Final paper: Effect of Maternal Lipid-Based Nutrient Supplementation Versus Iron and Folic Acid on Low-Birth-Weight Risk: A Randomized Controlled Trial in Rural Malawi

Introduction

Low birth weight (LBW), defined by the World Health Organization as a birth weight of less than 2500 grams (1) . It remains a major contributor to neonatal morbidity, mortality, and long-term developmental challenges, particularly in low- and middle-income countries (2,3). In Malawi and similar settings, maternal undernutrition during pregnancy is a critical underlying factor for LBW, compromising fetal growth and increasing the risk of adverse birth outcomes (4).

Iron and folic acid (IFA) supplementation during pregnancy has long been the cornerstone of prenatal nutritional care (5). While effective for preventing iron-deficiency anemia and neural tube defects, IFA supplementation may not fully address the broader macro- and micronutrient deficiencies that affect maternal health and fetal development (6,7). Lipid-based nutrient supplements (LNS) have been developed to bridge this nutritional gap (8). These supplements provide not only iron and folic acid but also essential fatty acids, protein, and multiple vitamins and minerals necessary to support optimal fetal growth (9). Although previous randomized controlled trials (RCTs) conducted in Ghana, Bangladesh, and other low-resource contexts have demonstrated that LNS supplementation can improve birth weight and linear growth outcomes, results have varied depending on baseline maternal nutritional status, adherence, and other contextual factors (10–12).

Furthermore, it is unclear whether maternal pre-pregnancy body mass index (BMI) modifies the effectiveness of LNS on birth outcomes (13). Understanding whether LNS offers consistent benefits across BMI categories is critical for tailoring interventions and maximizing public health impact.

This study aims to build upon existing evidence by evaluating the effect of maternal LNS supplementation compared to standard IFA supplementation on the risk of low birth weight among pregnant women in rural Malawi. Additionally, this study investigates whether maternal BMI modifies the relationship between LNS supplementation and neonatal birth weight outcomes.

Research Questions

1. **Primary Research Question:**

   Among pregnant women in rural Malawi, does daily maternal lipid-based nutrient supplementation (LNS) reduce the risk of low birth weight (<2500 grams) compared to standard iron and folic acid (IFA) supplementation?
2. **Secondary Research Question:**

   Does maternal body mass index (BMI) modify the effect of LNS supplementation on neonatal birth weight outcomes?

Methods

This study was an individually randomized, parallel-group randomized controlled trial conducted between 2023 and 2024 across rural health centers in Malawi. This randomized controlled trial was designed, conducted, and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. A CONSORT flow diagram was developed to document participant enrollment, randomization, follow-up, and inclusion in the final analysis.

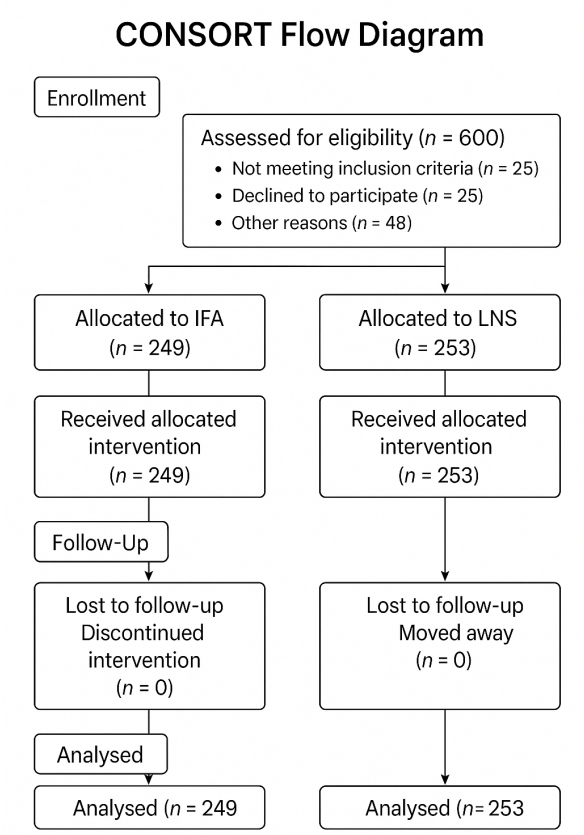


Figure 1: CONSORT flow diagram of the study participants

Study Design

This study was an individually randomized, parallel-group randomized controlled trial conducted between 2023 and 2024 across rural health centers in Malawi. The allocation ratio was 1:1 between the two intervention groups: lipid-based nutrient supplementation (LNS) and standard iron-folic acid (IFA) supplementation.

