

Effectiveness of Red Ginger (*Zingiber officinale* var. *rubrum*) Consumption on Low Back Pain, Stress Levels, and Sleep Quality among Third-Trimester Pregnant Women

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ARTICLE INFO	ABSTRACT
Keywords: Low Back Pain; Pregnancy; Red Ginger; Sleep Disturbance; Stress Article History: Received: 5/3/2026 Revised: 5/26/2026 Accepted: 6/20/2026	Background: Discomfort in the lower back is commonly experienced during the final stage of pregnancy and may affect emotional condition, daily activities, and sleeping patterns. Although ginger has long been used in traditional care, evidence regarding oral red ginger intake for maternal comfort during late pregnancy is still insufficient. Method: This community-based pre-experimental study applied a single-group before-and-after approach. The study was conducted in the Sukadamai Public Health Center area, South Lampung, during March 2026. Twenty-one pregnant women in the third trimester who reported low back pain participated in the study. Participants consumed a drink prepared from fresh red ginger mixed with warm water twice daily for seven days. Pain intensity, stress condition, and sleep disturbance were evaluated before and after the intervention period. Result: Significant improvements were identified following the intervention. Mean pain scores declined from 4.10 to 2.10. Stress scores also decreased from 5.90 to 2.33. In addition, sleep disturbance scores showed substantial improvement, decreasing from 8.14 to 2.81. Statistical testing demonstrated significant differences between pre-intervention and post-intervention measurements ($p < 0.001$). Conclusion: Seven-day consumption of red ginger was associated with reduced discomfort and better maternal well-being among third-trimester pregnant women. Improvements were observed in low back pain, stress condition, and sleep quality. Nevertheless, further studies using controlled research designs are required to strengthen the evidence.

How to cite this article:

Maternity, D., Herlina, N., Hatta, M. (2026). Effectiveness of Red Ginger (*Zingiber officinale* var. *rubrum*) Consumption on Low Back Pain, Stress Levels, and Sleep Quality among Third-Trimester Pregnant Women, 11(1). 441-452. <https://doi.org/10.51851/jmis.v11i1.1009>

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INTRODUCTION

Low back pain is a common musculoskeletal complaint among pregnant women, particularly during the third trimester. In late pregnancy, fetal growth and uterine enlargement lead to a shift in the body's center of gravity, increased lumbar lordosis, stretching of the pelvic ligaments, and greater mechanical load on the lower spine. These physiological adaptations may contribute to discomfort, restricted mobility, and limitations in daily activities among pregnant women (Çoban et al., 2011; Sabino & Grauer, 2008; Wulandari et al., 2023). Beyond physical discomfort, persistent low back pain during pregnancy may also affect psychological well-being and maternal rest. Pregnant women in the third trimester frequently experience fatigue, difficulty resting, anxiety related to childbirth, hormonal fluctuations, and bodily discomfort, all of which may aggravate stress and impair sleep quality. Therefore, low back pain, stress levels, and sleep quality represent interrelated maternal health problems that should be considered comprehensively within midwifery care for third-trimester pregnant women (Çoban et al., 2011; Wulandari et al., 2023).

Various non-pharmacological interventions have been introduced to reduce low back pain and improve maternal comfort during pregnancy, including pregnancy exercise, prenatal yoga, prenatal massage, back rub, warm compresses, acupressure, and body mechanics education (Amperaningsih et al., 2022; Astuti et al., 2022; Handayani, 2023; Saptyani et al., 2020). Although these approaches may provide benefits, several interventions require trained personnel, specific facilities, additional costs, or longer implementation time, which may limit their feasibility for independent application in community settings. Consequently, there is a need for simple, affordable, and home-based complementary interventions that can be more easily implemented by pregnant women.

