

A Randomized Controlled Trial of the Effects of Reducing Cramps in Pregnancy Between the Stretching-Exercise Versus No Stretching-Exercise Groups

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ABSTRACT

This randomized controlled trial assessed the effectiveness of a two-week stretching exercise regimen in reducing leg cramps among pregnant women, compared to a non-exercise group. A total of 86 participants, pregnant women between 24-36 weeks' gestation experiencing leg cramps, were recruited from the HRH Maha Chakri Sirindhorn Medical Center in Thailand and randomly assigned to either the exercise or non-exercise group. The exercise involved performing four specific stretching exercises three times per week over two weeks, aiming to target muscle relaxation and cramp reduction. 81 participants were analyzed based on the intention-to-treat (ITT) approach. The result showed that the median number of leg cramps per week significantly decreased in both groups over two weeks. At week 1, the median cramp frequency was 2 (IQR: 1, 4) in the exercise group and 2 (IQR: 1, 3) in the non-exercise group ($p = 0.43$). At week 2, both groups experienced further reduction, with a median of 1 (IQR: 0, 2) in both groups ($p = 0.75$). Adherence to the prescribed exercise protocol in the intervention group was high. Participants in the exercise group reported a median total exercise duration of 60 minutes during the first week (IQR: 45, 60 minutes) and 47.5 minutes during the second week (IQR: 45, 60 minutes). No adverse events related to the intervention were reported in either group. The stretching exercises is a safe and feasible intervention for pregnant women, remain a recommended practice, as they offer additional benefits for maternal well-being, including improved flexibility and preparation for labor, though it did not significantly reduce leg cramp frequency compared to routine antenatal care. Strategies such as maintaining adequate hydration, consuming a balanced diet rich in essential minerals, and engaging in safe physical activities may be more effective when combined with stretching. Further research is warranted to explore the long-term effects of stretching and multi-modal approaches, ultimately enhancing the quality of antenatal care and maternal health outcomes.

1. Introduction

Pregnancy initiates a wide array of physiological changes across multiple organ systems, including cardiovascular, respiratory, hematologic, renal, and musculoskeletal systems, to support the growing fetus and prepare the maternal body for childbirth. These adaptations are essential but often come with side effects that can affect the quality of life for pregnant individuals. One of the most common discomforts experienced during pregnancy is muscle cramps, particularly in the legs. These cramps are characterized by sudden, involuntary muscle contractions that can cause intense pain and disrupt daily activities. Bordoni et al. (2024) propose that the underlying causes of muscle cramps in pregnancy may include neuromuscular dysfunction, excessive maternal weight gain, peripheral nerve compression, and reduced blood flow to the muscles due to uterine expansion. Additionally, the increased muscular workload during pregnancy and mineral depletion, such as magnesium and calcium, required to meet fetal developmental needs, may exacerbate the risk of cramps. The accumulation of metabolic byproducts, such as lactic and pyruvic acids, has also been implicated (Li X,2022), though no single definitive cause has been established (Zhou K et al. ,2015)

Leg cramps are not only a physical discomfort but can also have cascading effects on a pregnant woman's overall well-being. Studies by Duan et al. (2018) and Valbø and Bøhmer (1999) estimate that 32.9% to 45% of pregnant women experience calf muscle cramps. The prevalence is higher during the third trimester, reaching up to 58% (Abandeh et al., 2024). These cramps frequently occur at night, causing severe pain and disrupting sleep patterns. Mansouri et al. (2019) highlighted the potential consequences of such sleep disturbances, including increased fatigue, mood disturbances, and adverse pregnancy outcomes. Poor sleep quality, exacerbated by cramping, has been associated with fetal growth restriction (FGR), spontaneous preterm labor, and other complications. Additionally, increased snoring and obstructive sleep apnea, can further aggravate maternal and fetal health risks. (Hensley J.G.,2009)

Despite the high prevalence of leg cramps in pregnancy and their impact on quality of life (Allen R.E. et al. 2012), there is a paucity of effective management strategies. According to the "Physical Activity and Exercise During Pregnancy and the Postpartum Period: ACOG Committee Opinion, Number 804" (2020), exercise should be encouraged in women with uncomplicated pregnancies. Regular physical activity is known to reduce the risks of complications such as excessive gestational weight gain, gestational diabetes mellitus (GDM), pregnancy-induced hypertension (PIH), preterm birth (PTB), cesarean delivery (CD), and low birth weight (LBW). However, while the general benefits of exercise in pregnancy are well-documented, its role in alleviating muscle cramps remains underexplored. The effects of stretching exercise through mechanisms related to either increased blood flow, decreased muscular activity (i.e., relaxation), or elevated tissue temperature. It has been hypothesized that increased muscular blood flow in response to heating can lessen muscle spasm by enhancing local circulation and waste product clearance (Jiro et al. ,2012)

Given this gap, the present randomized controlled trial aims to assess the effectiveness of a structured stretching exercise regimen in reducing muscle cramps during pregnancy, with a focus on leg cramps. Stretching exercises, as a low-risk, non-pharmacologic intervention, may offer a viable solution for improving maternal comfort and well-being. By comparing outcomes between women who engage in stretching exercises and those who do not, this study seeks to contribute valuable evidence to inform antenatal care practices.

