Original Article

A quasi-experimental study on fortified tempeh: A nutritional intervention for fetal growth in Indonesia

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Background and Objectives: Stunting is a global health challenge, especially in developing countries like Indonesia, where its prevalence reached 21.6% in 2022. This condition stems from malnutrition, recurrent infections, and inadequate care during the first 1,000 days of life. Maternal nutrition is critical for fetal growth, as deficiencies can lead to low birth weight and short birth length, increasing the risk of stunting. This study evaluates the potential of fortified tempeh as a nutritional intervention to improve birth outcomes. **Methods and Study Design:** A quasi-experimental study with a quantitative approach was conducted to compare the effects of regular and fortified tempeh on BW and BL among pregnant women in Kuningan Regency. Participants were divided into two groups: one receiving fortified tempeh and the other regular tempeh. BW and BL were measured at birth and statistically analyzed for differences. **Results:** The results showed no statistically significant differences in BW and BL between the two groups. However, the fortified tempeh group exhibited a positive trend, with an average BW of 2.92 kg and an average BL of 49.1 cm, compared to the regular tempeh group. **Conclusions:** Fortified tempeh demonstrates potential as a cost-effective, locally sourced intervention to support fetal growth and reduce stunting risks. Its integration into public health programs could enhance maternal nutrition and improve birth outcomes in Indonesia.

Key Words: stunting, fortified tempeh, pregnancy, maternal nutrition, local nutrition

INTRODUCTION

Stunting remains a major global health challenge, particularly in developing countries like Indonesia.[1] Stunting, characterized by low height-for-age in children, reflects chronic growth impairment caused by malnutrition, recurrent infections, and inadequate stimulation during the critical first 1000 days of life.[2] According to data from the World Health Organization (WHO), the prevalence of stunting among children under five in Indonesia reached 21.6% in 2022, placing the country among those with the highest stunting burden in Southeast Asia.[3] The long-term impacts of stunting include reduced cognitive capacity, increased risk of degenerative diseases in adulthood, and significant economic losses.[4,5] Therefore, effective nutrition-based interventions during pregnancy are a priority to prevent stunting from an early stage.

Maternal nutrition during pregnancy plays a fundamental role in supporting fetal growth and development.[6,7] Inadequate nutrition during the prenatal period can lead to intrauterine growth restriction, contributing to the birth of normal birth weight (NBW), low birth weight (LBW) infants and those with short birth length—two factors strongly associated with the risk of stunting later in life. In addition to energy needs, pregnant women require high-quality protein, iron, zinc, and other micronutrients to support optimal fetal growth.[8] However, limited access to high-quality animal protein in many regions of Indonesia necessitates the exploration of alternative plant-based protein sources, such as tempeh, which is rich in essential nutrients and both accessible and affordable.[9–11]

Tempeh, a fermented soybean-based product, has long been a staple in the Indonesian diet.[12] It contains high-quality protein and micronutrients such as iron, zinc, calcium, and isoflavones, which support fetal development and maternal health.[13] Fortified tempeh, in particular, has greater potential to meet the nutritional needs of pregnant women, especially in areas with a high risk of stunting. Previous studies have highlighted the benefits of tempeh

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consumption in improving nutritional status and supporting child growth.[14] However, data on the effectiveness of fortified tempeh during pregnancy in improving birth outcomes such as birth weight (BW) and birth length (BL) remain limited and require further investigation.

This study aims to evaluate and compare the effects of consuming regular tempeh and fortified tempeh on the BW and BL of infants. Focusing on pregnant women in Kuningan Regency, this research provides valuable insights into the potential of fortified tempeh as a local food-based intervention to improve birth outcomes. The findings of this study are expected to serve as a basis for developing public health programs and nutrition policies to prevent stunting starting from the prenatal period, while also reinforcing tempeh's position as an economically and socially relevant local solution for improving community nutritional status.

METHODS

Type of research

Kuningan Regency was selected due to its intermediate stunting prevalence and strong collaboration with local health authorities, which facilitated data collection and participant follow-up.

This study employed a quantitative approach with a Quasi-Experimental design. Specifically, it utilized the Non-Randomized Pre-Test – Post-Test Control Group Design involving two groups: an experimental group and a control group, see Table 1. Both groups underwent a pre-test to assess their initial conditions before implementing the intervention. The purpose of the pre-test was to ensure there were no significant differences between the experimental and control groups before the treatment.

Participants were pregnant women in their second trimester with singleton pregnancies, residing in Kuningan Regency for at least one year. Women with chronic diseases, smoking habits, or known pregnancy complications were excluded to ensure group homogeneity.

Research design

A total of 52 pregnant women participated in this study, with 26 assigned to the fortified tempeh group and 26 to the regular tempeh group. The group design is presented in Table 2.