Red ginger (*Zingiber officinale* var. *rubrum*) has attracted attention as a potential non-pharmacological intervention for pregnancy-related discomforts. The herb contains several active phytochemicals, including gingerol, shogaol, oleoresin, and essential oils, which are known for their anti-inflammatory, antioxidant, and pain-relieving effects (Baihaqi et al., 2022; Grzanna et al., 2005). Although ginger has been extensively utilized and studied for reducing nausea and vomiting during pregnancy, its application for managing low back pain has received comparatively less attention. Available studies have primarily focused on topical methods, such as warm ginger compresses, rather than oral supplementation (Abidah & Anggraini, 2022; Khairiah & Herawati, 2022; Lukmana et al., 2024; Purba et al., 2025; Tiani et al., 2024; Viljoen et al., 2014). Consequently, evidence supporting the effectiveness of oral red ginger intake for relieving low back pain in third-trimester pregnant women remains scarce. Moreover, few studies have simultaneously assessed low back pain, maternal stress, and sleep quality, even though these factors frequently interact and influence maternal well-being during late pregnancy.

This research was undertaken to explore the possibility that consuming red ginger orally may offer comprehensive benefits for pregnant women, not only by alleviating pain but also by improving overall physical and psychological comfort. Emerging evidence suggests that red ginger contains active compounds capable of influencing inflammatory mechanisms and stress-related pathways that may contribute to low back pain during pregnancy (Maternity et al., 2026). These findings support the perspective that red ginger represents more than a conventional herbal remedy and may function as a biologically plausible complementary therapy targeting multiple aspects of maternal health, including pain, inflammation, emotional stress, and comfort. Consequently, this study investigated changes in low back pain severity, perceived stress, and sleep quality following a seven-day period of oral red ginger consumption among women in the third trimester of pregnancy residing within the Sukadamai Public Health Center catchment area, South Lampung. It is anticipated that the study findings will provide initial evidence for the potential integration of red ginger into community-level complementary midwifery care programs.

METHOD

Research Design

A quantitative pre-experimental design employing a single-group pretest–posttest approach was applied in this study. It was designed to examine changes in low back pain, psychological stress, and sleep quality following oral consumption of red ginger among third-trimester pregnant women. Because the study did not incorporate a comparison group or randomization process, the outcomes are regarded as initial evidence only, and their interpretation may be limited by the presence of uncontrolled confounding factors and external influences.

Participants

This research was conducted within the service coverage area of Sukadama Public Health Center, South Lampung, in March 2026. The study involved pregnant women in their third trimester who reported low back pain symptoms. A purposive sampling method was applied, resulting in a total of 21 selected participants who fulfilled the established inclusion criteria. This non-probability sampling technique was employed to ensure that only individuals with relevant characteristics were included in the study. Participants were required to be in the third trimester of pregnancy, experience low back pain, consent to participate in the study voluntarily, and be able to complete both the intervention and data collection instruments independently. The inclusion criteria included willingness to participate, provision of informed consent, and the ability to respond to questionnaires without assistance. Conversely, women were excluded if they had severe obstetric complications, a documented hypersensitivity to ginger, gastrointestinal conditions that could interfere with intervention tolerance, or if they were undergoing other treatments that might confound outcomes related to pain, stress, or sleep quality.

Instrumentation

The intervention variable investigated in this study was oral red ginger consumption. Outcome variables included low back pain intensity, stress condition, and sleep disturbance. Pain intensity was assessed using an adapted form of the Visual Analog Scale (VAS). Stress condition was evaluated using a modified version of the stress subscale from the Depression Anxiety Stress Scale (DASS), while sleep disturbance assessment referred to an adjusted Pittsburgh Sleep Quality Index (PSQI).

Several modifications were introduced to improve questionnaire clarity and suitability for community-based respondents. The wording and format of the instruments were simplified according to participant characteristics and the study setting. Prior to data collection, content suitability assessment was performed to evaluate instrument feasibility. Reliability testing demonstrated a Cronbach's alpha coefficient of 0.565, indicating moderate internal consistency. Although the reliability value was relatively modest, the instrument remained acceptable for exploratory community-based assessment. Lower scores represented more favorable participant conditions, including reduced pain intensity, lower stress levels, and fewer sleep-related disturbances.

Procedures and Time Frame

The intervention was administered for seven consecutive days. Participants consumed fresh red ginger prepared as a warm beverage using 1 gram of crushed red ginger mixed with 250 ml of hot water without additional sugar. The drink was consumed twice daily after meals. The study procedure began with participant recruitment based on eligibility criteria. Researchers then explained the objectives, procedures, benefits, and potential discomforts related to the study. Respondents who agreed to participate provided written informed consent prior to baseline assessment.