2. Literature review

Numerous studies have investigated interventions and supplements aimed at reducing skeletal muscle cramps, including electrolyte supplements, vitamins, and physical therapies. These approaches are particularly relevant for pregnant women, who often experience muscle cramps due to physiological and biochemical changes during pregnancy. However, the effectiveness of these interventions remains inconsistent, with varied outcomes reported across different study populations and methodologies.

Electrolyte supplementation, particularly with magnesium, has been one of the most commonly explored strategies for managing leg cramps. Liu et al. (2021) conducted a systematic review and meta-analysis (SRMA) of five studies investigating the effect of magnesium supplementation on leg cramps. The results indicated that magnesium supplements did not significantly reduce the frequency of leg cramps, with a weighted mean difference of -0.47 (95% CI: -1.14 to 0.20). Similarly, magnesium supplementation showed no statistically significant improvement in cramp recovery, as evidenced by an odds ratio (OR) of 0.47 (95% CI: 0.14 to 1.52). These findings suggest that magnesium supplementation may not be effective in addressing leg cramps, aligning with earlier reports by Zhou et al. (2015). Zhou's review highlighted inconsistent outcomes regarding the efficacy of oral magnesium in reducing muscle cramp frequency, while its effect on pain intensity remained inconclusive. These mixed results highlight the need for further investigation into the role of magnesium in managing pregnancy-related cramps, considering variations in dosage, study duration, and baseline magnesium levels among participants.

In addition to magnesium, calcium and vitamin D have been evaluated for their potential to alleviate muscle cramps. A randomized controlled trial (RCT) by Mansouri et al. (2017) assessed the effects of calcium and vitamin D supplementation in 126 pregnant women. The study found no significant improvement in cramp frequency, duration, or intensity among participants. Conversely, Hammar et al. (1981) reported more promising results in a smaller study involving 42 pregnant women. Participants receiving oral calcium experienced a clinically significant reduction in leg cramp frequency. The discrepancy between these studies could stem from differences in study design, sample size, and participant characteristics, suggesting that calcium supplementation may benefit specific subgroups. However, larger and more rigorously designed trials are needed to confirm these findings and establish the role of calcium in cramp management.

Stretching Exercises

Physical therapies, particularly stretching exercises, have gained attention as non-invasive and cost-effective interventions for muscle cramps. (Blyton F. et al, 2012 and Hallegraeff J.M. et al 2012). A SRMA conducted by Hawke et al. (2021) examined the effects of stretching exercises, including calf and hamstring stretches, on reducing leg cramps in 201 participants aged 50 years and older. The findings indicated that daily stretching exercises performed over six weeks significantly reduced nighttime pain intensity compared to a no-intervention group, with a mean difference of -1.3 on the visual analog scale (95% CI: -1.74 to -0.86). However, the frequency of leg cramps did not significantly improve, particularly in studies focusing solely on calf stretches performed over 12 weeks. These findings suggest that while stretching exercises may alleviate cramp-related pain, their

effectiveness in reducing cramp frequency remains inconclusive.

The limited evidence on stretching exercises specifically tailored for pregnant populations highlights an important gap in the literature, presenting an opportunity to explore interventions designed for this unique demographic. Most existing studies have primarily focused on older adults or non-pregnant individuals, whose physiological, hormonal, and neuromuscular conditions differ significantly from those of pregnant women. These studies often investigate the effects of stretching on conditions such as muscle cramps or flexibility, but the results may not be directly transferable to pregnant women due to the profound anatomical and physiological changes that occur during pregnancy. Pregnancy induces changes such as increased weight, altered posture, and shifts in the center of gravity, all of which contribute to a higher risk of discomforts like leg cramps. These cramps, typically caused by neuromuscular strain, vascular changes, and mineral imbalances, warrant specific interventions that account for the unique demands of pregnancy.

To address this gap, the present study focuses on a specific stretching regimen for uncomplicated pregnant women. This regimen includes four equipment-free postures recommended by the Faculty of Physical Therapy, Mahidol University (Theptong, 2017). These postures were carefully chosen to be safe, feasible, and effective for pregnant women, with the goal of reducing the frequency and severity of leg cramps over a two-week period. The exercises are simple enough to be performed at home without the need for specialized equipment or professional supervision, making them highly accessible for a broad range of pregnant individuals. Additionally, the regimen aligns with recommendations from antenatal care guidelines that encourage regular physical activity during pregnancy to enhance maternal health and well-being.