Intervention procedure

The experimental group received fortified tempeh daily for six months. This fortification was designed to enhance the nutritional content of tempeh to better meet the needs of pregnant women better. Both groups also received education on the importance of proper nutrition during pregnancy. Measurements were conducted at the start of the study (pre-test) to collect baseline data on maternal height, weight, and mid-upper arm circumference (MUAC), as shown in Table 3. Participant adherence was monitored through weekly home visits by trained community health workers. A monthly 24-hour dietary recall was conducted to evaluate additional food intake and confirm compliance with the tempeh intervention protocol. After six months of intervention, post-test measurements of birth length and birth weight were performed to evaluate the outcomes of the intervention. Participant adherence was monitored through weekly home visits by trained community health workers. A monthly 24-hour dietary recall was conducted to evaluate additional food intake and confirm compliance with the tempeh intervention protocol. Birth weight and birth length were measured within 24 hours after delivery for all newborns born to participating mothers in both groups.

Fortified tempeh was enriched with moringa leaf extract and iron-zinc premix. Nutritional content was analyzed using AOAC proximate analysis methods to ensure consistency and measurable nutrient differences with regular tempeh.

Data analysis

The data collected from the pre-test and post-test measurements were analyzed using appropriate statistical methods to determine significant differences between the two groups. Hypothesis testing was conducted to assess the effect of fortified tempeh on birth outcomes, including birth weight and length. Independent samples t-test was used to compare mean differences, and Odds Ratio (OR) analysis for categorical outcomes. The primary hypothesis was that fortified tempeh consumption improves birth weight and birth length compared to regular tempeh.

Table 1. Baseline anthropometric characteristics of participants

Group	Height (cm)	Weigh (kg)	BMI (kg)
Fortified	152 ± 5.6	41 ± 4.2	17.7 ± 1.5
Regular	150 ± 5.3	40 ± 4.0	17.8 ± 1.4

BMI: Body Mass Index.
Values are presented as mean ± standard deviation.

Table 2. Study design: Pre-test and post-test group assignments

Group	Pre-test	Intervention	Post-test
PTF1	O1	X1	O2
PTF2	O3	X2	O4

PTF1: Case group receiving fortified tempeh and education; PTF2: A control group receiving regular tempeh and education; X1: Intervention for the experimental group involving fortified tempeh (Formula 1); X2: Intervention for the control group involving regular tempeh; O1, O3: Height, weight, and MUAC measurement before the intervention; O2, O4: Birth weight and birth length measurement after the intervention.

Table 3. Nutrient composition of fortified and regular tempeh (per 100 g)

Nutrient	Fortified tempeh	Regular tempeh
Water	61.8 %	19 g
Energy	199 kcal	199 kcal
Protein	19.8 %	19 g
Carbohydrate	7 %	17 g
Fat	10.2 %	7.7 g
Fiber	5.9 %	4.8 g

Significance of study

The findings of this study are expected to provide deeper insights into the effectiveness of fortified tempeh as a nutritional intervention in supporting fetal growth and preventing stunting among pregnant women in Kuningan Regency. Furthermore, this research can serve as a foundation for developing public health programs and nutritional policies to prevent stunting from the prenatal period. It also reinforces the role of tempeh as an economically and socially relevant local solution in improving the community's nutritional status.

Ethical approval and informed consent statement

We obtained ethical clearance from the Faculty of Medicine, Universitas Hasanuddin. The ethical clearance reference number is 6529/UN4.14.1/TP.01.02/2023. This study has been registered under the clinical trial certificate number SIG.LHP.XII.2023.131606241. The certificate is available at the following link: http://siglab.co.id/#/certificate/pdf-certificate/514852/id.

Nutritional monitoring during intervention

Nutritional monitoring during the intervention period is crucial to understanding the dietary differences between the fortified tempeh group and the regular tempeh group. Table 4. presents the average daily dietary intake of participants in both groups and compares it with the Recommended Daily Allowance (RDA) values for pregnant women. The Recommended RDA values used refer to the 2022 guidelines issued by the Indonesian Ministry of Health.

RESULTS

Characteristics of birth weight based on treatment

The analysis of BW among infants born to mothers who received fortified tempeh and regular tempeh treatments revealed that the mean birth weight in the fortified tempeh group was slightly higher compared to the regular tempeh group. The findings are visually summarized in Figure 1, clearly illustrating the mean birth weight for both groups. Specifically, the fortified tempeh group

Table 4. Average daily dietary intake compared to RDA during intervention

Nutrient/ dietary component	Fortified tempeh group	Regular tempeh group	Recommended Daily Allowance (RDA)	*p*-value
Energy (kcal)	2200 ± 250	2100 ± 260	2500	0.05
Protein (g)	75 ± 10	68 ± 12	70	0.03
Carbohydrates (g)	290 ± 30	280 ± 35	300	0.09
Fat (g)	80 ± 15	78 ± 14	85	0.21
Fiber (g)	25 ± 5	22 ± 4	28	0.04