Pre-intervention measurements of low back pain, stress condition, and sleep disturbance were conducted before the intervention period. Participants subsequently followed the seven-day red ginger consumption protocol. During the intervention phase, adherence and participant complaints were monitored regularly. After completion of the intervention, post-intervention assessments were performed using the same measurement instruments.

Data Analysis

Statistical analysis in this study was carried out using IBM SPSS Statistics version 26. Initially, descriptive statistics were applied to summarize respondent characteristics, such as maternal age, gestational age, and parity. Before conducting inferential testing, the distribution of data was evaluated using the Shapiro Wilk normality test, which is appropriate for studies with a limited sample size. The test results confirmed that the data followed a normal distribution. Based on this assumption, a Paired Samples t-test was subsequently used to compare pre-test and post-test outcomes. The level of statistical significance was set at $p < 0.05$ to determine meaningful differences between the two measurements.

Ethical Approval

This research was conducted following ethical approval granted by the Health Research Ethics Committee of Universitas Malahayati, with reference number 5127A/EC/KEP-UNMAL/II/2026. Before enrolling in the study, all prospective participants were fully informed about the aims of the research, the procedures involved, as well as the potential benefits and risks associated with participation. Informed consent was obtained in written form from every respondent prior to the commencement of data collection, ensuring voluntary participation and adherence to ethical research standards.

RESULTS AND DISCUSSION

Results

Respondent Characteristics

This study involved 21 third-trimester pregnant women who experienced low back pain in the working area of Sukadamai Public Health Center, South Lampung. The respondent characteristics included maternal age, gestational age, and parity.

Table 1. Respondent Characteristics (n = 21)

Characteristics	n	%
Age <20 years	2	9.5
Age 20–35 years	17	81.0
Age >35 years	2	9.5
Gestational age 28–31 weeks	2	9.5
Gestational age 32–36 weeks	17	81.0
Gestational age 37–40 weeks	2	9.5
Primigravida/parity 1	10	47.6
Multigravida/parity 2–3	11	52.4

Based on Table 1, most respondents were aged 20–35 years, totaling 17 participants (81.0%). Based on gestational age, most respondents were in the 32–36-week range, also totaling 17 participants (81.0%). This indicates that the majority of respondents were in the late phase of pregnancy. Based on parity, 10 respondents (47.6%) were primigravida, while 11 respondents (52.4%) were multigravida.

The normality test was conducted using the Shapiro-Wilk test because the sample size was fewer than 50 respondents (Avram & Mărușter, 2022). The results showed that all variables had significance values greater than 0.05, indicating that the data were normally distributed.

Table 2. Normality Test Results of the Study Variables

Variable	Shapiro-Wilk Sig.	Interpretation
Low back pain pre-test	0.125	Normal
Low back pain post-test	0.094	Normal
Sleep disturbance pre-test	0.180	Normal
Sleep disturbance post-test	0.137	Normal
Stress pre-test	0.185	Normal
Stress post-test	0.129	Normal

Based on Table 2, all study variables demonstrated Shapiro–Wilk significance values exceeding 0.05. For low back pain, the p-values were 0.125 at pre-test and 0.094 at post-test. In terms of sleep disturbance, the significance values were 0.180 before the intervention and 0.137 after the intervention. Similarly, stress levels showed p-values of 0.185 at pre-test and 0.129 at post-test. These results indicate that all datasets were normally distributed. Consequently, the comparison between pre-intervention and post-intervention outcomes was analyzed using the Paired Samples t-test.

Effects of Red Ginger Consumption on Low Back Pain, Stress Levels, and Sleep Quality

The effects analysis was conducted by comparing the mean pre-test and post-test scores of the three main variables: low back pain, stress levels, and sleep quality. The results are presented in Table 3.

