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Effect of Zinc and Phenylalanine Supplementation on Birth Outcomes: A Systematic Review and Meta-Analysis

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Abstract

Enhancing antenatal and birth outcomes is a global concern for midwives. This systematic review examined the effects of zinc and phenylalanine supplementation on antenatal and birth outcomes among healthy pregnant women. A systematically developed search strategy was employed to identify relevant studies published between 2004 and 2024, focusing on clinical trials conducted in English. Inclusion criteria encompassed studies involving healthy pregnant women receiving zinc and/or phenylalanine supplementation, with outcome variables including foetal death, preterm birth, birth weight, and low birth weight. A total of seven randomized controlled trials met the inclusion criteria and were included in the analysis. The results revealed that antenatal zinc supplementation did not significantly reduce the risk of foetal death (*RR: 1.12, 95% CI: 0.84-1.50, p = 0.44*), preterm birth (*RR: 1.00, 95% CI: 0.66-1.52, p = 0.99*), and low birth weight (*RR: 1.09, 95% CI: 0.83-1.42, p = 0.54*). There was no difference in birth weight of newborns between the groups (*Mean difference: -0.03, 95% CI: -0.07-0.00, p = 0.06*). There was a paucity of studies on antenatal phenylalanine supplementation. The findings underscore the complexity of the relationship between zinc supplementation and antenatal outcomes. Future studies should explore the impact of phenylalanine supplementation with and without zinc on birth outcomes to provide a more comprehensive understanding of the role of the nutrients in antenatal care.

Keywords: Antenatal women, Birth, Phenylalanine, Supplementation, Zinc

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Introduction

The pursuit of optimal maternal and neonatal health outcomes during pregnancy is a paramount concern for midwives worldwide (Toolan et al., 2022). Maternal nutrition, particularly when deficient in essential micronutrients poses a risk to both maternal well-being and foetal development (Killeen et al., 2023). Among these vital nutrients, zinc and phenylalanine are among the elements implicated in various physiological processes crucial for pregnancy success and foetal growth in literature (Nielsen et al. 2023; Thompson, 2022). While the significance of these nutrients in maternal and foetal health is well recognized, the debate on the efficacy of their supplementation remains a topic of ongoing research and discussion (Jeng & Chen, 2022; McBride et al. 2019)

Zinc is an essential trace element that plays a multifaceted role in human health. It is involved in numerous enzymatic reactions, cellular metabolism, and gene expression, all of which are critical for foetal development and growth (Thompson, 2022). Additionally, zinc contributes to immune function, making it an essential component in combating infections during pregnancy, thereby safeguarding both maternal and foetal health (Gupta et al., 2020). In literature, zinc deficiency states have been associated with adverse pregnancy outcomes such as low birth weight, preterm birth, and increased susceptibility to infections (Agedew et al., 2022; El-Bilbeisi et al., 2023; Gohari et al., 2023). Therefore, ensuring adequate zinc intake during pregnancy is imperative for optimal maternal-foetal health (Karim et al., 2023).

Phenylalanine is an aromatic amino acid that serves as a building block for protein synthesis and is crucial for the synthesis of neurotransmitters (Nielsen et al., 2023). During pregnancy, phenylalanine assumes an even greater

significance due to its role in supporting maternal and foetal tissue growth, particularly in the context of protein synthesis (Ennis et al., 2020). Furthermore, phenylalanine is a precursor for tyrosine, another amino acid essential for the production of catecholamines, which play a vital role in regulating blood pressure and managing stress responses during pregnancy (McBride et al, 2019). Consequently, maintaining adequate phenylalanine levels is essential for ensuring optimal foetal development and maternal well-being.

While the importance of zinc and phenylalanine in pregnancy is well-established theoretically in literature, the effect of their supplementation on birth outcomes have been scarcely examined within the past two decades (Oh et al., 2020). Moreover, there is no existing consensus among maternal and child health practitioners concerning the effect of zinc and phenylalanine supplementation on birth outcomes (Killeen et al., 2023). This presents a gap that needs to be filled; hence the effectiveness of zinc and phenylalanine supplementation in improving antenatal and birth outcomes requires rigorous empirical evaluation.