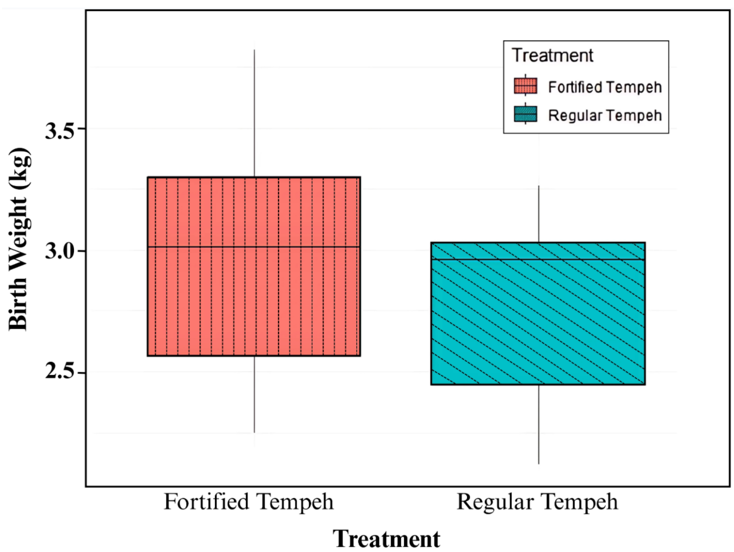

Figure 1. Distribution of mean birth weight by treatment. This figure compares average birth weights between infants born to mothers consuming fortified tempeh versus those consuming regular tempeh

Table 5. Mean birth weight by treatment group

Treatment	Mean (kg)	SD	*p* value
Fortified tempeh	2.92	0.45	0.33
Regular tempeh	2.81	0.35	

Table 6. Mean birth length by treatment group

Treatment	Mean (cm)	SD	*p* value
Fortified tempeh	49.1	2.25	0.23
Regular tempeh	48.4	2.47	

demonstrated a mean birth weight of 2.92 kg with a standard deviation (SD) of 0.45. In contrast, the regular tempeh group exhibited a mean birth weight of 2.81 kg with an SD of 0.35. Statistical analysis using the Independent Sample T-Test yielded a *p*-value of 0.327, indicating no statistically significant difference between the two groups regarding birth weight. The detailed summary of these findings is presented in Table 5.

Distribution of mean birth length based on treatment

An Independent Samples T-Test was used to assess differences in mean birth length between groups. The distribution of BL outcomes is presented in Figure 2, highlighting the differences in the mean BL between the groups. In the fortified tempeh group, the mean birth length was 49.1 cm with an SD of 2.25, while in the regular tempeh group, the mean birth length was slightly lower at 48.41 cm with an SD of 2.47. Hypothesis testing showed a *p*-value of 0.288, confirming that there was no statistically significant difference in birth length between the two groups. A detailed summary of the mean birth length data is provided in Table 6.

Relationship between treatment and birth weight categories

Further analysis was conducted to evaluate the relationship between treatment and birth weight categories, specifically NBW and LBW. In the fortified tempeh group, 84.6% of infants were categorized as NBW, and 15.4% as LBW. In comparison, the regular tempeh group had 80.8% of infants in the NBW category and 19.2% in the LBW category. The results are detailed in Figure 3, showing that 84.6% of infants in the fortified tempeh group fell under the NBW category, compared to 80.8% in the regular tempeh group. The OR analysis yielded a value of 1.31 (95% CI: 0.31–5.55) with a p-value of 1.00, indicating no significant association between treatment type and birth weight categories. These categorical birth weight results are summarized in Table 7.

Relationship between treatment and birth length categories

The distribution of birth length categories (normal and short) is depicted in Figure 4, providing a comparison between the fortified tempeh and regular tempeh groups. Among infants in the fortified tempeh group, 76.9% were classified as having a normal birth length, while 23.1% were categorized as having a short birth length. In the regular tempeh group, 65.4% were in the normal category, and 34.6% were classified as having a short birth length. The Odds Ratio analysis produced a value of 1.76 (95% CI: 0.52–5.67) with a p-value of 0.54, suggesting no significant relationship between treatment type and birth length categories. A detailed comparison of birth length categories by treatment group is presented in Table 8.