Table 3. Effects of Red Ginger Consumption on Low Back Pain, Stress Levels, and Sleep Quality

Variable	Pre-test Mean $\pm$ SD	Post- test Mean $\pm$ SD	Mean Difference	95% CI of Mean Difference	P Value	t	Effect Size (dz)	df
Low back pain	4.10 $\pm$ 2.343	2.10 $\pm$ 1.179	2.000	1.373–2.627	<0.001	6.649	1.451	20
Stress Level	5.90 $\pm$ 3.833	2.33 $\pm$ 1.528	3.571	2.379–4.763	<0.001	6.250	1.364	20
Sleep disturbance score	8.14 $\pm$ 2.496	2.81 $\pm$ 1.601	5.333	4.609–6.057	<0.001	15.355	3.351	20

Table 3 shows that all outcome scores decreased after seven days of red ginger consumption. The mean low back pain score decreased by 2.000 points (95% CI: 1.373–2.627; dz = 1.451; p < 0.001). The mean stress score decreased by 3.571 points (95% CI: 2.379–4.763; dz = 1.364; p < 0.001). The mean sleep disturbance score showed the largest reduction, decreasing by 5.333 points (95% CI: 4.609–6.057; dz = 3.351; p < 0.001). These findings indicate statistically significant within-group changes after the intervention. However, because this study did not include a control group, the observed changes should be interpreted as preliminary within-group findings.

Figure 1. Comparison of the mean scores of low back pain, stress levels, and sleep disturbance before and after the intervention

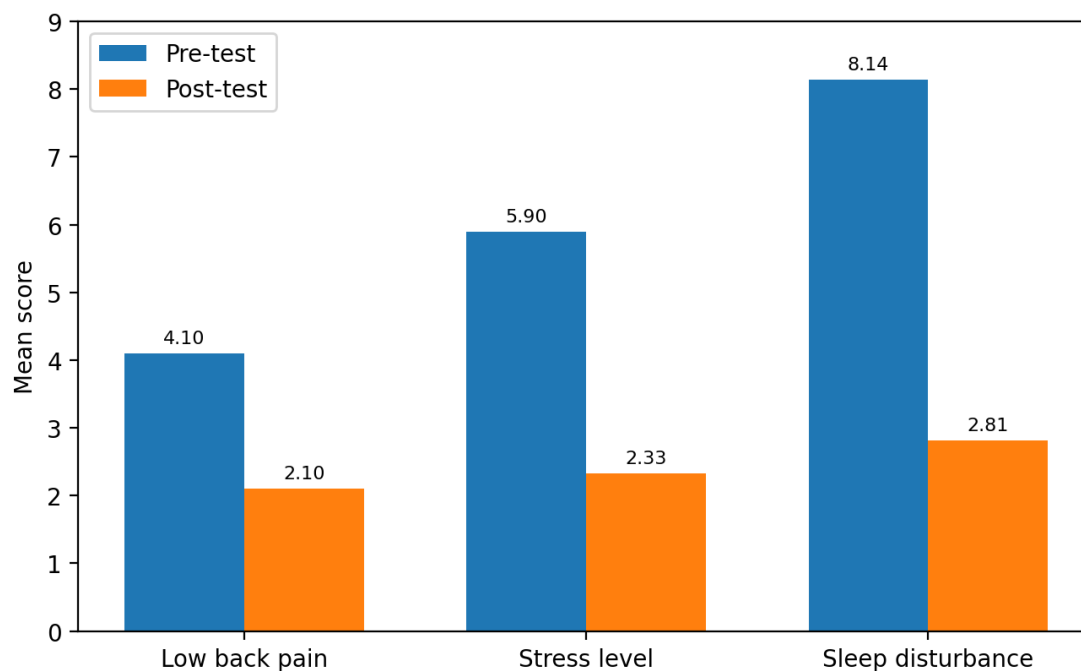


Figure 1 illustrates consistent decreases in the mean scores of low back pain, stress levels, and sleep disturbance after the intervention. The largest mean reduction was observed in sleep disturbance, followed by stress levels and low back pain. This pattern suggests improvement in maternal comfort; however, the interpretation remains limited to within-group changes because no comparison group was included.