This study's focus on uncomplicated pregnancies is intentional, as it seeks to establish the foundational efficacy and feasibility of the intervention without the confounding effects of pregnancy complications. By targeting a low-risk population, the study can provide clear insights into the benefits of the stretching regimen under controlled conditions. By tailoring the stretching exercises to the unique needs of pregnant women, this study aims to provide more targeted evidence for managing pregnancy-related muscle cramps.

3. Material and methods

Study design and participants

This study was conducted as a single-center, randomized, parallel, superiority clinical trial. The trial aimed to assess the effectiveness of a structured stretching exercise program in reducing pregnancy-related leg cramps. This design allowed for a direct comparison between the exercise and non-exercise groups, highlighting potential benefits attributable to the intervention.

The study recruited pregnant women attending the antenatal outpatient clinic of the Obstetrics Department at HRH Maha Chakri Sirindhorn Medical Center (MSMC), Nakorn Nayok, Thailand. Recruitment occurred between May 2024 and September 2024. Eligible participants were required to meet the following inclusion criteria: (1) singleton pregnant women with a gestational age (GA) of 24 to 36 weeks; (2) the ability to communicate in Thai; and (3) regular availability for follow-up and communication. Exclusion criteria encompassed participants with contraindications to exercise, including a history of pregnancy complications such as spontaneous abortion, preterm labor, PIH, FGR, premature rupture of membranes (PROM), cervical incompetence, or vaginal bleeding in the second or third trimester. Additional exclusions applied to individuals unable to perform the four prescribed stretching exercises consistently once before bed or morning, at least three times per week for two weeks, or those developing complications during the study period, such as PIH or preterm labor.

Participants were informed about the study's purpose, procedures, and potential risks before enrollment. Written informed consent was obtained from all participants, ensuring ethical compliance. Women were advised to refrain from engaging in other forms of physical activity, such as swimming, running, or yoga, for the duration of the study to isolate the effects of the prescribed stretching regimen.

Block randomization was employed with varying block sizes of four and an allocation ratio of 1:1. This method ensured balanced group assignments while minimizing selection bias. An independent statistician generated the randomization sequence, consisting of six possible patterns: EENN, ENEN, ENNE, NNEE, NEEN, and NENE (E = exercise group; N = non-exercise group). The randomized assignments were concealed in sequentially numbered, sealed, opaque envelopes, which were opened by a research nurse immediately before the intervention. Both participants and research team members remained blinded to the randomization sequence.

throughout the study. Eligible participants were systematically enrolled based on their compliance with the inclusion criteria.

Procedures

The study protocol divided data collection into three distinct parts to minimize bias. Each part was managed by a separate researcher.

Baseline Data Collection: At the initial visit, demographic information (e.g., age, weight, height, BMI, and contact details), medical history (e.g., underlying conditions, surgical history), and pregnancy-related data (e.g., parity, GA, history of abortion, last menstrual period [LMP], estimated date of confinement [EDC]) were recorded. Participants were also assessed for leg cramp frequency per week at baseline.

Exercise Monitoring: After randomization, participants in the exercise group were provided with detailed instructions on performing four specific stretching exercises. Participants were instructed to perform these exercises three times per week for two weeks. Exercise data, including the date, duration, and specific postures completed, were recorded weekly. Non-exercise participants continued their routine antenatal care.

Follow-Up Assessments: Follow-up visits were scheduled at 1- and 2-weeks post-enrollment to evaluate the frequency of leg cramps, adherence to the prescribed exercises, and duration of each exercise session. All collected data were anonymized using unique code numbers to protect participant confidentiality.

Participants were advised to warm up by walking for 5–10 minutes before initiating the stretching exercises to reduce the risk of muscle injury. Detailed guidance was provided on identifying adverse symptoms, such as vaginal bleeding, abdominal or chest pain, dizziness, or amniotic fluid leakage, that would necessitate discontinuation of the exercises. Research assistants were available to assist participants and ensure the proper execution of exercises. Adherence was monitored by self-reported exercise logs, and participants completing at least 70% of the exercises were considered compliant. Non-compliance was defined as missing more than one session per week. Any adverse events were documented and addressed during follow-up visits.

Participants in the exercise group were assigned a structured stretching protocol designed to relax muscles and alleviate cramp frequency. The protocol, adapted from the Faculty of Physical Therapy at Mahidol University, included four equipment-free postures:

1. **Side Bend Stretch:** Participants stood with their feet shoulder-width apart, placed one hand on their hip, extended the opposite arm overhead, and leaned toward the side with the hand on the hip. The position was held for 10 seconds before switching sides, with 10 repetitions performed per side.
2. **Seated Forward Stretch:** In a seated position, participants extended one leg forward and bent the other outward at the knee. They leaned forward, reaching for the toes of the extended leg, holding for 10 seconds before switching legs. Each side was stretched 10 times.
3. **Bridge Exercise:** Participants lay on their backs with knees bent, raised their hips, and held the position for 5 seconds. This exercise was performed in 15 repetitions per set, with two sets completed per session.
4. **Side-Lying Leg Lift:** Participants lay on one side, bending the lower leg and extending the upper leg slightly backward before lifting it and holding for 5 seconds. Ten repetitions were performed per side for two sets.