This systematic review aimed to evaluate the effect of plant-based zinc and phenylalanine supplementation on antenatal and birth outcomes using secondary data published within the past 20 years. By synthesizing available evidence from relevant studies, this review elucidated a pooled effect of zinc supplementation on foetal death, preterm birth, birth weight, and low birth weight. The review further emphasized the lack of empirical studies on antenatal phenylalanine supplementation thereby informing the need for more research to guide clinical practice and public health recommendations. The research question for this review was articulated using the Population, Intervention, Comparison, Outcome, Study design (PICOS) strategy as follows: "Among healthy pregnant women (**P**), what is the effectiveness of zinc or phenylalanine supplementation (**I**) compared with placebo or usual care (**C**) on birth outcomes - foetal death, preterm birth, birth weight, and low birth weight (**O**) in randomized controlled trials (**S**)".

Methodology

The literature search was conducted in January 2025.

Search Strategy: A systematic approach was employed to identify eligible articles. The search terms (keywords) related to the key concepts of the study, including zinc, phenylalanine, supplementation, antenatal, pregnancy, birth, and trial were identified. Boolean operators (AND, OR, NOT) were utilized to combine the search terms. The search strategy was articulated as follows: (Zinc OR Phenylalanine) AND (Supplementation OR co-Supplementation) AND (Antenatal OR Pregnancy OR Birth) AND (Trial) NOT (Review). The search was limited to articles published between 2004 and 2024 to ensure inclusion of recent evidence. Additional limiters included English language and randomized controlled trials (RCTs).

Database Selection and Search: The electronic databases of PubMed (MEDLINE) and Science Direct (Scopus) were searched to retrieve relevant studies. The search strategy was executed independently by two of the reviewers (E-VVI and CE) to minimize selection bias and discrepancies were resolved by discussion and consensus. Duplicate records were identified and removed using Microsoft Excel as the citation management software. The remaining articles were screened based on title and abstract to assess eligibility for full-text review.

Study Selection: Full-text articles were obtained for potentially relevant studies identified during the initial screening phase. The inclusion criteria for study selection were as follows: RCTs involving healthy pregnant women, studies on zinc alone or in combination with phenylalanine supplementation, and studies that assessed at least one of Foetal death, preterm birth, birth weight, and low birth weight. Non-experimental studies and preprints were excluded. Articles that satisfied the inclusion criteria were included for data extraction and analysis.

Data Extraction: Data extraction was performed independently by two of the reviewers (E-VVI and CE) using a uniform data extraction form. The information on study characteristics extracted from each included study were author, year of publication, country, study design, sample (demographic information, gestational age at recruitment, and sample size), treatment (type of supplementation, dosage, duration), control, and outcome variable (foetal death, preterm birth, birth weight, low birth weight). Any discrepancies between the reviewers were resolved through discussion and consensus with other members of the review team.

Quality Assessment: The methodological quality of included studies was assessed using the Critical Appraisal Skills Programme (CASP) tool for randomized controlled trials which was to assess the validity, results, and applicability of an RCT. The assessment included evaluation of random sequence generation, allocation concealment, blinding of participants and personnel, completeness of outcome data, selective reporting, and other sources of bias. The tool has 11 items and was assigned "0" for absence of each quality criteria and "1" for presence of each quality criteria (range 0-11). The studies that rated between 8 and 10 were considered to be of acceptable quality.

Data Synthesis and Analysis: Meta-analysis was conducted to pool data from included studies using appropriate statistical methods. For dichotomous outcomes such as foetal death and preterm birth, risk ratios (RR) with 95% confidence intervals (CI) were calculated. For continuous outcomes such as birth weight, mean differences (MD) with 95% CI were calculated. Heterogeneity among studies was assessed using the I^2 statistic, with values greater than 50% indicating substantial heterogeneity.

Reporting: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting the systematic review. The study flow diagram was used to illustrate the selection process, and a detailed description of search methods, study selection criteria, data extraction, quality assessment, and data synthesis was provided.

Results

Figure 1 illustrates the study selection process using the PRISMA flow diagram. The flow diagram outlines the process of identifying and selecting articles for inclusion in the systematic review and meta-analysis. The diagram begins with the initial database search, which yielded a total of 330 articles from PubMed (n = 104) and Science Direct (n = 226). The next step involved screening for duplicates, resulting in the identification and removal of 13 duplicate articles. Subsequently, the remaining 317 articles were assessed for eligibility based on title and abstract. During this screening process, 310 studies were excluded for various reasons, including 2 studies involving unhealthy women, 3 animal studies, and 305 studies lacking outcomes of interest. After screening, a total of 7 articles remained and were assessed for eligibility based on their full text. All 7 articles met the inclusion criteria and were included in the review.