Discussion

The findings of this study showed that red ginger consumption for seven days showed significant changes in all variables examined, namely low back pain, stress levels, and sleep quality among third-trimester pregnant women. The mean low back pain score decreased from 4.10 to 2.10, the mean stress score decreased from 5.90 to 2.33, and the mean sleep disturbance score decreased from 8.14 to 2.81. All results yielded p -values < 0.001 , indicating statistically significant differences between the conditions before and after the intervention. These findings suggest that oral red ginger consumption was not only associated with a reduction in physical complaints, particularly pain, but also with improvements in psychological well-being and rest quality among pregnant women.

Although the findings showed significant within-group reductions in low back pain, stress levels, and sleep disturbance, they should be interpreted carefully. The one-group pretest-posttest design does not allow full separation between the intervention effect and other possible influences, such as placebo effect, maturation bias, changes in daily activity, rest patterns, family support, dietary intake, or natural adaptation during late pregnancy. Therefore, the observed improvements may reflect a combination of red ginger consumption and other uncontrolled contextual factors.

Effects of Red Ginger in Reducing Low Back Pain

The reduction in the mean low back pain score from 4.10 to 2.10 indicates that red ginger consumption for seven days was associated with a meaningful reduction in pain intensity. Clinically, a two-point decrease on the pain scale is important, as low back pain during the third trimester often interferes with daily activities, mobility, rest comfort, and maternal readiness for childbirth. Low back pain during pregnancy is generally associated with uterine enlargement,

changes in the body's center of gravity, increased lumbar lordosis, stretching of the pelvic ligaments, and increased mechanical pressure on the lumbopelvic structures (Çoban et al., 2011; Sabino & Grauer, 2008; Wulandari et al., 2023).

Red ginger has a biological basis that supports its use as a complementary intervention to help reduce pain. Its bioactive compounds, such as gingerol, shogaol, oleoresin, and essential oils, are known to possess analgesic, anti-inflammatory, and antioxidant properties (Baihaqi et al., 2022; Grzanna et al., 2005). The active compounds in ginger may suppress inflammatory pathways, including cyclooxygenase and lipoxygenase activity, thereby reducing the production of prostaglandins and other inflammatory mediators involved in pain processes (Grzanna et al., 2005). As inflammatory mediators decrease, the sensitization of peripheral pain receptors may also decline, resulting in lower pain perception.

The results of this study are consistent with previous research indicating that ginger-based interventions can reduce low back pain in third-trimester pregnant women. Earlier studies have shown that ginger compresses or warm ginger water applications were effective in decreasing pain intensity among pregnant women (Abidah & Anggraini, 2022; Khairiah & Herawati, 2022; Lukmana et al., 2024; Purba et al., 2025). However, this study differs in that the intervention was given orally rather than through topical application. As a result, the findings suggest that red ginger may produce not only localized effects, such as heat-induced relief on the skin, but also potential systemic effects following oral intake.

Another strength of this study lies in its continuity with previous preclinical findings. Maternity et al. reported that red ginger, particularly in combination with paracetamol, was associated with changes in inflammatory and stress markers in a model of low back pain during pregnancy (Maternity et al., 2026). This provides a translational basis suggesting that red ginger has biological potential in modulating inflammatory and stress pathways. The present study extends these findings into a simple clinical context among third-trimester pregnant women through subjective outcomes, namely pain, stress, and sleep quality.

Effects of Red Ginger in Reducing Stress Levels

The results of this study showed that stress scores significantly decreased after red ginger consumption. The mean stress score declined from 5.90 to 2.33 with $p < 0.001$. This reduction indicates that the red ginger intervention was not only associated with improvements in physical complaints but was also related to better psychological condition among third-trimester pregnant women.

Stress during the third trimester may be influenced by various factors, such as anxiety before childbirth, physical discomfort, sleep disturbance, fatigue, and activity limitations. Persistent low back pain may become a source of stress because it makes movement difficult, disrupts sleep, and creates discomfort in daily activities. The relationship between pain and stress is bidirectional. Pain may increase stress through activation of the sympathetic nervous system and heightened bodily alertness to unpleasant stimuli, whereas stress may intensify pain perception because the body becomes more sensitive to painful stimuli (Vinstrup et al., 2018).