These exercises were performed three times per week over a two-week intervention period, preferably before bedtime. Adherence was monitored, and deviations were documented to ensure protocol compliance.

The primary outcome of the study was the number of leg cramps experienced per week, measured at baseline, 1 week, and 2 weeks after the intervention. Secondary outcomes included adherence to the prescribed exercises and the occurrence of adverse events.

Sample size and statistical analysis

Sample size calculations were performed using hypothesis testing for the difference between two independent means. Based on variables from Joannes et al. (2012), the study aimed to detect a mean difference (\pm SD) in the change in cramp frequency between the exercise group (1.4 ± 1.4) and the non-exercise group (2.4 ± 1.7). With a two-sided alpha error of 0.05 and a power of 80%, the required sample size was calculated as 79 participants. To account for potential dropouts, 10% was added, resulting in a final target sample size of 86 singleton pregnant

women, equally divided into the exercise and non-exercise groups (43 participants per group).

Baseline characteristics of participants were summarized separately for the exercise and non-exercise groups. Continuous variables, such as age, GA, and BMI were presented as means with standard deviations (SD) when they followed a normal distribution. For variables that did not meet the assumption of normality, medians and IQR were used instead. This approach ensured an accurate and comprehensive description of the data, taking into account its underlying distribution. Categorical and ordinal variables, such as parity, history of abortion, and adherence rates, were described as frequencies and percentages. To compare baseline characteristics between the exercise and non-exercise groups, appropriate statistical tests were selected based on the type of data. For continuous variables, independent t-tests were employed to determine whether there were statistically significant differences between group means. If the data were not normally distributed, non-parametric alternatives, such as the Mann-Whitney U test, were considered to compare medians. For categorical and ordinal variables, χ^2 tests were used to evaluate differences in frequencies between groups. In cases where the expected cell counts were too small, Fisher's exact test provided a reliable alternative to the χ^2 test.

The primary analysis of the study was conducted based on the intention-to-treat (ITT) principle. This approach ensures that all randomized participants are analyzed within the groups to which they were originally assigned, regardless of adherence to the intervention or any deviations from the protocol. By preserving the integrity of the randomization process, the ITT analysis minimizes the risk of bias and provides a more realistic assessment of the intervention's effectiveness under typical clinical conditions.

Statistical significance was defined as a p-value of less than 0.05 for all comparisons, reflecting the threshold for rejecting the null hypothesis in favor of a significant difference between groups. All data analyses were performed using STATA version 18.0 (StataCorp, College Station, Texas, USA).

Ethical consideration

The study received approval from the institute's ethics committee under the reference number SWUEC-671002, ensuring that all research activities complied with ethical standards for human subject research. To uphold transparency and adherence to recognized ethical guidelines, the trial protocol was registered with the Thai Clinical Trials Registry (identifier: TCTR20240529003). This registration ensures public accessibility to the study's objectives, methodology, and planned analyses, aligning with international standards for clinical research transparency.

4. Results

Participant Enrollment and Follow-Up

A total of 89 participants visited the outpatient antenatal clinic and were screened for eligibility. Of these, three participants declined to participate due to personal reasons, leaving 86 eligible participants who met the inclusion criteria. These participants were subsequently randomized into the exercise group ($n = 43$) or the non-exercise group ($n = 43$), achieving equal allocation.

In the exercise group, 40 participants completed the two-week study protocol, with three participants lost to follow-up. Similarly, in the non-exercise group, 41 participants completed the protocol, with two participants lost to follow-up. The reason for loss F/U in both groups due to unable to contact. All 81 participants were analyzed based on the ITT approach, maintaining the integrity of the study's randomization process. The flow of participants through each stage of the trial is detailed in Figure 1.

