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Effectiveness of a 4% Emprit Ginger Gel in Reducing Pain Intensity and Salivary Cortisol Levels Among Adolescents with Primary Dysmenorrhea

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ABSTRACT

Dysmenorrhea is highly prevalent among Indonesian adolescents in Indonesia and adversely affects pain perception, concentration, daily functioning, and quality of life. This study aimed to develop a stable and standardized 4% emprit ginger gel, a topical formulation designed to enhance penetration and ease of use, and to evaluate its effectiveness in reducing pain intensity and modifying salivary cortisol levels in adolescents with primary dysmenorrhea. This study employed a randomized controlled true experimental design was conducted at a senior high school in Surakarta, Indonesia, between June and July 2025. Inclusion criteria included female students experiencing primary dysmenorrhea for the previous three menstrual cycles, who had never married or given birth, not using other complementary therapies, and willing to participate. Thirty-six eligible adolescents were randomly assigned to the intervention group (4% ginger gel, 2 grams) or the control group (cajeput oil, 2 ml) using a lottery system. Both interventions were applied twice daily for three consecutive days during menstruation. Pain intensity was measured using Numeric Rating Scale (NRS), and salivary cortisol levels was measured using enzyme-linked immunosorbent assay (ELISA) on the first and third days. Compared with cajeput oil, the 4% emprit ginger gel produced significantly greater reduction in pain intensity. Meanpain reduction was greater in the intervention group (3.67±0.97, p=0.017). Mean cortisol reduction also was greater in the intervention group 4.972±6.65, p=0.043). The findings support the use of 4% emprit ginger gel safe and effective complementary therapy adolescents with primary dysmenorrhea.

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INTRODUCTION

Adolescence is the transitional phase between childhood and adulthood, occurring between ages 10 and 19.(1) During this period, adolescent girls experience menstruation as part of their physical development.(2) One of the most common gynecological conditions during adolescence is primary dysmenorrhea, which results from increased prostaglandin production that induces strong uterine contractions and may trigger a physiological stress response via activation of the hypothalamic pituitary adrenal (HPA) axis.(3) Activation of the HPA axis increases cortisol secretion, potentially affecting sleep, immunity immune fuction, and mood, thereby contributing to the broader impact of primary dysmenorrhea on adolescents' daily functioning.(4)

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Dysmenorrhea interferes with concentration, academic performance, and quality of life, making it an important public health concern.(5) The global prevalence of primary dysmenorrhea ranges from 16%–81%, with higher rates reported in Europe and Africa.(6) In Indonesia, the prevalence exceeds 64.25%(7), underscoring the significant burden of this condition both internationally and locally.

Various approaches have been explored to alleviate primary dysmenorrhea, including pharmacological interventions such as nonsteroidal anti-inflammatory drugs (NSAIDs) and non-pharmacological methods like heat therapy, aromatherapy, and herbal applications. While NSAIDs are effective, concerns regarding side effects, such as gastrointestinal irritation and potential renal complications, limit their long-term use in adolescents.(8) However, few standardized tropical formulations with demonstrated clinical efficacy are currently available, resulting in inconsistent therapeutic outcomes across individuals. Among topical complementary therapies, essential oils have attracted increasing attention. Essential oils, including cajeput oil, have been reported to enhance blood circulation and provide relaxation effects.(9) In this study, cajeput oil was used as an active comparator because it produces mild warming and relaxing sensations that are commonly utilized in non-pharmacological pain therapies.(10) Therefore, cajeput oil functions as an active control rather than a pure placebo, allowing for a more relevant comparison between the effectiveness of cajeput oil and emprit ginger gel.

Ginger (*Zingiber officinale*) has garnered increasing attention due to its bioactive compounds, such as gingerol and shogaol, which exhibit anti-inflammatory and analgesic properties.(11) Previous studies have demonstrated the efficacy of ginger extracts in reducing inflammation.(12) However, most research has focused on oral formulations or general topical applications, with limited exploration of the specific emprit ginger variety (*Zingiber officinale var. amarum*). Emprit ginger is known to contain higher concentrations of essential oils than common ginger, giving it potentially greater therapeutic value. Despite this, evidence regarding its effectiveness when formulated into a standardized topical preparation remains scarce.