DISCUSSION

Interpretation of results

This study reveals minor yet consistent differences in the mean BW and BL of infants born to mothers consuming fortified tempeh compared to regular tempeh. The mean BW in the fortified tempeh group was 2.92 kg (SD = 0.45), slightly higher than the 2.81 kg (SD = 0.35) recorded in the regular tempeh group. Similarly, the mean BL in the fortified tempeh group was 49.1 cm (SD = 2.25), exceeding the 48.4 cm (SD = 2.47) observed in the regular tempeh group. Although these differences were not statistically significant ($p > 0.05$), the trends suggest a potential for fortified tempeh to yield better birth outcomes, particularly in terms of neonatal indicators.[15] The results in Figure 1 and Figure 2 illustrate the trends in mean BW and BL between the fortified and regular tempeh groups. While these differences are not statistically significant, they suggest potential clinical relevance in improving neonatal outcomes.

Statistical analysis showed *p*-values of 0.33 for BW and 0.29 for BL, indicating no significant differences between the groups. However, in public health research, especially with a limited sample size, *p*-values should not always be the sole determinant of relevance.[16] With a sample size of 52 pregnant women (26 in each group), the study had limited statistical power to detect small differences. Average differences of 0.11 kg for BW and 0.71 cm for BL, although statistically insignificant, could hold clinical importance in the context of stunting prevention and reducing neonatal morbidity risks.

An in-depth look at the distribution of NBW and LBW categories further underscores the potential benefits of fortified tempeh. In the fortified tempeh group, 84.6% of infants fell under the NBW category, slightly higher than the 80.8% in the regular tempeh group. An odds ratio analysis yielded a value of 1.31 (95% CI: 0.31–5.55) with a *p*-value of 1.00, indicating no significant association. However, the observed trends remain relevant for assessing fortified tempeh's potential in lowering LBW risks. A similar trend was observed for BL categories, where the proportion of infants with normal BL was

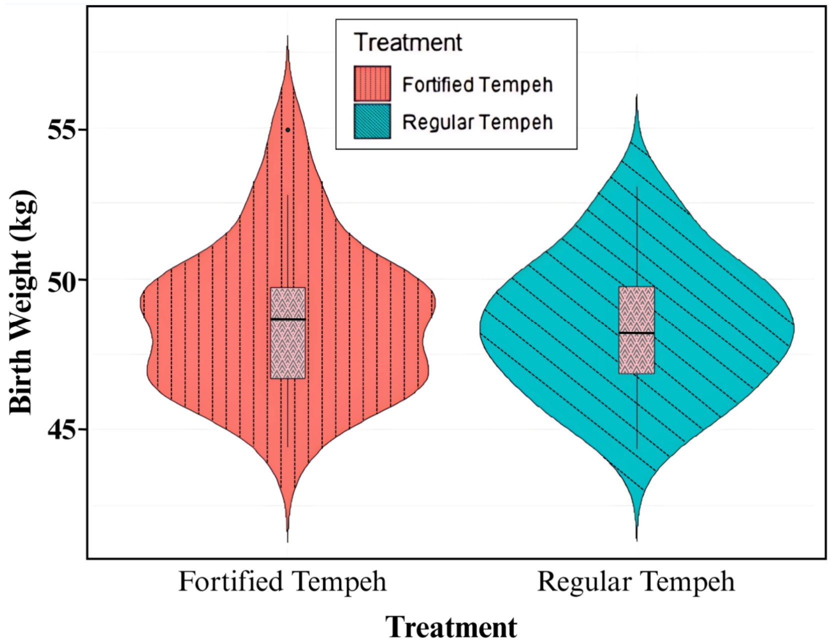

Figure 2. Distribution of mean birth length by treatment. This figure presents the average birth lengths of infants from both treatment groups, highlighting differences between fortified and regular tempeh consumption

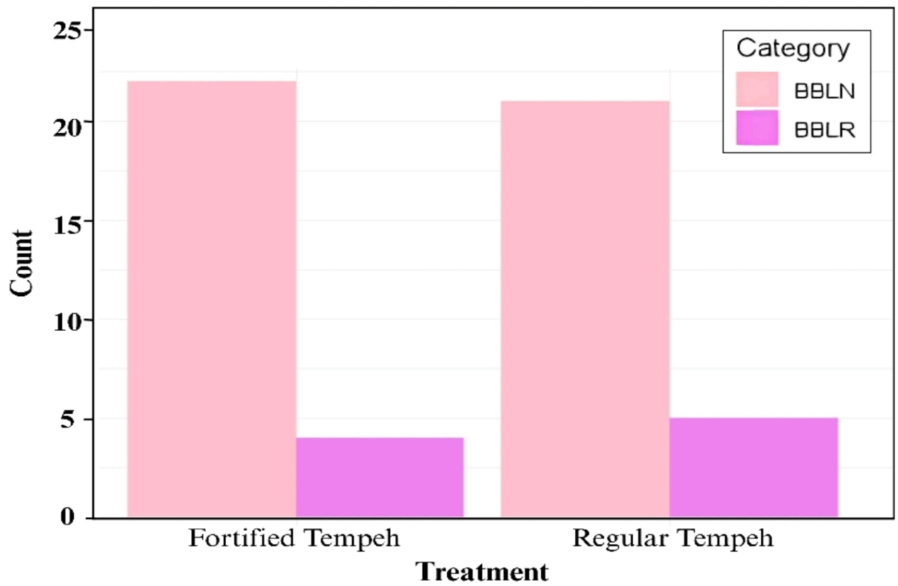

Figure 3. Relationship Between Treatment and Birth Weight Categories. This figure depicts the categorization of infants into NBW and LBW based on maternal consumption of fortified versus regular tempeh

higher in the fortified tempeh group (76.9%) than in the regular tempeh group (65.4%), despite these results also lacking statistical significance.