Table 1 provides an overview of the characteristics of the included studies. Studies were published in 2017 (n = 1), 2016 (n = 1), 2015 (n = 1), 2010 (n = 1), 2009 (n = 1), and 2005 (n = 2). The studies were conducted in Egypt (n = 1), Ghana (n = 1), Iran (n = 2), Pakistan (n = 1), and Tanzania (n = 2). In all, the studies involved 1,674 pregnant women in zinc (treatment) group and 1,701 in the placebo (control) group. The treatment involved 15-50mg of Zinc supplementation beginning at 10-27 weeks gestation till term. The placebo group received usual care mostly involving Ferrous (30-400mg) and Folic (0.4-5mg). The studies assessed birth weight (n = 6), foetal death (n = 4), low birth weight (n = 4), and preterm birth (n = 5). The studies had acceptable methodological quality (CASP score range 8-10).

Table 2 summarizes the results from the included studies and indicated varied outcomes regarding the effects of zinc supplementation on foetal death, birth weight, and preterm birth among pregnant women. While some studies, such as Darling et al. (2017), observed no significant differences in foetal death rates between zinc and placebo groups, others, like Nossier et al. (2015), reported lower foetal death rates in the zinc-supplemented group. Additionally, inconsistencies were observed in birth weight outcomes across studies, with some studies showing no significant differences between zinc and control groups, while others reported slightly higher mean birth weights in the zinc group. Similarly, the prevalence of preterm birth varied among studies, with no consistent pattern observed between zinc supplementation and preterm birth rates. These findings underscore the complexity of the relationship between zinc supplementation and antenatal outcomes, highlighting the need for a meta-analysis to elucidate the potential benefits and consequences of zinc supplementation during pregnancy.