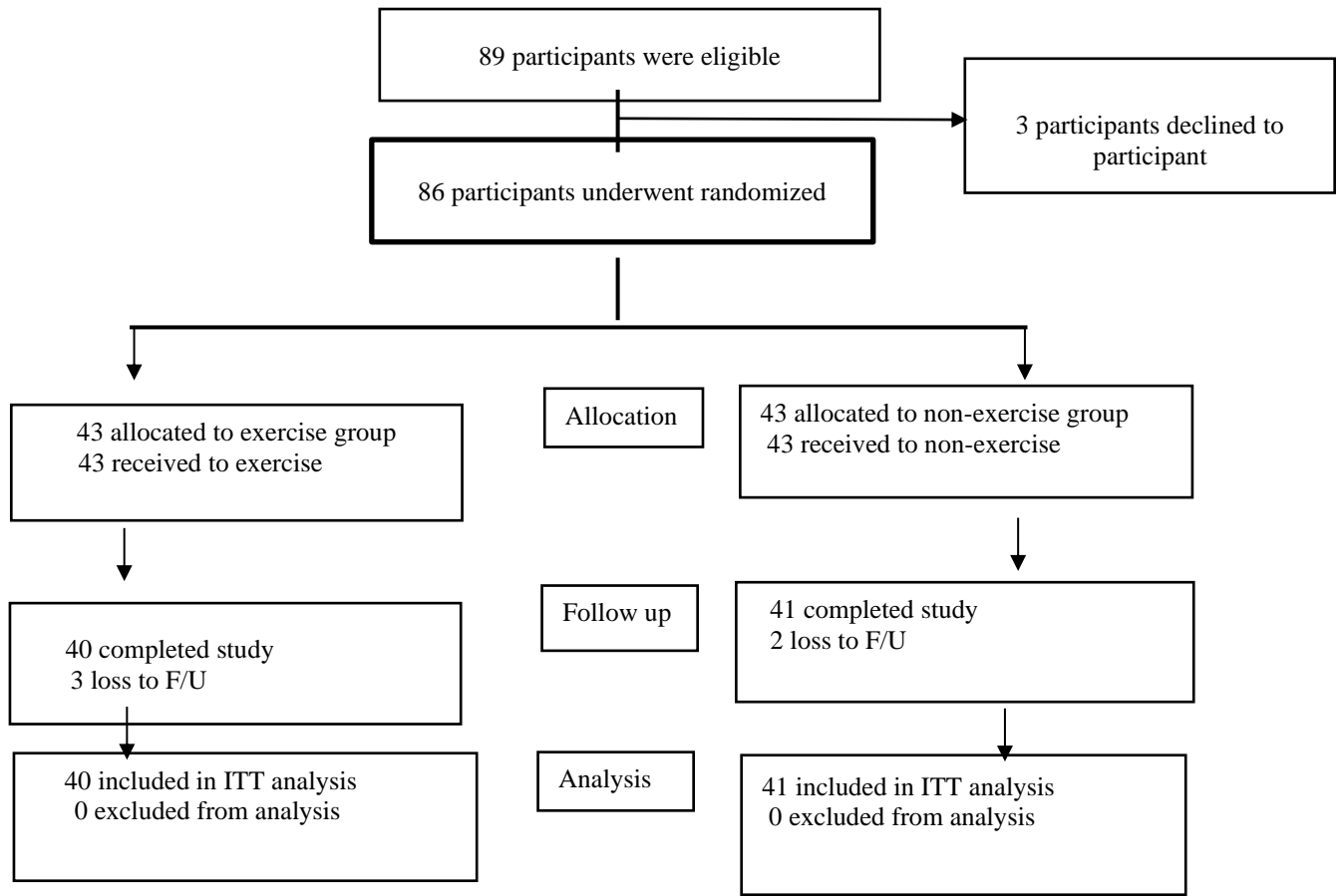


Figure 1 Flowchart showing trial profile; ITT

Baseline Characteristics

Baseline characteristics of all participants, including demographic and clinical variables, are summarized in Table 1. Key variables such as age, gestational age (GA), parity, history of abortion, body weight, height, and body mass index (BMI) were comparable between the two groups. The mean age of participants was 30.6 ± 4.1 years, and the median GA at enrollment was 28 weeks (IQR: 26, 32 weeks). Approximately 62% of participants were multiparous, and the median BMI was 26.4 kg/m^2 (IQR: 24.5, 28.9). No statistically significant differences were observed between the exercise and non-exercise groups for any baseline variables ($p > 0.05$).

Table 1 Clinical characteristics of patients

Characteristics	Exercise group (N=40)		Non-exercise group (N=41)		p-value
	mean	±SD	mean	±SD	
Age (year)	28.52	4.04	28.95	5.29	0.69
GA (weeks and days)	29.71	3.63	30.47	4.65	0.43
Parity (no, %)					0.50
0	25	62.50	22	53.66	
1	11	27.50	13	31.71	
2	4	10.00	4	9.76	
3	0	0	2	4.88	
History of abortion (no, %)					0.54
0	35	87.5	37	90.24	
1	3	7.50	4	9.76	
2	1	2.50	0	0	
3	1	2.50	0	0	
Weight (kg)	59.4	9.70	62.93	11.95	0.15
Height (cm)	159.25	3.71	159.02	6.21	0.84
Body mass index (kg/m ²)	23.40	3.69	24.85	4.35	0.11
Duration of exercise per weeks in week1 (minutes); (Median, IQR)	60	(45,60)	NA	NA	
Duration of exercise per weeks in week 2 (minutes); (Median, IQR)	47.5	(45,60)	NA	NA	

Not applicable (NA), interquartile range (IQR), evidence of difference (p-value)