Compared with common ginger, emprit ginger is widely available cost-effective, and richer in essential oil components including zingiberene, zingiberol, and gingerol which may further enhance its therapeutic benefits.(13) Formulating emprit ginger as an emulgel offers additional advantages, such as improved skin penetration, stability, and ease of use(14). Despite the growing interest in ginger-based interventions for primary dysmenorrhea, existing studies have predominantly focused on oral ginger preparations and subjective pain outcomes. To date, no previous study has simultaneously evaluated the clinical effectiveness of an emprit ginger (*Zingiber officinale var. amarum*) emulgel as a topical formulation, assessed salivary cortisol levels as an objective biomarker of stress response, and applied a randomized controlled trial design in women with primary dysmenorrhea. Consequently, evidence remains insufficient regarding the combined analgesic and stress-modulating effects of topical emprit ginger formulations for the management of primary dysmenorrhea.(15)

The novelty of the present study lies in the integration of four components that have not previously been investigated together, the use of emprit ginger as the active herbal ingredient, the development of an emulgel as a topical drug delivery system, the measurement of salivary cortisol as an objective stress-related biomarker, and the implementation of a randomized controlled trial to evaluate clinical effectiveness. This integrated approach is expected to provide new evidence regarding the potential role of emprit ginger emulgel as a non-pharmacological therapy for primary dysmenorrhea that addresses both pain symptoms and physiological stress responses.

This gap underscores the need to develop a safe and stable emprit ginger gel capable of delivering therapeutic effects through transdermal absorption. Evaluating this formulation

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against an active comparator is necessary to establish its relative clinical effectiveness, such as cajeput oil, is essential to establish a clear benchmark for its effectiveness. Accordingly, this study aims to develop a standardized 4% emprit ginger (*Zingiber officinale var. amarum*) gel and evaluate its effectiveness, compared with cajeput oil, in reducing pain intensity and salivary cortisol levels among adolescents with primary dysmenorrhea.

METHOD

This study employed a true experimental randomized pretest–posttest control group design. The required sample size was determined a priori power analysis (α = 0.05, power = 0.80, and a medium effect size of Cohen's d = 0.50, yielding a minimum required sample of 36 participants.

Eligible participants were female adolescents aged 14–17 years with regular menstrual cycle (28 ± 7 days) during the previous six months and a history of primary dysmenorrhea during the preceding three menstrual cycles. Participants had never married or having given birth, were not using hormonal contraception or analgesics, had no known allergy to ginger or cajuput oil, and agreed to participate. Exclusion criteria included acute illness, irregular menstrual bleeding, use of pharmacological pain treatment during the study, or failure to complete the intervention protocol.

Randomization was performed using a lottery-based allocation system in which participants selected opaque sealed envelopes containing pre-generated allocation codes: Code A (Group 1 = Intervention) and Code B (Group 2 = Control). The random allocation sequence was generated using the Random Allocation Software (version 2.0) with a 1:1 allocation ratio. The codes were then placed in identical opaque sealed envelopes to ensure allocation concealment. Participants were single blinded to treatment allocation, while outcome assessors and laboratory personnel were blinded to group assignment throughout the study period.

The intervention group received 2 grams of 4% emprit ginger gel applied to the lower abdomen twice daily (morning and evening) for three consecutive days during menstruation. The control group received 2 mL of cajeput oil applied to the same region with identical frequency. Dosages were standardized to ensure comparable application volumes across both groups. The emprit ginger emulgel and cajeput oil were applied directly by the participants themselves following standardized instructions provided by the research staff, who also supervised the first application session to ensure consistency in the amount, location, and method of application. Cajeput oil was selected as an active comparator because of its mild warming sensation, which provided sensory similarity to the intervention without containing the anti-inflammatory constituents present in ginger.

Pain intensity was assessed using a self-reported Numerical Rating Scale (NRS), in which participants independently rated their pain severity on a scale ranging from 0 (no pain) to 10 (worst imaginable pain) at baseline (the first day of menstruation, before treatment) and three days after the intervention. Baseline assessments were performed immediately before the first intervention. The Numerical Rating Scale (NRS) was used because it has demonstrated good psychometric properties for assessing pain intensity in clinical and research settings. A recent systematic review reported that the NRS possesses strong validity, responsiveness, and reliability across musculoskeletal pain populations, supporting its widespread use as a standardized pain assessment instrument.(16) This study was not prospectively registered in a clinical trial registry because registration was not required by the institutional ethics committee at the time the study was initiated. However, ethical approval was obtained prior to participant recruitment, and all study procedures were conducted in accordance with established ethical principles for human subject research.