Participants

Pregnant women were eligible for enrollment if they were between 15 and 45 years of age, had a singleton pregnancy confirmed at or before 20 weeks of gestation, and intended to remain in the study area until delivery. Women were excluded if they had chronic medical conditions such as diabetes or hypertension, presented with severe anemia (hemoglobin <7 g/dL), exhibited major fetal anomalies, or were unable to provide informed consent. Recruitment was conducted through antenatal care clinics, and written informed consent was obtained from all participants before enrollment.

Intervention

Participants randomized to the LNS group received a daily 20-gram lipid-based nutrient supplement containing essential fatty acids, protein, and 22 micronutrients, including 20 mg of iron and 400 µg of folic acid. Those randomized to the IFA group received a daily supplement containing 60 mg elemental iron and 400 µg folic acid, according to national prenatal care guidelines. Supplements were distributed monthly at antenatal care visits, and adherence was encouraged through regular counseling sessions.

Randomization and Blinding

Randomization was performed using a computer-generated randomization list with a block size of four to ensure balanced allocation between groups. Allocation concealment was maintained using sequentially numbered, sealed, opaque envelopes that were opened at the time of assignment. Outcome assessors and data analysts were blinded to participant group assignments. Participants themselves were not blinded due to visible differences in the appearance, texture, and taste of the supplements; efforts to mask these differences would have compromised the nutritional composition and biological effectiveness of the interventions.

Attrition Prevention and Participant Support

To minimize attrition, the study implemented proactive engagement strategies throughout pregnancy. Participants were scheduled for regular follow-up visits aligned with routine antenatal care to promote continued involvement. For those who missed appointments, community health workers conducted home visits to provide reminders and deliver supplements when necessary. To further support retention, all participants received modest, non-coercive incentives, including transportation reimbursements and a small care package of household or hygiene items at each follow-up visit. These tokens were provided to acknowledge participants' time and encourage sustained participation. Additionally, adherence was reinforced through counseling sessions delivered during clinic visits. All analyses followed the Intention-to-Treat (ITT) principle, including all randomized participants regardless of adherence status, to mitigate potential bias due to dropout.

Sample Size and Power Calculation

To achieve 80% power at a two-sided significance level of 0.05, the study initially aimed to enroll 600 pregnant women to detect a relative risk of 1.2 for normal birth weight (≥2500 grams) between the lipid-based nutrient supplementation (LNS) and iron-folic acid (IFA) groups. Accounting for potential exclusions and loss to follow-up, 502 women were ultimately randomized into the two intervention groups.

Outcomes

The primary outcome was the incidence of low birth weight, defined as a birth weight less than 2500 grams, measured within 72 hours of delivery using calibrated digital infant scales. The secondary outcome was mean birth weight, treated as a continuous variable. Baseline characteristics, including maternal age, parity, educational attainment, socioeconomic status, and body mass index (BMI) were collected at enrollment through structured questionnaires and anthropometric measurements.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Review Board (IRB) at the collaborating institution in Malawi. All participants provided written informed consent. Participant confidentiality, rights, and safety were maintained throughout the study. Adverse events were monitored and reported according to IRB regulations.

Statistical Analysis

All statistical analyses followed the intention-to-treat (ITT) principle, whereby participants were analyzed in the groups to which they were originally assigned, regardless of adherence to the intervention. Descriptive statistics were used to summarize baseline characteristics across the two intervention groups. Categorical variables were presented as frequencies and percentages, while continuous variables were summarized using means and standard deviations. For the primary outcome of low birth weight (<2500 grams), log-binomial regression models were used to estimate unadjusted risk ratios (RR) and risk differences (RD) along with their corresponding 95% confidence intervals (CIs). The secondary outcome, mean birth weight (grams), was analyzed as a continuous variable using linear regression models to estimate the mean difference between groups and the corresponding 95% CIs.

Effect modification by maternal body mass index (BMI) was assessed by including an interaction term between intervention group and BMI category (underweight, normal weight, overweight) in the regression models. In addition, stratified analyses by BMI categories were conducted to evaluate the effect of lipid-based nutrient supplementation within each BMI group. All statistical tests were two-sided, and a p-value of less than 0.05 was considered statistically significant. Analyses were performed using SAS version 9.4(14).