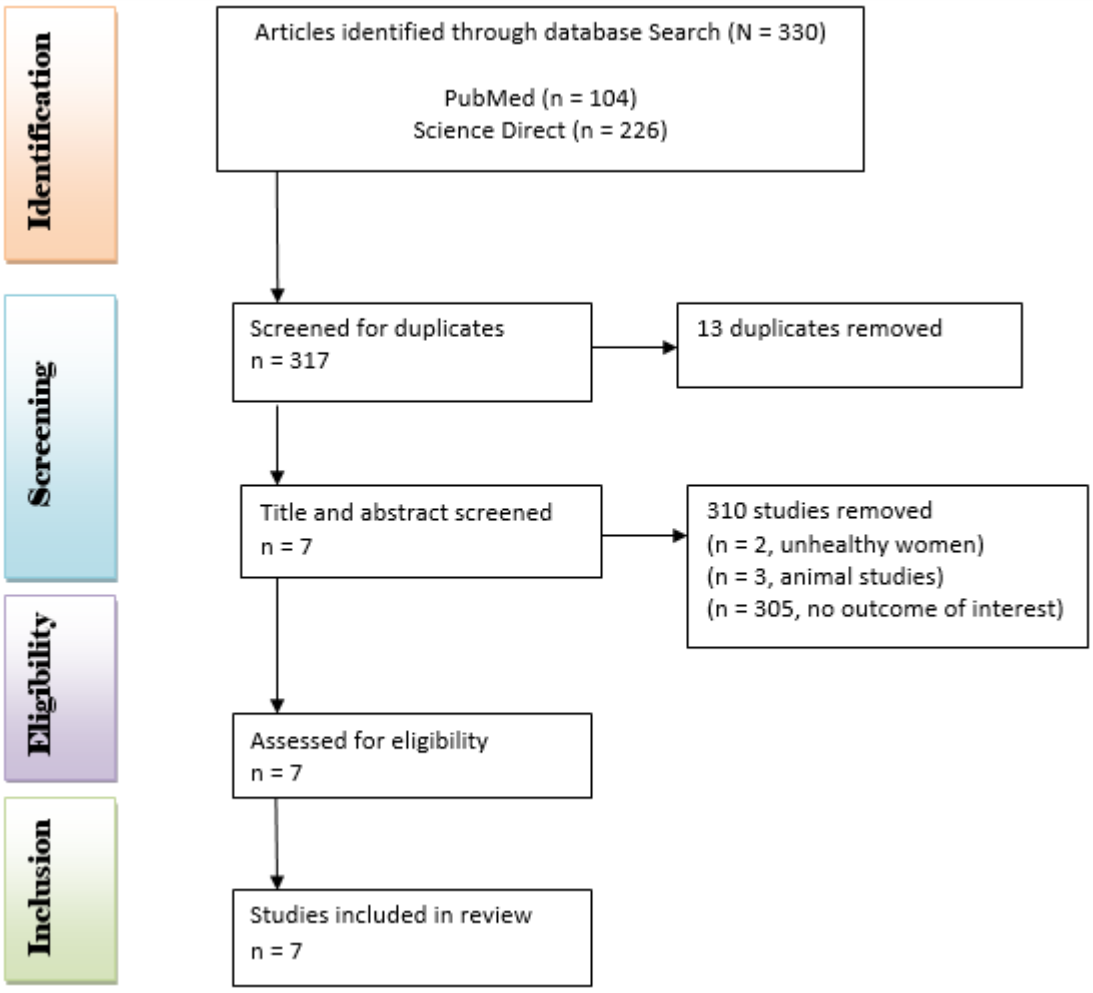

Figure 1: PRISMA flow diagram

Table 1: Characteristics of the included studies (n = 7)

Author (Year)	Country	Design	Sample	Treatment	Control	Outcome parameter	Quality of evidence (CASP)
Darling et al. (2017)	Tanzania	RCT	n = 608 in Zinc only group; n = 625 in placebo group Health pregnant women randomized at 10 weeks gestation.	25 mg per day of zinc (as zinc sulphate) to take the regimen orally until delivery. Participants were also provided with iron (60 mg daily) and folic acid (5 mg daily) in line with Tanzanian health regulation.	Placebo to take the regimen orally until delivery.	Foetal death, Birth weight, Preterm birth, and Low birth weight	10
Zahiri et al. (2016)	Iran	RCT	n = 235 in Zinc group; and n = 244 in placebo group. Healthy pregnant women randomized at 16 weeks gestation.	15 mg of zinc (zinc sulphate) in a tablet to be consumed every other day along with 400 ug folic acid, 30 mg iron (ferrous sulphate)	400 ug folic acid, 30 mg iron (ferrous sulphate) every other day	Birth weight	8
Nossier et al. (2015)	Egypt	RCT	n = 198 in the Zinc group and n = 199 Healthy pregnant women randomized at 15 weeks gestation	Received a daily dose of 30 mg $ZnSO_4$	Received placebo (270 mg lactose).	Foetal death and preterm birth	9
Danesh et al. (2010)	Iran	RCT	n = 42 in zinc group and n = 42 in control Healthy pregnant women randomized at 12-16 weeks gestation	50 mg per day Zinc sulphate	Placebo	Birth weight	8
Saaka et al. (2009)	Ghana	RCT	The Zinc group (n 272) and The control group (n 271) Healthy pregnant women randomized at 13 weeks gestation.	40 mg of zinc as zinc gluconate along side 40mg of ferrous (iron) sulphate	Received 40mg of ferrous (iron) sulphate	Birth weight, Preterm birth, and Low birth weight	9
Fawzi et al. (2005)	Tanzania	RCT	The Zinc group (n 198) and Control group (n 199). Healthy pregnant women randomized at 12-27 weeks gestation	25 mg of zinc alongside ferrous sulphate (400 mg) and folate (5 mg) daily,.20 mg thiamine, 20 mg riboflavin, 25 mg vitamin B-6, 100 mg niacin, 50 µg vitamin B-12, 0.8 mg folate, 500 mg vitamin C, and 30 mg vitamin E	Placebo = ferrous sulphate (400 mg) and folate (5 mg) daily,.20 mg thiamine, 20 mg riboflavin, 25 mg vitamin B-6, 100 mg niacin, 50 µg vitamin B-12, 0.8 mg folate, 500 mg vitamin C, and 30 mg vitamin E	Foetal death, Birth weight, Preterm birth, and Low birth weight	10
Hafeez et al. (2005)	Pakistan	RCT	n = 121 in zinc group and n = 121 in Control Healthy pregnant women randomized at 10-16 weeks gestation.	20mg elemental Zinc	Placebo	Foetal death, Birth weight, Preterm birth, and Low birth weight	10