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Saliva samples for cortisol analysis were collected between 07:00 and 10:00 local time to control for circadian variations in cortisol secretion. Participants were instructed to fast for at least 30 minutes and to refrain from brushing teeth, drinking, or chewing gum before sample collection to prevent contamination and avoid blood microleakage that might influence cortisol levels. Samples were collected via passive drool. Salivary cortisol concentrations were measured using a commercially available ELISA kit (Diagnostics Biochem Canada Inc., Canada; Cortisol Saliva ELISA, Catalog No. CAN-C-240) and expressed in ng/mL. Each sample was analysed in duplicate to ensure analytical reliability. All assays were conducted according to the manufacturer's validated instructions with internal quality control procedures controls.

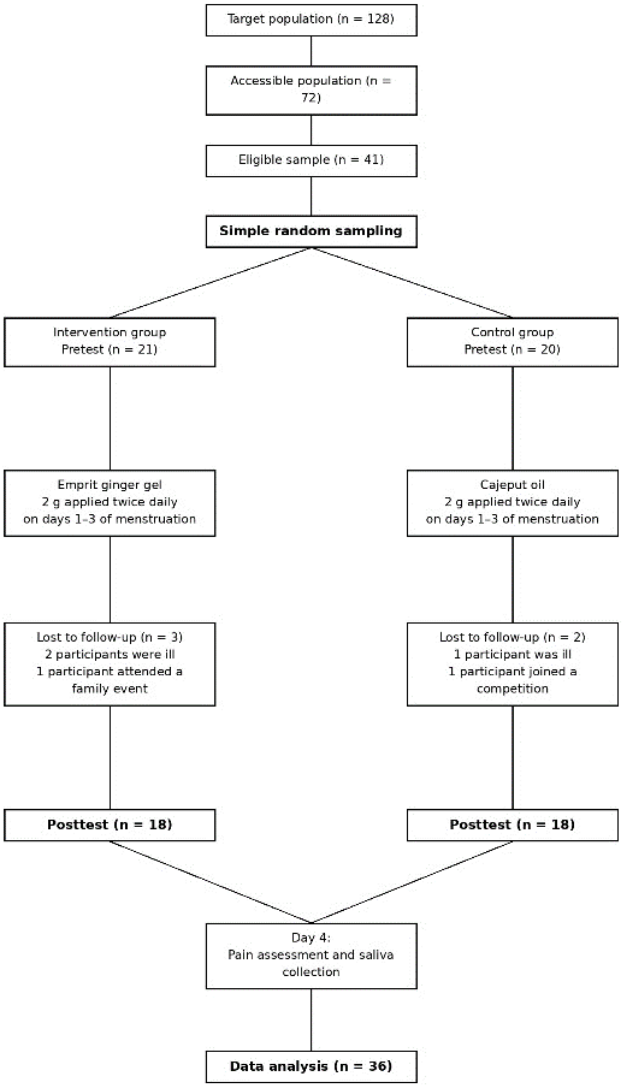

Figure 1. CONSORT Flow Diagram of Participant Recruitment, Randomization, Follow-up, and Analysis

Data analysis was performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Homogeneity testing of respondent characteristics was conducted prior to analysis. Data normality was assessed using the Shapiro–Wilk test. Numerical data were presented not normally distributed, within-group comparisons were performed using the Wilcoxon signed-rank test, and between-group effectiveness was analysed using the Mann–Whitney

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U test. The significance level was set at α = 0.05. Numerical data are presented as median and interquartile range (IQR) unless otherwise specified.

This research received ethical approval from the Research Ethics Committee of Poltekkes Kemenkes Semarang (No. 811/EA/F.XXIII.38/2025). All participants provided consent after receiving explanations (informed consent), and all research procedures were conducted in accordance with ethical principles, including maintaining data confidentiality and ensuring no risks that could harm the participants. Written informed consent was obtained from all participants and from parents or legal guardians because participants were minors.