Primary Outcome: Leg Cramp Frequency

The primary outcome, the median number of leg cramps per week, showed a significant reduction in both groups over the two-week intervention period (Table 2). At week 1, the median cramp frequency in the exercise group was 2 (IQR: 1, 4), while the non-exercise group also reported a median of 2 (IQR: 1, 3). The between-group comparison at week 1 revealed no statistically significant difference ($p = 0.43$). By week 2, both groups experienced further reductions in cramp frequency, with a median of 1 (IQR: 0, 2) in both groups. Again, no statistically significant difference was observed between the exercise and non-exercise groups at week 2 ($p = 0.75$). These findings suggest that while the stretching exercise was associated

Table 2: Details of outcome according to exercise and non-exercise after randomization

Time and intervention	No of cramp /week		Difference between exercise and non-exercise (p-value)
	Median	IQR	
Week 1:			0.43
Exercise (n =40)	2	(1,4)	
Non-exercise (n =41)	2	(1,3)	
Week 2			0.75
Exercise (n =40)	1	(0,2)	
Non- exercise (n =41)	1	(0,2)	

Interquartile range (IQR), Evidence of difference (p-value)

Adherence and Compliance

Adherence to the prescribed exercise protocol in the intervention group was high. Participants in the exercise group reported a median total exercise duration of 60 minutes during the first week (IQR: 45, 60 minutes) and 47.5 minutes during the second week (IQR: 45, 60 minutes). Adherence was defined as completing over 70% of the prescribed exercises. Notably, all participants in the exercise group met this adherence criterion, demonstrating excellent compliance with the intervention. Non-compliance, defined as missing more than one session per week, was not observed among participants in the exercise group.

No adverse events related to the stretching exercise were reported in either group, further supporting the safety and feasibility of the prescribed stretching regimen. Follow-up assessments were completed successfully, with participants providing accurate self-reports on exercise frequency and duration.

5. Discussion

This study evaluated the effectiveness of a structured stretching regimen in reducing leg cramps during pregnancy. Both the exercise and non-exercise groups experienced a reduction in the frequency of leg cramps over the two-week intervention period, with no statistically significant differences between the groups. While these findings indicate that stretching exercises may not be more effective than routine antenatal care in reducing cramp frequency, the reductions observed in both groups may reflect the natural variability in symptomatology related to increased awareness and self-monitoring. Notably, adherence to the prescribed stretching protocol was high among participants in the exercise group, with all completing over 70% of the sessions. Additionally, no adverse events were reported, suggesting that the regimen is safe and feasible for pregnant women. These findings underscore the potential role of stretching exercises as a supportive, low-risk intervention in antenatal care.

Our results are consistent with previous research reporting mixed findings on the effectiveness of non-pharmacologic interventions for managing muscle cramps during pregnancy. For instance, Hawke et al. (2021) demonstrated that calf and hamstring stretches could reduce the intensity of cramps in older adults, but the frequency of cramps remained largely unaffected. Similarly, while our study did not measure cramp intensity, we found no significant improvement in cramp frequency with stretching exercises. These parallels highlight the potential limitations of stretching exercises as a standalone intervention for reducing cramp frequency, although they may still provide benefits in alleviating cramp-related discomfort. For comparing with the previous study (Peter B. Melad et al, 2018), investigated the effect of continuous ultrasound and stretching exercise on calf muscle cramp during pregnancy, there was significant difference between study group and control group in frequency, time of having cramp and quality of life deterioration. However, this study concluded the different result from this study.

Conversely, the study contrasts with research on other interventions, such as magnesium and calcium supplementation. Systematic reviews (e.g., Liu et al., 2021) have consistently demonstrated minimal or no

impact of magnesium on cramp frequency, while calcium supplementation has shown variable efficacy depending on study design and participant characteristics. The disparity in outcomes across studies highlights the need for further investigation into the physiological and biochemical contributors to pregnancy-related cramps.

The lack of significant differences between the exercise and non-exercise groups in our study may be attributed to several factors. First, the relatively short duration of the intervention, limited to just two weeks, may not have been sufficient to produce measurable differences in cramp frequency (Hala M. Hanafy et al,2018). Previous studies suggest that prolonged and consistent exercise programs may be necessary to achieve clinically meaningful reductions in cramp frequency. Additionally, variability in participants' adherence to the exercise routine, as well as differences in individual physiological responses, could have influenced the outcomes. Factors such as baseline physical activity levels, muscle conditioning, and individual variations in neuromuscular function may have impacted the effectiveness of the intervention.