Table 1: Baseline characteristics of participants

Variable	LNS (n = 253)	IFA (n = 249)
Maternal characteristics		
Age (years), mean (SD)	25.3 (5.8)	25.0 (5.7)
Married or living with partner, n (%)	237 (94%)	232 (93%)
Education level, n (%)		
No formal schooling	49 (19%)	52 (21%)
Primary education	91 (36%)	88 (35%)
Secondary/technical education	96 (38%)	92 (37%)
Tertiary or higher	17 (7%)	17 (7%)
Gestational age at enrollment (weeks), mean (SD)	16.9 (2.1)	16.8 (2.0)
Maternal BMI (kg/m²), mean (SD)	22.0 (3.0)	21.9 (2.4)
Hemoglobin at enrollment (g/dL), mean (SD)	11.8 (1.5)	11.7 (1.4)
Food insecurity score (0–15), mean (SD)	4.5 (4.1)	5.0 (4.3)
Primiparous (first pregnancy), n (%)	53 (21%)	50 (20%)
Infant characteristics		
Infant sex: Male, n (%)	130 (51%)	128 (51%)
Study site: Lungwena, n (%)	127 (50%)	124 (50%)

At baseline, maternal and infant characteristics were similar between the LNS and IFA groups. The mean maternal age was 25.3 years (SD 5.8) in the LNS group and 25.0 years (SD 5.7) in the IFA group. The majority of participants were married or living with a partner, with 94% in the LNS group and 93% in the IFA group. Educational attainment was comparable between groups: approximately 19–21% had no formal schooling, 35–36% had primary education, 37–38% had secondary or technical education, and 7% had tertiary or higher education. The mean gestational age at enrollment was 16.9 weeks (SD 2.1) in the LNS group and 16.8 weeks (SD 2.0) in the IFA group.

Maternal BMI was similar across groups, with a mean of 22.0 kg/m² (SD 3.0) in the LNS group and 21.9 kg/m² (SD 2.4) in the IFA group. Mean hemoglobin levels at enrollment were also comparable, at 11.8 g/dL (SD 1.5) and 11.7 g/dL (SD 1.4) in the LNS and IFA groups, respectively. Food insecurity scores were slightly higher in the IFA group (mean 5.0, SD 4.3) compared to the LNS group (mean 4.5, SD 4.1). The proportion of first-time mothers (primiparous) was similar, at 21% and 20% in the LNS and IFA groups, respectively. Infant sex distribution was balanced, with 51% male infants in both groups. Lastly, enrollment at the Lungwena study site was evenly distributed, with 50% of participants in both groups recruited from this location.

Table 2: Effect of LNS vs. IFA on Low Birth Weight

Outcome	Intervention: LNS (n = 253)	Control: IFA (n=249)	Risk Ratio (95% CI)	p-value	Risk Difference (95% CI)	p-value
Low birth weight (<2500g)	45 (17.8%)	89 (35.7%)	0.50 (0.36, 0.69)	<0.001	–17.9% (–25.0%, –10.8%)	<0.001

Table 2 presents the effect of LNS compared to IFA on the risk of low birth weight (<2500g). The proportion of infants born with low birth weight was 17.8% in the LNS group and 35.7% in the IFA group. The risk ratio was 0.50 (95% CI: 0.36, 0.69; p <0.001), indicating a 50% lower risk of low birth weight among infants in the LNS group relative to the IFA group. The risk difference was –17.9% (95% CI: –25.0%, –10.8%; p<0.001), demonstrating a substantial absolute reduction in low birth weight associated with the LNS intervention.

Table 3: Effect of Maternal LNS Supplementation on Mean Birth Weight Compared to IFA

Outcome	LNS Group (n = 253) Mean (SD)	IFA Group (n = 249) Mean (SD)	β (95% CI)	p-value
Birth weight (g)	2,980 (470)	2,880 (490)	100.0 (35.0, 165.0)	0.003

Table 3 shows the comparison of mean birth weight between the LNS and IFA groups. The mean birth weight was 2,980 g (SD 470) in the LNS group and 2,880 g (SD 490) in the IFA group. The adjusted mean difference (β) was 100.0 g (95% CI: 35.0, 165.0; p = 0.003), indicating that infants in the LNS group had significantly higher birth weights compared to those in the IFA group.