RESULTS

Baseline demographics characteristics indicated that participants were middle adolescents aged 14–17 years, with most having normal menstrual duration (3–7 days), normal body mass index (BMI), and moderate physical activity levels. Baseline characteristics, including age, BMI, menstrual duration, history of dysmenorrhea, physical activity, and sleep quality, were comparable between groups. These findings indicated adequate baseline homogeneity.

Univariate analysis

In this study, confounding variables included respondent characteristics such as age, BMI (body mass index), menstrual duration, history of dysmenorrhea, physical activity, and sleep quality. A descriptive analysis of these characteristics was conducted, and the results are presented in the following table:

Table. Baseline Characteristics of Participants

Characteristics	**Group**				***p-value***
	Intervention		**Control**		
	n	**%**	**n**	**%**	
BMI					0.372*
Severely underweight: ≤17 kg/m^2	0	0	0	0	
Underweight: 17 – <18.5 kg/m^2	1	5.5	3	16.7	
Normal: 18.5 – 25 kg/m^2	16	89	14	77.8	
Overweight: >25 – 27 kg/m^2	0	0	1	5.5	
Obesity: > 27 kg/m^2	1	5.5	0	0	
Menstrual duration					0.189*
Normal 3-7 days	15	83.3	16	88.9	
Abnormal: <3 days or > 7 days	3	16.7	2	11.1	
Menstrual cycle					0.597*
Normal: 21-35 days	3	16.7	8	44.4	
Short: <21 days	13	72.2	9	50	
Long: >35 days	2	11.1	1	5.6	
History of dysmenorrhea					0.735*
Yes	11	61.1	10	55.6	
No	7	38.9	8	44.4	
Physical activity					0.674*
Light: < 600 METs-min/week	0	0	0	0	
Moderate: 600 – 3000 METs-min/week	15	83.3	14	77.8	
Vigorous: > 3000 METs –min/week	3	16.7	4	22.2	
Sleep quality					0.054*
Good: ≤5	2	11.1	8	44.4	
Poor: > 5	16	88.9	10	56.6	

Table 1 presents the characteristics of respondents, where all participants were in the age range of 14–17 years (100%), indicating homogeneity of age. Most respondents had a

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normal BMI (83.3%), normal menstrual duration of 3–7 days (86.1%), and moderate physical activity (80.6%). However, a majority reported short menstrual cycles (<21 days, 61.1%) and more than half had a history of dysmenorrhea (58.3%). In addition, most respondents experienced poor sleep quality (72.2%), particularly in the intervention group (88.9%). Homogeneity testing using Levene's test confirmed that all characteristics were comparable between groups ($p > 0.05$), indicating that these potential confounding variables did not influence the study outcomes. After confirming baseline comparability between groups, intervention outcomes were analyzed. Pain intensity was evaluated first, followed by salivary cortisol levels.

Bivariate Analysis

To determine the effectiveness of the 4% emprit ginger gel, bivariate statistical tests were performed to compare pain intensity and salivary cortisol levels between the intervention and control groups. Since the data were not normally distributed ($p < 0.05$), nonparametric tests were used, specifically the Wilcoxon signed-rank test for within-group comparisons and the Mann–Whitney U test for between-group comparisons, with a 5% significance level or a 95% confidence interval:

Table 2. Comparison of Pain Intensity Before and After Intervention

Variable	Data	Group				*p-value*
		Intervention (n: 18)		Control (n: 18)		
		Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	
Pain intensity	Pretest	4.17 ± 0.98	4.00 (3.25–5.00)	4.05 ±1.211	4.00 (3.25-5.00)	0.705**
	Posttest	0.50 ± 0.51	0.50 (0.00–1.00)	0.61 ± 0.516	1.00 (0.00–1.00)	0.508**
p-value		< 0.001*		< 0.001*		
	Δ	3.67 ± 0.97	3.00 (3.00–4.75)	3.44 ± 1.04	3.00 (3.00–4.00)	0.017**

* *Wilcoxon Signed-Rank Test* ***Mann-Whitney U Test*

Table 2 shows that pain intensity decreased significantly in both groups following the intervention. However, participants receiving 4% emprit ginger gel experienced a greater reduction in pain intensity than those receiving cajeput oil (mean change 3.67 ± 0.97 ± 3.00 vs. 3.44 ± 1.04 ± 3.00; $p = 0.017$). The between-groups effect size was moderate to large (Cohen's $d = 0.72$) indicating superior analgesic efficacy of the emprit ginger gel.