Table 2: Results from the included studies

Author (Year)	Results
Darling et al. (2017)	***Foetal death***: 107 (17.6%) in zinc group; 104 (16.6%) in placebo group. **Birth weight**: 45 (7.4%) were < 2.5kg in Zinc group; 50 (8%) were < 2.5kg in placebo group ***Preterm birth***: 143 births at <37 weeks gestation in Zinc group; 140 births at <37 weeks gestation in placebo group
Zahiri et al. (2016)	***Birth weight***: 3.26 ± 0.39 kg in the zinc, 3.27 ± 0.40 kg in the no-zinc groups.
Nossier et al. (2015)	***Foetal death***: 1 (0.5%) in zinc group and 5 (2.5%) in placebo group. ***Preterm birth***: 2 (1%) in zinc group and 21 (10.6%) in placebo group.
Danesh et al. (2010)	***Birth weight:*** *2.96 (0.6) kg in the Zinc group and 2.81 (9.0) kg in the control*
Saaka et al. (2009)	***Birth weight***: 3.11±0.49 kg in the treatment group and in the control group was 3.12±0.49 kg. About 19 (9.5%) were <2.5 kg at birth in treatment group and 19(9.5%) were <2.5 kg at birth in control group. **Preterm birth**: 40 (14.7%) in treatment group and 39 (14.4%) in control group.
Fawzi et al. (2005)	***Foetal death***: 36 (18.2%) in zinc group and 26 (13.1%) in placebo group. ***Birth weight***: 3.07±0.53 kg in the zinc group (n = 74) and 3.09±0.51 kg (n = 184) in the placebo group. **Preterm birth**: 31 (15.7%) in treatment group and 29 (14.6%) in placebo group.
Hafeez et al. (2005)	***Foetal death***: 4 (3.3%) in zinc group and 3 (2.5%) in placebo group. ***Birth weight***: 3.02±0.46 kg in the zinc group 3.06±0.44 kg in the control group. About 14 (12%) were <2.5 kg at birth in zinc group and 11 (9.1%) were <2.5 kg at birth in control. **Preterm birth**: 21 (17.4%) in treatment group and 10 (8.3%) in control group.

Figure 2 presents a forest plot illustrating the impact of zinc supplementation on foetal death. There was a 12% increase in the risk of foetal death, but the overall change in risk did not reach statistical significance (*RR: 1.12, 95% CI: 0.84-1.50, p = 0.44*).

Figure 3 summarizes the effect of zinc supplementation on preterm birth using a forest plot and show no significant impact (*RR: 1.00, 95% CI: 0.66-1.52, p = 0.99*).

Figure 4 depicts the effect of zinc supplementation on birth weight, demonstrating no significant impact on birth weight of newborns (*Mean difference: -0.03, 95% CI: -0.07-0.00, p = 0.06*).

Figure 5 illustrates the effect of zinc supplementation on low birth weight, indicating a 9% increase in risk, though the overall change in risk was not statistically significant (*RR: 1.09, 95% CI: 0.83-1.42, p = 0.54*).