These trends suggest that fortified tempeh contains nutritional components that could support fetal growth more effectively than regular tempeh. Higher protein content and fortification with micronutrients such as zinc and iron likely contributed to these improvements. The positive effects of fortified tempeh on birth outcomes align with previous literature, albeit with relatively modest impacts in this study.[14,17,18] This may be attributed to other factors such as maternal nutritional status at baseline, dietary variability during pregnancy, or the suboptimal duration of intervention. Consequently, the findings highlight the need for further research with larger sample sizes and robust designs to evaluate the benefits of fortified tempeh more comprehensively.

Clinical versus statistical significance

In public health research, particularly involving birth outcomes like BW and BL, distinguishing between statistical significance and clinical significance is crucial.19 In this study, although there were no statistically significant differences between the fortified and regular tempeh groups for BW (p = 0.33) and BL (p = 0.29), the results carry clinical relevance. The observed increases in mean BW by 0.11 kg and mean BL by 0.71 cm in the fortified tempeh group may not be large enough to achieve statistical significance but could still have tangible impacts in public health contexts. These increments could reduce the

Table 7. Birth weight categories by treatment group

Treatment	Birth weight category				Total		OR (95% CI)	*p*-value
	NBW		LBW					
	n	%	n	%	n	%		
Fortified tempeh	22	84.6	4	15.4	26	100	1.31 (0.31 – 5.55)	1.00
Regular tempeh	21	80.8	5	19.2	26	100		
Total	43	81.1	9	18.9	52	100		

NBW: Normal Birth Weight; LBW: Low Birth Weight

Table 8. Birth length categories by treatment group

Treatment	Birth length category				Total		OR (95% CI)	*p*-value
	Normal		Short					
	n	%	n	%	n	%		
Fortified tempeh	20	76.9	6	23.1	26	100	1.76 (0.52-5.67)	0.54
Regular tempeh	17	65.4	9	34.6	26	100		
Total	37	71.2	15	28.8	52	100		

risk of LBW and short BL, both of which are primary predictors of stunting and neonatal morbidity.

Previous studies indicate that even small increases in BW can have substantial impacts on infant survival and health. For instance, Yildirim et al. (2024) demonstrated that every 100 g increase in BW reduces neonatal complications like hypothermia, hypoglycemia, and infections by up to 5%.[20] Similarly, improved BL at birth is linked to more optimal long-term growth potential and reduced stunting risks during early childhood. In this context, the mean BW and BL differences observed in this study, though statistically insignificant, warrant attention. Further supporting this interpretation, Figures 3 and 4 show a higher proportion of normal BW and BL categories among infants in the fortified tempeh group, highlighting potential benefits despite statistical limitations. They suggest that consuming fortified tempeh during pregnancy could positively influence birth outcomes, contributing to stunting prevention efforts in Indonesia.

This study's failure to achieve statistical significance may stem from the small sample size (n = 52), limiting the statistical power to detect slight differences between groups. Furthermore, maternal dietary patterns may have influenced outcome variability beyond tempeh consumption, intervention duration, and participant adherence levels. Importantly, *p*-values are not the sole indicators in public health research. In many cases, interpretations considering clinical relevance and public health implications offer a more comprehensive understanding.[21] Despite lacking statistical significance, the findings indicate positive trends supporting fortified tempeh as a potential strategy to improve birth outcomes and prevent stunting in high-prevalence regions.

Potential biological mechanisms

The study findings indicate that fortified tempeh provides better outcomes in and BL compared to regular tempeh. These differences can be attributed to several biological mechanisms related to the nutritional content of fortified tempeh, including higher levels of protein, iron, zinc, and the benefits of fermentation. Although the observed differences were not statistically significant, the understanding of these biological mechanisms offers a strong foundation to explain the potential advantages of fortified tempeh.