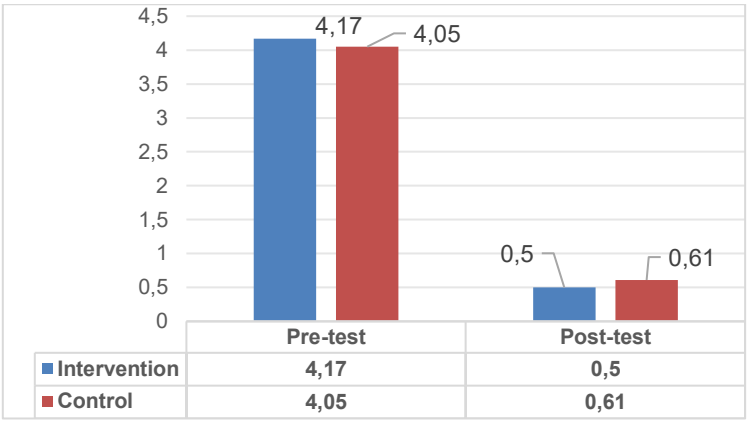

Figure 2. Mean Reduction in Dysmenorrhea Pain Intensity

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Figure 2 illustrates a reduction in pain intensity in both the intervention and control groups. In the intervention group, the mean pain intensity decreased from 4.17 at pretest to 0.50 at post-test. Meanwhile, in the control group, the mean pain intensity also decreased from 4.06 at pretest to 0.61 at post-test.

Table 3. Comparison of Salivary cortisol levels between Intervention and Control

Variable	Data	Group				*p-value*
		Intervention (n: 18)		Control (n: 18)		
		Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	
Salivary Cortisol Levels	Pretest	16.68 ± 6.04	15.7 (14.5–16.85)	15.31 ± 4.49	14.95 (11.25–17.55)	0.646**
	Posttest	11.65 ± 2.97	11.3 (9.1–12.8)	13.74 ± 3.84	11.90 (9.60–14.05)	0.069**
p-value		0.001*		0.043*		
	Δ	4.97 ± 6.65	3.8 (0.85–6.15)	0.567 ± 4.97	3.85 (–1.1–5.75)	0.043**

* *Wilcoxon Signed-Rank Test* **Mann-Whitney U Test*

Table 3 shows that salivary cortisol levels significantly decreased in both groups, with a greater reduction in the emprit ginger gel intervention group. Cortisol levels in this group decreased from 16.68 ± 6.04 ± 15.70 ng/dL to 11.65 ± 2.97 ± 11.3 ng/dL (p = 0.001), whereas in the control group receiving cajeput oil, levels decreased from 15.31 ± 4.49 ± 14.95 ng/dL to 13.74 ± 3.84 ± 11.90 ng/dL (p = 0.043). The mean change score (Δ) was higher in the intervention group (4.97 ± 6.65 ± 3.55 ng/dL) compared to the control group (0.567 ± 4.97 ± 3.85 ng/dL), with a significant difference (p = 0.043). Effect size analysis showed Cohen's d = 0.72, indicating a medium-to-large effect, suggesting that emprit ginger gel more effectively reduces salivary cortisol, a biomarker of physiological stress.

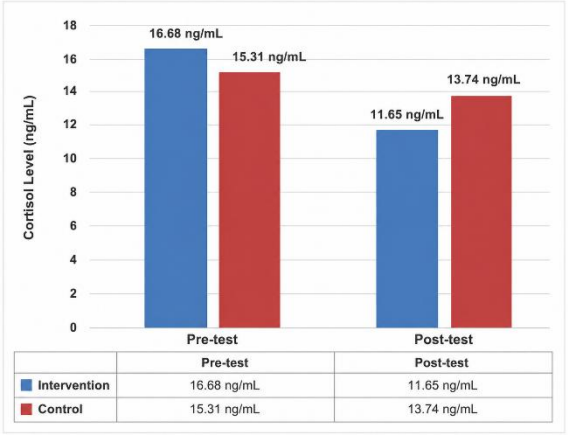

Figure 3. Mean Reduction in Salivary Cortisol Levels

The result of Figure 3 showed a difference in the reduction of salivary cortisol levels between the intervention and control groups. In the intervention group, cortisol levels decreased significantly from a mean of 16.689 at pretest to 11.65 at posttest. Meanwhile, the control group also experienced a decrease in cortisol levels, but to a lesser extent, from a mean of 15.31 at pretest to 13.74 at posttest.