Table 4. Effect of Maternal LNS Supplementation on Mean Birth Weight, Stratified by Maternal BMI Category

Maternal BMI Category	Group	Mean Birth Weight (g) Mean (SD)	Mean Difference (β) (95% CI)	p-value
BMI <18.5 kg/m²	LNS	2,960 (470)		
	IFA	2,880 (460)	80 (–20, 180)	0.12
BMI ≥18.5 kg/m²	LNS	3,000 (460)		
	IFA	2,930 (490)	70 (–10, 150)	0.09

Table 4 presents the effect of LNS supplementation on mean birth weight, stratified by maternal BMI category. Among mothers with a BMI <18.5 kg/m², the mean birth weight was 2,960 g (SD 470) in the LNS group and 2,880 g (SD 460) in the IFA group, with a mean difference of 80 g (95% CI: –20, 180; p = 0.12), which was not statistically significant.

Among mothers with a BMI ≥18.5 kg/m², the mean birth weight was 3,000 g (SD 460) in the LNS group and 2,930 g (SD 490) in the IFA group, with a mean difference of 70 g (95% CI: –10, 150; p = 0.09), also not reaching statistical significance. These results suggest that the positive effect of LNS on birth weight was consistent across BMI categories but did not achieve statistical significance within either stratum. Though differences were not statistically significant within strata, the consistent direction of effect suggests potential universal benefits of LNS irrespective of BMI category.

Discussion

This randomized controlled trial demonstrates that maternal lipid-based nutrient supplementation (LNS) is significantly more effective than standard iron and folic acid (IFA) supplementation in reducing the risk of low birth weight (LBW) in rural Malawi. The proportion of LBW was markedly lower in the LNS group (17.8%) compared to the IFA group (35.7%), and the mean birth weight was 100 grams higher in the LNS group. These findings underscore the benefits of comprehensive prenatal nutrition interventions in low-resource settings where undernutrition during pregnancy remains widespread, providing a broader spectrum of nutrients beyond what IFA offers, including essential fatty acids, protein, and 22 vitamins and minerals (15).

This broader nutritional profile may address multiple simultaneous deficiencies affecting fetal growth, particularly in populations with high food insecurity (16). While both groups received folic acid and iron, the added value of LNS likely lies in its support for maternal metabolic demands and placental development, mechanisms crucial for fetal weight gain (10).

Our findings align with prior studies in Ghana and Bangladesh, where LNS improved birth outcomes; however, the effect size in this study was more pronounced (9,17). This may be attributed to higher rates of maternal undernutrition at baseline or stronger adherence to the intervention. Importantly, the consistent direction of effect across maternal BMI strata suggests that LNS may benefit all pregnant women, regardless of pre-pregnancy nutritional status. While stratified analysis did not yield statistically significant interaction by BMI, the direction of effect was consistent. Among women with a BMI <18.5 kg/m², the mean birth weight was 80 g higher in the LNS group, and among women with a BMI ≥18.5 kg/m², the difference was 70 g, both favoring LNS. These trends suggest potential universality in LNS benefits but indicate a need for future studies powered specifically to assess effect modification.

Strengths and Limitations

The trial employed a rigorous randomized controlled design with a 1:1 allocation ratio, which effectively reduced the risk of selection bias. High participant retention and the use of standardized outcome measurements further enhanced the reliability of the findings.

To minimize measurement bias, both data analysts and outcome assessors were blinded to group assignments. Additionally, the study adhered closely to CONSORT guidelines, including the use of a detailed flow diagram and comprehensive reporting of participant flow throughout the trial. First, blinding of participants was not feasible due to visible differences between the supplements, which may have introduced performance bias. Although adherence was encouraged through counseling, it was not objectively

measured using biomarkers or pill counts, limiting the precision of dose-response assessment. Selection bias is also possible, as participants who enrolled in the study may have differed systematically from the broader population in terms of health-seeking behavior or nutritional status.

Additionally, while birth weight was objectively measured, adherence data were self-reported, introducing potential nondifferential misclassification of exposure. The study was adequately powered to detect differences in the primary outcome of low birth weight, but it was underpowered for detecting interaction effects in subgroup analyses, such as those stratified by maternal BMI. Finally, the generalizability of these findings may be limited to rural, low-income populations with high rates of maternal undernutrition and limited access to antenatal care. Caution should be exercised in extrapolating the results to more urbanized or nutritionally diverse settings.