One of the primary benefits of fortified tempeh is its higher protein content compared to regular tempeh. Protein is a critical component for fetal growth, especially during the second and third trimesters of pregnancy, when the rate of fetal growth increases significantly. Adequate protein intake supports the formation of new tissues, organ development, and the synthesis of enzymes and hormones essential for growth. The protein in fortified tempeh may also have a more complete amino acid profile due to the addition of fortifying ingredients such as legumes or specific grains. Research by Givens (2024) demonstrated that high-quality plant-based protein intake during pregnancy could increase birth weight by 150–200 g, particularly when consumption starts in the first trimester.[22]

Iron in fortified tempeh also plays a crucial role in improving birth outcomes. Iron is essential for haemoglobin synthesis, responsible for oxygen transport in the mother and fetus. Iron deficiency anaemia during pregnancy can reduce oxygen supply to the fetus, subsequently restricting growth. Consuming iron-rich fortified tempeh can help prevent maternal anaemia, thus enhancing oxygen delivery to the fetus. A study by Sharma et al. (2023) found that iron supplementation during pregnancy increased birth weight by up to 250 g in populations with high anaemia prevalence, aligning with the trends observed in this study.[23]

Zinc, also present in fortified tempeh, is vital for cell division, DNA synthesis, and tissue development. Zinc supports fetal skeletal growth, particularly during the third trimester, when bone cell division and elongation intensify. Zinc deficiency during pregnancy has been associated with intrauterine growth restriction and an increased risk of shorter birth length. In this study, the mean BL increase of 0.71 cm in the fortified tempeh

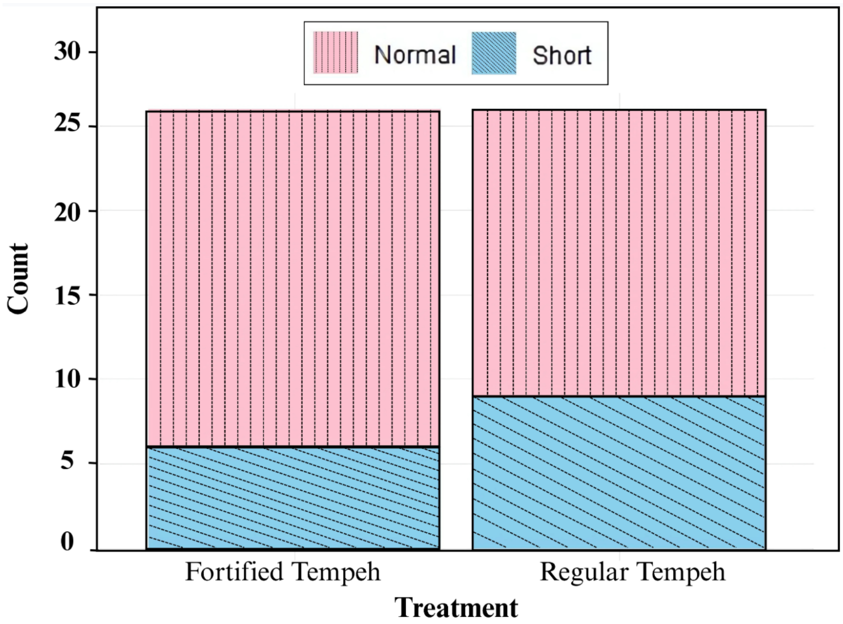

Figure 4. Relationship Between Treatment and Birth Length Categories. This figure shows the classification of infants into normal and short birth lengths according to the type of tempeh consumed by their mothers.

group compared to the regular tempeh group may be attributed to zinc's role in promoting skeletal development. Das et al. (2024) reported that zinc supplementation during pregnancy could enhance BL by 0.5–1 cm, especially in populations with common zinc deficiencies.[24]

Additionally, as a fermented food, fortified tempeh offers extra benefits through its impact on gut microbiota. Fermentation produces bioactive compounds such as bioactive peptides, isoflavones, and short-chain fatty acids (SCFAs), which enhance nutrient bioavailability and metabolic health. For instance, bioactive peptides have been shown to improve iron and zinc absorption efficiency, supporting fetal growth. Moreover, isoflavones in tempeh possess antioxidant properties that may protect fetal tissues from oxidative stress, a risk factor for restricted fetal growth. This aligns with findings by Sajdel-Sulkowska and Elizabeth (2023), highlighting that fermented foods could improve pregnancy outcomes by modulating gut microbiota and enhancing maternal nutritional status.[25]

In summary, the findings of this study are supported by biological mechanisms explaining how fortified tempeh's protein, iron, zinc, and fermentation benefits contribute to improved birth outcomes. Although the results were not statistically significant, the positive trends in the data provide additional support for the hypothesis that fortified tempeh can serve as an effective nutritional intervention to support fetal growth, particularly in regions with high risks of stunting and nutritional deficiencies. Further research is necessary to explore these mechanisms in greater depth, including potential interactions between the nutritional components of fortified tempeh and genetic or environmental factors influencing birth outcomes.