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Multivariate Analysis

Multivariate analysis was not performed to adjust for potential confounding variables such as history of dysmenorrhea, sleep quality, and BMI; however, all baseline characteristics were statistically homogeneous between groups, reducing the likelihood that these factors influenced the outcomes

DISCUSSION

Consistent with the study hypothesis, the 4% emprit ginger gel significantly reduced menstrual pain intensity and salivary cortisol concentrations in adolescent with primary dysmenorrhea, indicating clinically relevant reductions based on the observed magnitude of change analgesic effects accompanied by reductions in physiological stress. Beyond statistical significance, the observed reduction in pain intensity of approximately 3.67 points on the Numerical Rating Scale (NRS) represents a clinically meaningful improvement, as reductions of at least two points on the NRS are generally considered clinically important in pain management studies. These findings suggest that topical emprit ginger gel provides benefits that are not only statistically detectable but also relevant to daily functioning and quality of life among adolescents with primary dysmenorrhea The gel demonstrated satisfactory physicochemical characteristics, including an appropriate viscosity, a characteristic ginger aroma, a cream-white appearance, and a pH range of 6.89–7.50. Skin irritation testing on four panellists revealed no adverse reactions, confirming its safety for topical application. The emulgel formulation ensured uniform distribution of active constituents, minimized excessive warming sensations, and improved transdermal absorption, supporting its suitability for topical application in adolescents.

This study extends the current evidence by demonstrating that a standardized 4% topical emprit ginger gel provides measurable reductions in both pain intensity and salivary cortisol concentrations, particularly because previous research on ginger has largely relied on oral preparations such as capsules, extracts, or decoctions.(15,16) The development of a 4% emprit ginger topical emulgel introduces a novel, non-invasive, adolescent-friendly therapeutic option that avoids gastrointestinal metabolism and reduces the risk of systemic side effects. This innovation has clinically relevant implication for midwifery practice, especially in adolescent reproductive health services where safe, accessible, and culturally satisfactory non-pharmacological interventions are increasingly needed. By demonstrating reductions in both pain intensity and cortisol levels, this formulation expands the complementary therapies that midwives can integrate into school-based and community settings.

The analgesic effects of emprit ginger gel are largely attributed to its bioactive essential oils, such as zingiberene, bisabolene, farnesene, and cineole, which possess anti-inflammatory, analgesic, and antispasmodic properties.(17) phytochemicals inhibit cyclooxygenase (COX) and lipoxygenase (LOX) pathways, thereby reducing prostaglandin synthesis.(18) The gel's mild warming sensation also promotes endorphin release and counter-irritation, further relieving neuromuscular tension and primary dysmenorrhea.(19)

Comparison with earlier studies shows both similarities and differences that can be explained by variations in dosage form, pharmacokinetics, and ginger species. Previous studies using oral preparations required higher doses (750–2000 mg/day) because gastrointestinal absorption and first-pass metabolism reduce bioavailability.(15) In contrast, the transdermal route used in this study provides localized, stable release of active compounds directly at the pain site, enhancing penetration of lipophilic constituents such as zingiberol and camphene.(10) This pharmacokinetic advantage likely contributes to the faster and pronounced analgesic response observed.

