modulatory mechanisms (20–22), which were not measured in this study; mechanistic interpretation should therefore remain tentative.

Technological Context and Scope of Contribution

Advances in embedded system technology have enabled the use of sensors and microcontrollers to support temperature monitoring and automated thermal control in health-related devices (14–19). In this study, the Smart Paraffin Bath was developed using an Arduino Uno microcontroller and DS18B20 temperature sensor to support more controlled thermal applications. Paraffin also has heat-storage capacity and phase-change characteristics, making it suitable as a heat-transfer medium in therapeutic applications (23–25).

However, the technological contribution of this study should be interpreted within its methodological scope. This study did not include separate laboratory-based validation of device performance, such as temperature accuracy, calibration precision, safety cut-off testing, or long-term thermal stability. Therefore, the sensor-based temperature control system should be understood as a supportive feature of the intervention, not as an independently validated technological outcome. The main empirical finding of this study remains the immediate change in pain intensity after the intervention.

Respondent Characteristics and Contextual Interpretation

Most participants were aged 20–35 years, and multigravida women formed the largest overall category. These variables are presented descriptively to characterize the study sample rather than to infer a general antenatal-care profile. The baseline characteristics of the control and intervention groups were presented separately to support the interpretation of group comparability in the absence of randomization.

Age-related pregnancy outcomes have been examined in studies of advanced maternal age (26–28), however, this small study was not designed to test age-related differences in treatment response. Plantar-surface pain is described in the broader foot-pain literature (28), but the present study did not collect or report pain-location data. Accordingly, no location-specific interpretation is made.

Implications for Maternal Health Services

The findings suggest that Smart Paraffin Bath therapy may be considered a potential non-pharmacological option for immediate leg-pain relief among third-trimester pregnant women, but they are not sufficient for routine implementation. Its potential health-promotion relevance is as an option discussed within antenatal education about non-pharmacological symptom management. The present study did not evaluate a separate health-promotion program. More broadly, sensor-enabled, microcontroller-based, and biomedical engineering technologies illustrate the use of automated systems in healthcare applications (29–33). Decisions about clinical adoption should remain evidence-based and should be supported by stronger clinical studies and objective device-performance evaluation.

Study Limitations and Future Directions

This study has several limitations. First, the quasi-experimental design without random allocation may introduce selection bias and residual confounding, which limit causal interpretation. Second, the sample size was relatively small, reducing statistical power and limiting the generalizability of the findings. Third, pain intensity was measured using a self-reported 0–10 pain rating scale, which may be influenced by individual perception, expectation, and reporting differences. The exact instrument format should be reported as specified in the Methods.

Fourth, the intervention was delivered in a single session, and the post-test measurement was conducted immediately after therapy. Therefore, the findings reflect short-term perceptual pain reduction and cannot determine whether the analgesic effect is sustained over time. Fifth, the study did not include objective validation of device performance, such as temperature calibration, thermal stability testing, or independent assessment of sensor accuracy. This limits the interpretation of the technological contribution of the Smart Paraffin Bath device.

Further research is recommended using randomized controlled trial designs with larger sample sizes, longer follow-up periods, and adjustment for potential confounding factors. Future studies should also include objective evaluation of device performance, safety parameters, and clinical outcomes such as functional activity, sleep quality, maternal comfort, and quality of life.

CONCLUSION

This exploratory quasi-experimental study showed that one session of Smart Paraffin Bath therapy was associated with an immediate reduction in leg pain intensity among third-trimester pregnant women compared with conventional supportive care. However, these findings should be interpreted cautiously because the study used a small sample, non-random group allocation, subjective pain measurement, and immediate post-intervention assessment without longitudinal follow-up. Therefore, the results should be considered preliminary evidence of short-term pain reduction rather than definitive evidence of sustained clinical effectiveness. Further randomized studies with larger samples, longer follow-up periods, and objective evaluation of device performance are needed before routine clinical implementation can be recommended.

DECLARATIONS

Author contributions: Conceptualization: JA, SA; Data curation: MAP, SH; Formal analysis: JA, SH; Investigation: JA, SA, SH; Methodology: JA, MAP; Project administration: SA; Resources: MAP, ESA; Software: MAP, JA; Supervision: SA, SH; Validation: JA; Visualization: MAP; Writing—original draft: JA, ESA; Writing—review & editing: all authors.

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