Factors influencing study outcomes (expanded analysis)

The study results revealed minor differences in BW and BL between the fortified and regular tempeh groups. However, these differences were not statistically significant. To better understand why these differences were insignificant, it is essential to evaluate various factors that may have influenced the study outcomes. These factors include maternal characteristics, intervention duration and adherence, dietary variability, research design and analytical considerations.

Maternal socioeconomic and nutritional status

Baseline maternal anthropometric characteristics, such as height, weight, and MUAC, were measured to account for their potential influence on fetal growth. These variables serve as covariates and are not directly compared with neonatal outcomes, but are important indicators of maternal nutritional reserves, which may affect birth weight and birth length. The mismatch in the type of measurements, maternal (pre-intervention) and neonatal (post-intervention), reflects the nature of the quasi-experimental design and the intention to explore maternal nutritional status as a predictor rather than an outcome variable. The maternal anthropometric characteristics (height, weight, MUAC) were recorded at baseline to control for initial nutritional status. These measures were not intended as pre-test equivalents to neonatal outcomes, but rather as contextual variables influencing fetal development, in accordance with the design of a quasi-experimental study.

One of the primary factors influencing the results is the pregnant woman's initial nutritional status and socioeconomic background. This study lacked detailed data on the maternal pre-pregnancy nutritional status (e.g., body mass index). Pre-pregnancy nutritional status plays a crucial role in determining birth outcomes. Mothers with suboptimal nutritional reserves are less likely to support optimal fetal growth, regardless of the intervention provided during pregnancy.[26] Additionally, socioeconomic factors affect mothers' access to other nutritious foods, healthcare services, and prenatal supplementation, such as iron and folic acid, all contributing to birth weight and length. Maternal height, weight, and MUAC are well-established predictors of birth outcomes, particularly birth weight and length. These indicators help to interpret the effect of nutritional intervention by accounting for maternal reserves that support fetal growth.

Dewidar et al. (2023) found that nutritional interventions during pregnancy had more pronounced effects on women from lower socioeconomic backgrounds than those with better nutrition and healthcare access.[27] This suggests that imbalances in socioeconomic status distribution between treatment groups could attenuate or obscure the effects of the fortified tempeh intervention.

Dietary variability

Beyond tempeh consumption as part of the intervention, the overall dietary patterns of pregnant women may have influenced the study outcomes. Participants in the fortified tempeh group may have also consumed additional protein and micronutrient-rich foods, while those in the regular tempeh group might have had lower overall nutritional intake. Such variability could lead to overlapping effects between treatment groups, ultimately reducing the study's ability to detect statistically significant differences.

For instance, Leonard & Kiely (2024) demonstrated that a diet rich in animal protein and micronutrients during pregnancy directly impacts birth outcomes, regardless of specific interventions.[28] In this study, more detailed measurements of dietary patterns, such as the frequency of consuming protein-rich, healthy fats, and micronutrient-dense foods, could provide deeper insights into the contribution of fortified tempeh to birth outcomes.

Duration and adherence to intervention

The duration of tempeh consumption during pregnancy is also a crucial factor influencing the outcomes. This study did not specifically record when the mothers began consuming tempeh (e.g., during the first, second, or third trimester) or how often they consumed it according to the study protocol. Longer consumption durations and higher adherence levels significantly affect birth outcomes.

For instance, a study by Bernier et al. (2024) showed that nutritional interventions during pregnancy had more significant impacts when initiated in the first trimester compared to the second or third trimester.[29] In this study, if the duration of fortified tempeh consumption varied among participants, the cumulative effects of the intervention might not have been fully reflected in the final analysis. Adherence to the consumption protocol is also a factor that could introduce bias in the results, especially if there are disparities between intervention groups regarding the frequency and amount of tempeh consumed.

Study design and sample size

The research design also influences the ability to detect the actual effects of the intervention. In this study, the non-randomized design may introduce selection bias, where the baseline characteristics of pregnant women in the two groups may not be balanced. For example, suppose mothers with better initial nutritional status are more likely to be in the fortified tempeh group. In that case, the final results may reflect pre-existing differences rather than the intervention's effect.

Furthermore, the relatively small sample size (n = 52) limits the statistical power of this study. A small sample size increases the likelihood of a type II error or failure to detect significant differences, even if there is a real effect. A study by Wong et al. (2011) emphasized that detecting small but clinically meaningful differences requires a much larger sample size, especially in nutritional intervention research.[30]

Environmental factors and access to healthcare

Environmental factors, such as access to healthcare services and maternal stress levels, can also influence birth outcomes.[31] Mothers with limited access to prenatal care or those living in areas with a high prevalence of parasitic infections may not fully benefit from nutritional interventions like fortified tempeh.[15] These factors can affect nutrient absorption and the body's ability to utilize nutrients for fetal growth.