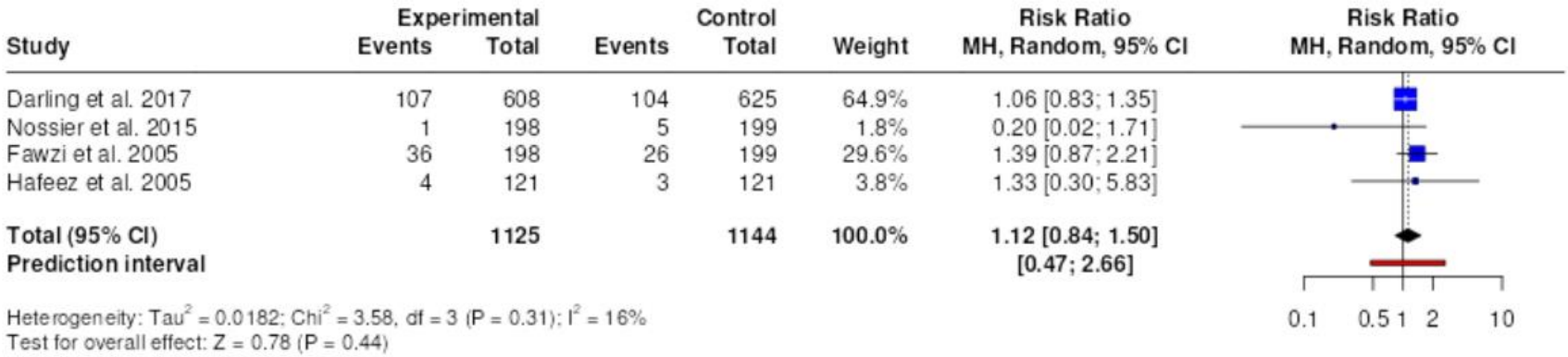

Figure 2: A forest plot showing effect of Zinc on Foetal death

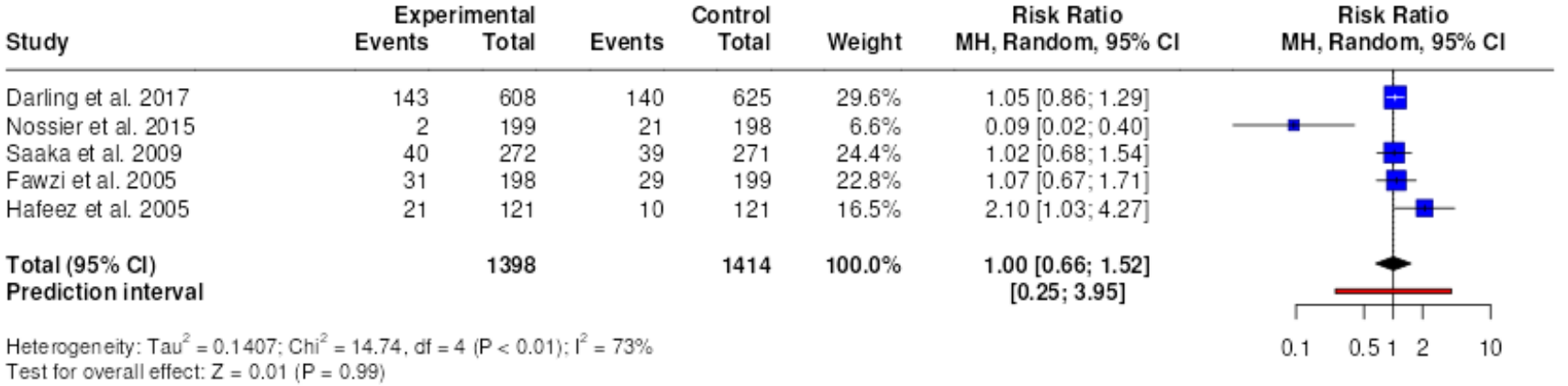

Figure 3: A forest plot showing effect of Zinc on preterm births

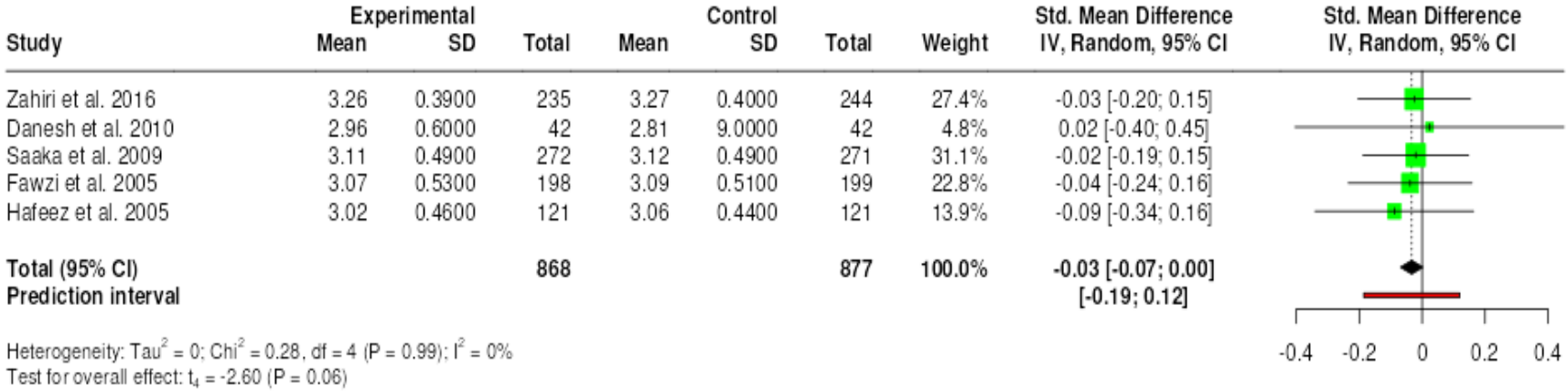

Figure 4: A forest plot showing effect of Zinc on Birth weight

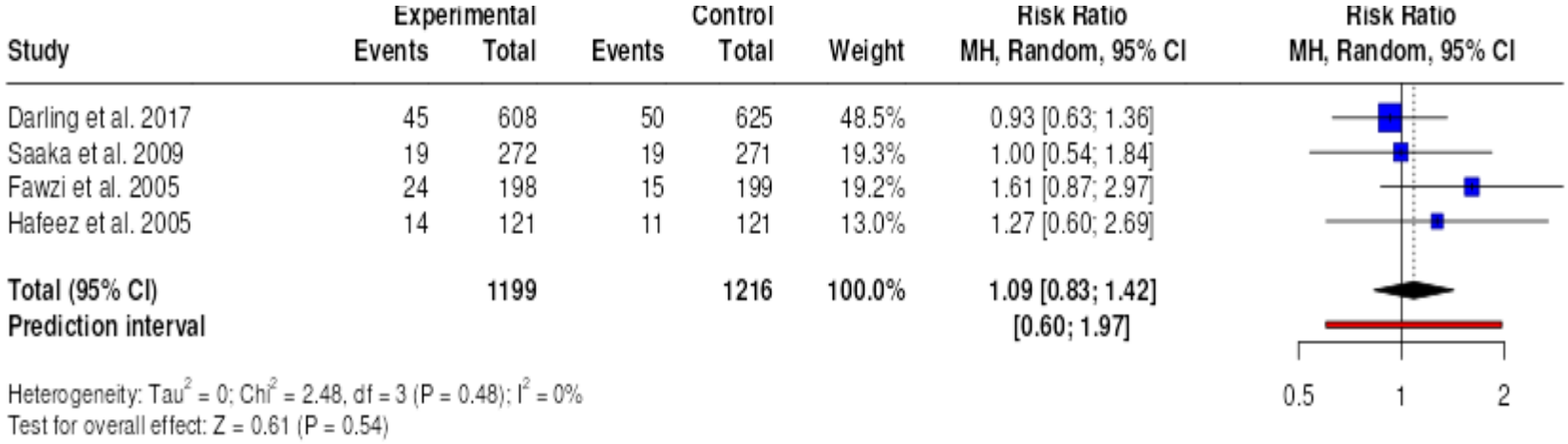

Figure 5: A forest plot showing effect of Zinc on Low birth weight

Discussion

The present systematic review and meta-analysis aimed to investigate the effect of plant-based zinc supplementation on antenatal and birth outcomes among pregnant women. The findings from this study revealed a range of outcomes across the included studies, shedding light on the complex relationship between zinc supplementation and birth outcomes. Unfortunately, there was a complete lack of studies on phenylalanine supplementation in pregnancy.

The overall change in risk of foetal death associated with zinc supplementation did not reach statistical significance in the meta-analysis even though there was a 12% increase in risk. This finding suggests that zinc supplementation did not exert a substantial impact on reducing foetal mortality. One possible reason why the observed 12% increase in the risk of foetal death associated with zinc supplementation did not reach statistical significance in the meta-analysis could be due to the small sample sizes of individual studies. Despite the increase in risk observed across studies, the overall effect estimate may not have achieved statistical significance due to limited statistical power resulting from the relatively small number of participants included in each study. As a result, the confidence intervals around the risk estimate were wide. This finding corroborates the results of Carducci et al. (2021) who in a similar Cochrane systematic review found no significant reduction in foetal deaths due to zinc supplementation.

This review found no significant impact of zinc supplementation on the prevalence of preterm birth. One potential reason for this review not finding any significant impact of zinc supplementation on the prevalence of preterm birth could be due to the complexity of factors influencing preterm birth. Preterm birth is a multi-factorial outcome influenced by various maternal, foetal, and environmental factors, including but not limited to maternal age, socioeconomic status, medical conditions (such as hypertension and diabetes), infection, stress, and lifestyle factors (such as smoking and nutrition). While zinc supplementation may play a role in supporting overall maternal health and immune function, its effect on preventing preterm birth may be overshadowed by the multitude of other factors contributing to preterm labour and delivery. Additionally, the timing, dosage, and duration of zinc supplementation, as well as the baseline zinc status of pregnant women, could also impact the effectiveness of zinc supplementation in preventing preterm birth. This finding contrasted Ota et al. (2015) who in a related Cochrane systematic review found a 14% significant reduction in premature birth. One possible reason for the contrasting findings between this current review and Ota et al. (2015) could be because the studies included in this review had higher methodological quality, contributing to the discrepancy in findings.