The reduction in stress observed in this study may have occurred through two possible pathways. First, indirectly through the reduction in low back pain. When pain decreases, the physical burden on the mother becomes lighter and the body is more likely to remain in a relaxed state. Second, biologically, red ginger may influence the stress response through its anti-inflammatory and antioxidant mechanisms. Physiological stress is associated with increased inflammation, oxidative stress, and activation of the hypothalamic-pituitary-adrenal axis (Kong et al., 2024; Spiers et al., 2015). The bioactive compounds in ginger are thought to help suppress inflammatory processes and maintain oxidative balance in the body (Grzanna et al., 2005; Shareef, 2022).

Nevertheless, stress reduction in this study was assessed using a questionnaire; therefore, the interpretation remains subjective. This study did not measure objective stress biomarkers such as cortisol. Accordingly, these findings may serve as preliminary evidence for future studies that combine subjective assessment with objective biomarkers, particularly cortisol or inflammatory markers. This is important because previous preclinical studies have demonstrated an association between red ginger and inflammatory as well as stress markers in models of low back pain during pregnancy (Maternity et al., 2026).

Effects of Red Ginger in Improving Sleep Quality

Among all study variables, sleep disturbance showed the greatest reduction, decreasing from 8.14 to 2.81 with $p < 0.001$. In this study, a lower sleep disturbance score indicated better sleep condition. Therefore, this decrease reflects an improvement in sleep quality following seven days of red ginger consumption.

Sleep disturbance is a common complaint among third-trimester pregnant women. As gestational age increases, women often find it more difficult to maintain a comfortable sleeping position. Uterine enlargement, back pain, increased urinary frequency, fetal movements, shortness of breath, and anxiety before childbirth may all contribute to fragmented sleep (Aukia et al., 2020; Moretti et al., 2021; Reichner, 2015). Low back pain is one of the factors that may make it difficult for pregnant women to maintain a comfortable sleeping position for a prolonged period (Fast & Hertz, 1992).

The improvement in sleep quality observed in this study was most likely related to reductions in low back pain and stress levels. When pain decreases, women may find it easier to adopt a comfortable sleeping position and are less likely to wake up due to discomfort. When stress decreases, the body may also enter a more relaxed state before sleep. Therefore, the effect of red ginger on sleep quality likely did not occur independently, but rather through the improvement of two important contributing factors, namely pain and stress.

These findings are consistent with previous studies showing that non-pharmacological interventions such as back rub, prenatal massage, and prenatal yoga may improve bodily comfort and sleep quality among third-trimester pregnant women (Amperaningsih et al., 2022; Astuti et al., 2022; Handayani, 2023; Paulino et al., 2022). These interventions generally work by reducing muscle tension, enhancing relaxation, and relieving discomfort. In the present study, red ginger appeared to exert a similar effect, although through a different pathway, namely oral consumption, which may reduce inflammation, alleviate pain, and improve overall bodily comfort.

Improved sleep quality has important implications in midwifery care. Adequate and good-quality sleep may help restore energy, maintain emotional stability, reduce fatigue, and support maternal readiness for childbirth (Bahani et al., 2024; Ma et al., 2022). Therefore, the reduction in sleep disturbance scores after red ginger consumption may be regarded as a clinically relevant finding, particularly in the context of community-based maternal self-care.

Relationship Between Pain, Stress, and Sleep Quality in Third-Trimester Pregnant Women

The findings of this study demonstrate that low back pain, stress, and sleep quality changed in the same direction after the intervention. Pain decreased, stress decreased, and sleep disturbance also decreased. This pattern suggests that these three variables are closely interrelated. Among third-trimester pregnant women, low back pain may serve as an initial trigger for sleep disturbance and stress. When the body experiences pain, rest becomes more difficult. Disrupted sleep may then increase fatigue and aggravate stress. Conversely, high stress levels may intensify pain perception and further impair sleep quality (Cortal & Domingues, 2018; Lang et al., 2022; Vinstrup et al., 2018).