Biological variability among individuals

Each individual exhibits a unique biological response to nutritional interventions, which genetic factors, initial health status, and metabolism can influence.[32] In this study, the biological variability among pregnant women might have led to overlapping outcome distributions between the fortified and regular tempeh groups, thus reducing the ability to detect significant differences.

The factors discussed above illustrate that the complex interplay of maternal characteristics, research design, and environmental context influences the results of this study. For future research, it is essential to control these factors more rigorously. Recommendations include increasing the sample size, employing a randomized controlled trial (RCT) design, and measuring additional variables such as baseline nutritional status and dietary patterns. These adjustments would provide a more accurate understanding of the effects of fortified tempeh on birth outcomes.

Limitations and future directions

This study provides valuable insights into the potential of fortified tempeh to improve BW and BL, particularly in the context of stunting prevention in Indonesia. However, these findings must be interpreted with an understanding of the methodological limitations and opportunities for future research. This section integrates discussions on study limitations, practical implications, and recommendations for future studies.

Study limitations

One of the primary limitations of this study is the relatively small sample size (n = 52), which restricts the statistical power to detect small but clinically meaningful differences between the fortified tempeh and regular tempeh groups. A small sample size increases the risk of type II error, where real effects might exist but remain undetected.[33] The small sample size may have contributed to the lack of statistically significant findings despite observable trends. The non-randomized study design also introduces selection bias, as baseline maternal characteristics in the two groups may differ, influencing the outcomes.

Additionally, the study did not capture detailed data on participants' additional dietary intake, adherence to tempeh consumption protocols, or the duration of intervention. Such variations could act as confounding factors that limit the interpretation of the results. Environmental factors such as access to healthcare, prevalence of infections, and maternal stress during pregnancy were not analyzed in detail, even though these are known to significantly impact birth outcomes.

Practical implications of the study

Despite its limitations, the findings of this study hold significant implications in the context of stunting prevention in Indonesia. Fortified tempeh, an affordable and accessible soybean-based product, offers a local solution to improve maternal nutrition and birth outcomes. Within public health programs such as the First 1000 Days of Life Movement, fortified tempeh could be integrated into sustainable nutritional interventions.

The findings also underscore the need to develop policies promoting the production and distribution of locally fortified food products. Efforts could include partnerships between the government, local food producers, and the healthcare sector to ensure access to fortified tempeh for pregnant women, particularly in areas at high risk of stunting. Public education about the benefits of fortified tempeh is also essential to improve its acceptance and adherence to its consumption.

Recommendations for future research

Based on this study's findings and limitations, several recommendations are proposed for future research to provide deeper insights and validate these results:

Randomized Controlled Trials (RCTs): Future studies should adopt an RCT design to reduce selection bias and ensure that observed differences reflect the true effects of fortified tempeh interventions.

Larger Sample Sizes: A larger sample size would enhance the statistical power of the study, enabling the detection of small but statistically significant differences.

Duration and Timing of Intervention: Follow-up studies should monitor the duration of tempeh consumption and the timing of intervention initiation (e.g., from the first trimester) to assess the cumulative effects of fortified tempeh on birth outcomes.

Multivariate Analysis: Future studies should incorporate multivariate analyses to control for confounding variables such as maternal baseline nutritional status, additional dietary intake, socioeconomic status, and stress levels during pregnancy.

Longitudinal Studies: The long-term effects of fortified tempeh consumption on child growth up to early childhood should be evaluated to provide broader insights into its potential for long-term stunting prevention.

Diversified Fortified Products: Research could develop and evaluate other fortified local food products to cater to a broader population with diverse nutritional needs.

By addressing these aspects, future studies can contribute to a more comprehensive understanding of fortified tempeh's role in improving maternal and child health outcomes and its potential impact on stunting prevention in Indonesia. Future research should consider including fetal biometric parameters, such as estimated fetal weight and length during pregnancy, to better assess the impact of maternal nutrition over time.

Conclusion

This study suggests a positive trend in birth weight and length among infants born to mothers consuming fortified tempeh, although these differences were not statistically significant. The findings should be interpreted cautiously due to methodological limitations. The mean BW in the fortified tempeh group was 0.11 kg higher, and the mean BL was 0.71 cm longer, indicating a positive trend in supporting birth outcomes. These findings are supported by biological mechanisms involving the protein, iron, zinc, and bioactive compounds in fortified tempeh, contributing to fetal growth.

Although the study observed a trend of higher birth weight and length among infants in the fortified tempeh group, these results were not statistically significant. Furthermore, due to the differences in measurement variables before and after the intervention (maternal vs. neonatal indicators), the findings should not be interpreted as direct evidence of causal improvement. Future studies should align outcome measurements with the intervention's objectives for a clearer interpretation.

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CONFLICT OF INTEREST AND FUNDING DISCLOSURE

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