Variation in ginger species also plays a contribution. *Zingiber officinale var. amarum* (emprit ginger) contains higher concentrations of pungent and aromatic phytochemicals,

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including zingiberol, citral, camphene, and farnesene, compared with common ginger varieties.(20) These compounds exhibit potent anti-inflammatory, antispasmodic, and vasodilatory effects, contributing to reduced prostaglandin activity, relaxation of uterine smooth muscles, and improved local blood flow. Previous experimental studies suggest that emprit ginger may modulate HPA-axis activity by reducing excessive CRH and ACTH activation, although these mediators were not directly measured in the precent study.(21) Stable transdermal absorption and the gel's warming effect further enhance parasympathetic activity, producing simultaneous reductions in pain perception and physiological stress.(22)

Cajeput oil was selected as the active control because it provides a mild warming sensation and sensory characteristics comparable to ginger gel while lacking the anti-inflammatory constituents, such as gingerols and shogaols, that are believed to mediate ginger's analgesic effects. The use of cajeput oil therefore allowed partial control for placebo and sensory effects associated with topical application while enabling clearer assessment of the pharmacological contribution of emprit ginger constituents

Variability in cortisol responses was observed, with some participants showing slight increases.(23) This may reflect differences in HPA-axis reactivity, sleep quality, psychological stress, physical activity, dietary habits, or natural circadian fluctuations in cortisol. Technical aspects of saliva collection may also have contributed.(24) These factors were not measured in the present study and therefore remain speculative.

Although multivariate analysis was not performed to control for covariates such as history of dysmenorrhea, sleep quality, or body mass index (BMI), all baseline characteristics were statistically homogeneous between groups. This reduces the likelihood of confounding, although the absence of multivariate modelling remains a methodological limitation

Study limitations include the relatively small sample size, short intervention duration (three days), reliance on single-point salivary cortisol levels measurements at each time point, and potential variability in adherence to gel application. The study involved a relatively small sample size and was conducted in a single senior high school, which may limit the external validity and generalizability of the findings to adolescents from different demographic, socioeconomic, and cultural background. Consequently, future multicenter randomized controlled trials involving larger and more diverse populations, longer intervention periods, and repeated biomarker measurements are necessary to confirm the clinical effectiveness and broader applicability of topical emprit ginger gel for primary dysmenorrhea management. These factors may limit the generalizability of the findings. Therefore, future research with larger sample sizes, longer intervention periods, and multiple biomarker assessments is recommended to strengthen evidence for the clinical effectiveness of emprit ginger gel in managing primary dysmenorrhea.

Emprit ginger 4% gel is a safe and effective non-pharmacological therapy for adolescents and may be incorporated into school-based reproductive health programs as an alternative or complementary option to conventional treatments. Healthcare professionals, including midwives, school nurses, and adolescent health workers, can consider using this topical intervention to support adolescent menstrual health.

The study provides further evidence of the bio psychophysiological mechanisms of dysmenorrhea, linking primary dysmenorrhea and cortisol-mediated stress, and highlighting the contribution of transdermal herbal therapy in managing both peripheral inflammatory pathways and central stress responses. These findings support a holistic approach to adolescent reproductive health and dysmenorrhea management. These findings contribute to evidence-based complementary midwifery care for adolescents experiencing primary dysmenorrhea.

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CONCLUSION

The 4% emprit ginger gel formulation demonstrated satisfactory performance stability, safety, and effectiveness as a complementary therapy for primary dysmenorrhea in adolescents. These findings demonstrate that the gel alleviates both subjective pain and physiological stress, indicating improvements in both subjective pain perception and physiological stress responses.

Clinically, the 4% emprit ginger gel may represents a safe, practical, and non-pharmacological alternative for managing primary dysmenorrhea in adolescents. It can be incorporated into school-based reproductive health programs or community health initiatives, providing low-cost alternative management of menstrual pain, particularly for adolescents who prefer herbal therapies or wish to avoid oral NSAIDs.

For future research, studies with larger sample sizes, longer intervention periods, and direct comparisons with NSAIDs are recommended to confirm and extend these findings through multicentre randomize controlled trials. Further investigations into long-term safety, optimal dosing, and stability of the gel formulation will facilitate future development as a standardized, evidence-based complementary therapy for primary dysmenorrhea management.

AUTHOR CREDIT STATEMENT

WMS contributed to conceptualization, methodology, formal analysis, investigation, data curation, writing original draft preparation, and visualization. **SH** and **SS** contributed to validation, supervision, and writing review and editing. All authors have read and approved the final version of the manuscript.

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DECLARATION OF COMPETING INTEREST

There is no conflict of interest.

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