Strengths

This study had several notable strengths. The study design was a randomized controlled with minimized selection bias, ensuring that participants were evenly distributed between the intervention and control groups. The use of block randomization ensured balanced allocation, while adherence to ethical guidelines and blinding of the randomization sequence minimized bias. The use of the intention-to-treat (ITT) approach further enhanced the robustness of the analysis by including all randomized participants, regardless of protocol adherence or dropout. This methodological rigor strengthens the validity of our findings and their applicability to real-world settings. Additionally, the exercise protocol was simple, equipment-free, and tailored to pregnant women, making it practical and accessible for implementation that could be performed at home with minimal guidance. Another strength is the high adherence rate, achieved through detailed instructions, regular follow-up, and user-friendly exercise logs. The lack of adverse events further reinforces the regimen's safety, making it a viable option for incorporation into routine antenatal care.

Limitations

Despite its strengths, the study has several limitations. First, the study evaluated only short-term outcomes over a two-week period. While this time frame was sufficient to assess initial trends, it may have been insufficient to detect significant changes in cramp frequency, particularly given the variability in symptom onset and progression during pregnancy. Long-term studies are needed to determine whether sustained stretching exercises can lead to more substantial reductions in cramp frequency or intensity. Second, the relatively small sample size, while adequate for detecting moderate effects, may have limited the study's power to identify smaller differences between the groups. A larger sample size could provide more precise estimates of the intervention's effectiveness. Additionally, although adherence to the exercise regimen was reported as high, the absence of a detailed assessment of participant experiences (e.g., perceived benefits or barriers to exercise) limits the understanding of the regimen's acceptability and feasibility across diverse populations. Then, self-reported adherence data may also be subject to recall bias, as participants may have under- or overestimated cramp frequency, potentially affecting the accuracy of the findings. Lastly, the study excluded women with pregnancy complications, limiting the generalizability of findings to low-risk populations.

Implications and future research

The findings have several implications for clinical practice and future research. The study contributes to the limited evidence base on non-pharmacologic interventions for pregnancy-related cramps. While the results do not support a direct effect of stretching on cramp prevention, the high adherence and safety profile indicate its potential as a supportive measure for improving maternal comfort and well-being, particularly for improving maternal comfort. The findings from existing studies underscore the need for more comprehensive research to evaluate the effectiveness of interventions for leg cramps during pregnancy. (Luo L, 2020) While electrolyte and vitamin supplementation have yielded mixed results, physical therapies like stretching exercises show promise as safe, non-pharmacologic options. However, future research should explore the effects of longer exercise periods and the incorporation of additional non-pharmacologic interventions. For example, yoga and aquatic exercises, which combine physical activity with relaxation techniques, may provide synergistic benefits for reducing muscle cramps. Investigating the role of dietary modifications, including magnesium and calcium supplementation, in combination with exercise could further enhance our understanding of effective management strategies. Additionally, studies with larger sample sizes and diverse populations are needed to

provide more definitive evidence on the effectiveness of stretching exercises and other interventions. Exploring the impact of these interventions on cramp intensity and associated sleep disturbances could also yield valuable insights. However, the lack of a major cause of cramps means that in the future, it is still necessary to find the cause by examining the underlying biochemical changes to understand the mechanisms that drive pregnancy-related cramps, so that better treatments can be developed.

6. Conclusion

In summary, this randomized controlled trial demonstrated that both the exercise and non-exercise groups experienced reductions in leg cramp frequency over a two-week period, with no statistically significant differences between them. These findings suggest that natural improvements in cramp frequency may occur in uncomplicated pregnancies, regardless of targeted interventions. However, stretching exercises remain a recommended practice for pregnant women, as they offer additional benefits for maternal well-being, including improved flexibility and preparation for labor. Our findings underscore the importance of integrating stretching exercises with other evidence-based lifestyle interventions for optimal management of pregnancy-related discomforts. Strategies such as maintaining adequate hydration, consuming a balanced diet rich in essential minerals, and engaging in safe physical activities may be more effective when combined with stretching. Further research is warranted to explore the long-term effects of stretching and multi-modal approaches, ultimately enhancing the quality of antenatal care and maternal health outcomes.