In this context, red ginger may be understood as a complementary intervention with the potential to produce a chain effect. Pain reduction may become the entry point for improved bodily comfort. When the body feels more comfortable, women may sleep better. Better sleep may then help reduce stress and improve emotional condition. Therefore, the findings of this study not only suggest the effects of red ginger on each individual variable but also indicate a possible clinical relationship among pain reduction, stress reduction, and improved sleep quality.

This interrelationship represents one of the important contributions of the study. Most previous studies have focused on a single primary outcome, such as low back pain alone or sleep quality alone. In contrast, the present study attempted to examine three interrelated outcomes within a single framework. Thus, the findings suggest that the management of low back pain among pregnant women should not be viewed solely from the perspective of pain, but also in terms of its impact on stress and sleep.

Implications

The findings of this study suggest that red ginger consumption may be considered a simple complementary intervention in community-based midwifery care, particularly for third-trimester pregnant women experiencing low back pain, mild stress, and sleep disturbance. This intervention is easy to implement at home, does not require special equipment, and may become part of self-care education. However, its use should still be accompanied by safety education, especially for pregnant women with a history of ginger allergy, severe gastric disorders, bleeding risk, the use of certain medications, or pregnancy complications (Arbak & Ersoy, 2024; Silveira et al., 2020). Theoretically, these findings reinforce the understanding that pain, stress, and sleep quality are interrelated aspects in third-trimester pregnancy. Reduced pain following red ginger consumption may contribute to lower stress levels and improved sleep quality, suggesting that red ginger has the potential to serve as a supportive therapy in the context of community-based midwifery care.

Research contribution

This study contributes preliminary clinical evidence on oral red ginger consumption as a simple home-based complementary intervention for three interrelated maternal outcomes: low back pain, stress levels, and sleep quality among third-trimester pregnant women.

Another methodological consideration is the modest reliability value of the adapted instrument. The Cronbach's alpha value of 0.565 suggests limited internal consistency, particularly because the instrument combined modified self-report measures related to pain, stress, and sleep. Although the instrument was adapted to improve feasibility and comprehension among pregnant women in a community setting, this reliability limitation may affect the precision of measurement. Therefore, future studies should use validated instruments with stronger psychometric properties or conduct separate reliability testing for each outcome domain.

Limitations

This study has several limitations. It used a one-group pretest–posttest design without a control group or randomization, so the results may be influenced by other factors such as placebo effect, daily activities, rest, diet, and natural pregnancy changes. The sample size was small (21 participants) from one health center, so the findings cannot be widely generalized. Data were collected using self-report questionnaires, which may cause bias, and the instrument had low reliability (Cronbach's alpha = 0.565). The study also did not include objective biological measures. Future studies should use a control group, larger samples, better instruments, and objective markers.

CONCLUSION

Red ginger consumption for seven days was associated with improvements in low back pain, stress levels, and sleep disturbance scores among third-trimester pregnant women. These findings suggest that oral red ginger consumption may have potential as a simple community-based complementary approach to support maternal comfort. However, because this study used a one-group pretest-posttest design without a control group, the results should be interpreted as preliminary evidence rather than confirmation of effects. Further studies with controlled or randomized designs, larger samples, validated instruments, and objective biomarker measurements are needed to confirm these findings.

ACKNOWLEDGMENT

The authors wish to extend their sincere appreciation to Sukadamai Public Health Center, South Lampung, TPMB Mariana Raeni, SST., Bdn, the study respondents, and all parties who assisted and supported the data collection process.

AUTHOR CONTRIBUTION STATEMENT

DM conceptualized the study, designed the methodology, collected and analyzed the data, and drafted the manuscript. NH contributed to methodology, interpretation of findings, and manuscript review. MH contributed to scientific supervision, data interpretation, and final manuscript revision. All authors read and approved the final manuscript.

AI DISCLOSURE STATEMENT

The authors used an AI-based language assistance tool during manuscript preparation to support grammar checking, language refinement, and formatting adjustment. After using the tool, the authors thoroughly reviewed and edited the content as needed and take full responsibility for the content of the publication.

CONFLICTS OF INTEREST

The authors declare no financial, institutional, or personal conflicts of interest that could influence the conduct of this study, the analysis of data, the preparation of the manuscript, or its publication.

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