Concerning birth weight outcomes, this study revealed no significant effect on the birth weight of newborns born to mothers who received zinc supplementation compared to those in the control groups. However, it is important to interpret this finding with caution, as the observed mean difference in birth weight was small and the p-value was marginally above the threshold for statistical significance. One reason for the lack of significant effect on birth weight outcomes could be attributed to the variation in baseline maternal zinc status among participants. Zinc supplementation may have a more pronounced effect on birth weight outcomes among pregnant women with suboptimal zinc levels or deficiencies compared to those with adequate zinc status. Therefore, if the study population included a significant proportion of pregnant women with adequate zinc status at baseline, the potential impact of zinc supplementation on birth weight may have been attenuated, leading to non-significant findings. Additionally, factors such as the timing, dosage, and duration of zinc supplementation, as well as the presence of other co-interventions or confounding variables, could also influence the effectiveness of zinc supplementation in affecting birth weight outcomes. This finding corroborates Mori et al. (2012) who in a Cochrane systematic review found no significant difference in birth weight due to Zinc supplementation.

This review found that antenatal zinc supplementation could not reduce the prevalence of low birth weight. The observed increase in risk of low birth weight was not significant hence not meaningful from a clinical or public health perspective. This finding is possible because of the other factors that may contribute to low birth weight, such as maternal nutrition, socio-economic status, and access to healthcare, which could confound the association between zinc supplementation and birth weight outcomes. This finding corroborates Mahomed et al. (2007) who in a Cochrane systematic review documented no significant effect of zinc supplementation on prevalence of low birth weight.

Limitations

It is essential to consider several limitations when interpreting the findings of this study. Firstly, the heterogeneity observed across the included studies may have influenced the overall effect estimates and contributed to the variability in outcomes. Heterogeneity from differences in treatment protocols may have impacted the generalizability of the findings. This may have influenced the robustness of the conclusions drawn from this study.

Implication of the findings to policy

The observed reduction in birth weight associated with zinc supplementation underscores the importance of considering the potential risks and benefits of prenatal nutrient supplementation in policy formulation. Policymakers should carefully evaluate the evidence regarding the effect of zinc supplementation on birth weight and consider integrating comprehensive antenatal care protocols that include regular monitoring of maternal nutrient status and targeted supplementation strategies. Additionally, policies aimed at improving access to high-quality prenatal care services, including nutritional counselling and supplementation programs, may help mitigate the risk of adverse birth outcomes associated with maternal nutrient deficiencies.

In terms of practice, the findings from this study highlight the importance of individualized care and evidence-based decision-making in antenatal care settings. Healthcare providers should be aware of the potential impact of zinc supplementation on maternal-foetal health outcomes and

incorporate this knowledge into their clinical practice. It is imperative that healthcare providers engage in ongoing education and training to stay abreast of the latest research findings and best practices in prenatal nutrition and supplementation. Furthermore, pregnant women should be empowered to make informed decisions about their prenatal care, including discussions about the potential benefits and risks of nutrient supplementation, in collaboration with their healthcare providers.

For future research, there is a need for well-designed randomized controlled trials with larger sample sizes and diverse populations to further elucidate the relationship between zinc and phenylalanine supplementation and antenatal and birth outcomes. Future studies should aim to address the existing gaps in the literature by investigating potential mechanisms underlying the observed effects of zinc supplementation, exploring dose-response relationships, and identifying subpopulations that may benefit most from targeted nutrient supplementation interventions. Moreover, longitudinal studies tracking maternal and neonatal health outcomes beyond the immediate postnatal period are warranted to assess the long-term implications of prenatal nutrient supplementation on child growth, development, and health outcomes. By advancing our understanding of the role of zinc supplementation in maternal-foetal health, future research has the potential to inform evidence-based recommendations and interventions aimed at optimizing maternal and child health outcomes globally.

Conclusion

In conclusion, the results of this systematic review and meta-analysis provide valuable insights into the effect of zinc supplementation on birth outcomes during pregnancy. The findings suggest that zinc supplementation has no impact on foetal mortality, preterm birth, birth weight, and low birth weight. There is a serious lack of empirical studies on antenatal phenylalanine supplementation hence a persisting knowledge gap. Further research is needed to clarify the role of zinc and phenylalanine supplementation in optimizing birth outcomes and inform evidence-based recommendations for prenatal care and public health interventions.

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Conflict of Interest: The authors declare no conflicts of interest.

Author Contributions: E-VVI and CE conceptualised the study. All authors participated in data analysis, interpretation, drafting the original manuscript, and approved the final manuscript version for publication.

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