References

- [1] Abandeh, A., Sindiani, A., Nazzal, M. S., Almasri, N. A., Megdadi, A., Morris, L., Alshdaifat, E., & Kanaan, S. F. (2024). Prevalence and Predictors of Leg Cramps in the Third Trimester of Pregnancy: A Cross-Sectional Study. *Int J Womens Health*, 16, 1377-1387. <https://doi.org/10.2147/ijwh.S465872>
- [2] Allen R.E. and Kirby K.A.: Nocturnal leg cramps. *American Family Physician*; 86 (4): 350-5, 2012.
- [3] Bordoni, B., Sugumar, K., & Varacallo, M. (2024). Muscle Cramps. In StatPearls. StatPearls Publishing Copyright © 2024, StatPearls Publishing LLC.
- [4] Blyton F., Chuter V., Walter K.E.L., and Burns J.: Non-drug therapies for lower limb muscle cramps. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No CD008496, 2012.
- [5] Duan, Y. F., Wang, J., Jiang, S., Bi, Y., Pang, X. H., Yin, S. A., & Yang, Z. Y. (2018). [Prevalence of calf muscle cramps and influencing factors for pregnant women in China during 2010-2012]. *Zhonghua Yu Fang Yi Xue Za Zhi*, 52(1), 14-20. <https://doi.org/10.3760/cma.j.issn.0253-9624.2018.01.004>
- [6] Hala M. Hanafy, Peter B Melad, & Amir A. GBR, Marwa A.E. Mohamed. (2018). Effect of Continuous Therapeutic Ultrasound and Stretching Exercise on Calf Muscle Cramp during Pregnancy. *The Medical Journal of Cairo University*, 86(March), 791-797. doi:10.21608/mjcu.2018.55563
- [7] Hallegraeff J.M., Vander Schans C.P., De Rulter R. and De Greef M.H.G.: Stretching before sleep reduces the frequency and severity of nocturnal leg cramps in older adults: A randomized trials. *Journal of Physiotherapy*, 58: 17-22, 2012.
- [8] Hammar, M., Larsson, L., & Tegler, L. (1981). Calcium treatment of leg cramps in pregnancy. Effect on clinical symptoms and total serum and ionized serum calcium concentrations. *Acta Obstet Gynecol Scand*, 60(4), 345-347. <https://doi.org/10.3109/00016348109154121>
- [9] Hawke, F., Sadler, S. G., Katzberg, H. D., Pourkazemi, F., Chuter, V., & Burns, J. (2021). Non-drug therapies for the secondary prevention of lower limb muscle cramps. *Cochrane Database Syst Rev*, 5(5), Cd008496. <https://doi.org/10.1002/14651858.CD008496.pub3>
- [10] Hensley J.G.: Leg cramps and restless legs syndrome during pregnancy. *Journal of Midwifery and Women's Health*; 54 (3): 211-8, 2009.
- [11] Jiro Nakano, Cristiane Y, Alex S. and Darlene R.: The effect of heat applied with stretch to increase range of motion. *Journal of Physical Therapy in Sport*; 13 (1) pp. 180-8, 2012.
- [12] Li X, Yang Y, Zhang B, Lin X, Fu X, An Y, Zou Y, Wang JX, Wang Z, Yu T. Lactate metabolism in human health and disease. *Signal Transduct Target Ther*. 2022 Sep 1;7(1):305. doi: 10.1038/s41392-022-01151-3. Erratum in: *Signal Transduct Target Ther*. 2022 Oct 31;7(1):372. doi: 10.1038/s41392-022-01206-5. PMID: 36050306; PMCID: PMC9434547.
- [13] Liu, J., Song, G., Zhao, G., & Meng, T. (2021). Effect of oral magnesium supplementation for relieving leg cramps during pregnancy: A meta-analysis of randomized controlled trials. *Taiwan J Obstet Gynecol*, 60(4), 609-614. <https://doi.org/10.1016/j.tjog.2021.05.006>
- [14] Luo L, Zhou K, Zhang J, Xu L, Yin W. Interventions for leg cramps in pregnancy. *Cochrane Database of Systematic Reviews* 2020, Issue 12. Art. No.: CD010655. DOI: 10.1002/14651858.CD010655.pub3.
- [15] Mansouri, A., Bahrami-Vazir, E., Mohammad-Alizadeh-Charandabi, S., Ghelichkhani, F., & Mirghafourvand, M. (2019). The Relationship Between Leg Muscle Cramps and Sleep Quality in Pregnant Women Visited the Health Centers

in Tabriz [Research Article]. Shiraz E-Med J, 20(7), e84279. <https://doi.org/10.5812/semj.84279>

- [16] Mansouri, A., Mirghafourvand, M., Charandabi, S. M. A., & Najafi, M. (2017). The effect of Vitamin D and calcium plus Vitamin D on leg cramps in pregnant women: A randomized controlled trial. J Res Med Sci, 22, 24. <https://doi.org/10.4103/1735-1995.200271>
- [17] Physical Activity and Exercise During Pregnancy and the Postpartum Period: ACOG Committee Opinion, Number 804. (2020). Obstet Gynecol, 135(4), e178-e188. <https://doi.org/10.1097/aog.0000000000003772>
- [18] Theptong, M. (2017). Exercise guidelines for expecting mothers. <https://pt.mahidol.ac.th/ptcenter/knowledge-article/แนวทางการออกกำลังกายสำหรับว่าที่คุณแม่/>
- [19] Valbø, A., & Bøhmer, T. (1999). [Leg cramps in pregnancy--how common are they?]. Tidsskr Nor Laegeforen, 119(11), 1589-1590. (Leggkramper i svangerskapet--hvor hyppig forekommer det?)
- [20] Zhou, K., West, H. M., Zhang, J., Xu, L., & Li, W. (2015). Interventions for leg cramps in pregnancy. Cochrane Database Syst Rev(8), Cd010655. <https://doi.org/10.1002/14651858.CD010655.pub2>