Implications for Policy and Practice

These findings provide actionable insights for shaping maternal nutrition policies in low- and middle-income countries. The observed reduction in low birth weight (LBW) and the improvement in mean birth weight suggest that lipid-based nutrient supplements (LNS) may serve as a superior alternative or complement to iron and folic acid (IFA), particularly in settings where food insecurity is prevalent. Incorporating LNS into routine antenatal care could yield substantial public health benefits by reducing neonatal mortality and mitigating long-term developmental challenges associated with LBW. Moving forward, implementation studies are essential to assess the scalability, cost-effectiveness, and logistical feasibility of integrating LNS into existing healthcare

delivery systems. Policymakers should also prioritize equity-focused strategies to ensure that LNS reaches the most nutritionally vulnerable populations.

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Annex I: Sample Size Calculation Using SAS POWER Procedure

The POWER Procedure
Pearson Chi-square Test for Proportion Difference

Fixed Scenario Elements	
Distribution	Asymptotic normal
Method	Normal approximation
Alpha	0.05
Reference (Group 1) Proportion	0.80
Proportion Difference	0.10
Nominal Power	0.80
Number of Sides	2
Group 2 Weight	1

Computed N Total	
Actual Power	0.800
N Total	600

This output shows the total sample size required (n = 600) to detect a 10% absolute difference in the proportion of normal birth weight with 80% power and a two-sided significance level of 0.05.

Annex II: SAS code

```
/* Power Analysis*/

proc power;
   chisq test=prop
   groupproportions = (0.80 0.70) /* Control = 80%, Intervention = 70% */
   alpha = 0.05
   ntotal = 600
   power = .;
run;

/* Table 1: Baseline Characteristics */

/* Maternal Age */

proc means data=malawi_data maxdec=2;
   var age_years;
   by group; /* LNS vs IFA */
   where include_flag = 1;
run;

/* Maternal Education */

proc freq data=malawi_data;
   tables education*group;
   where include_flag = 1;
run;

/* Gestational Age at Enrollment */

proc means data=malawi_data maxdec=2;
   var gest_age_weeks;
   by group;
   where include_flag = 1;
run;
```

/* Hemoglobin at Enrollment */

```
proc means data=malawi_data maxdec=2;
   var hemoglobin;
   by group;
   where include_flag = 1;
run;
```

/* Food Insecurity Score */

```
proc means data=malawi_data maxdec=2;
   var food_insec_score;
   by group;
   where include_flag = 1;
run;
```

/* Primiparity */

```
proc freq data=malawi_data;
   tables primiparous*group;
   where include_flag = 1;
run;
```

/* Infant Sex */

```
proc freq data=malawi_data;
   tables infant_sex*group;
   where include_flag = 1;
run;
```

/* Study Site */

```
proc freq data=malawi_data;
   tables study_site*group;
   where include_flag = 1;
run;
```

/* Table 2: Low Birth Weight – Risk Ratio & Risk Difference */

```
/* Risk Ratio (log link) */
proc genmod data=malawi_data;
   class group (ref='IFA');
   model lbw_flag = group / dist=bin link=log;
   estimate "LNS vs IFA RR" group 1 / exp;
   where include_flag = 1;
run;

/* Risk Difference (identity link) */
proc genmod data=malawi_data;
   class group (ref='IFA');
   model lbw_flag = group / dist=bin link=identity;
   where include_flag = 1;
run;

/* Raw Frequencies */
proc freq data=malawi_data;
   tables lbw_flag*group;
   where include_flag = 1;
run;
```

/* Table 3: Mean Birth Weight Difference */

```
/* Linear Regression (mean difference) */
proc genmod data=malawi_data;
   class group (ref='IFA');
   model birth_weight = group / dist=normal link=identity;
   where include_flag = 1;
run;
/* Group Means */
proc means data=malawi_data;
   var birth_weight;
   by group;
   where include_flag = 1;
run;
```

```
/* Table 4: Stratified by Maternal BMI */
```

```
/* BMI <18.5 kg/m² */
proc genmod data=malawi_data;
   class group (ref='IFA');
   model birth_weight = group / dist=normal link=identity;
   where bmi_category = "Underweight" and include_flag = 1;
run;

/* BMI ≥18.5 kg/m² */

proc genmod data=malawi_data;
   class group (ref='IFA');
   model birth_weight = group / dist=normal link=identity;
   where bmi_category = "NormalOverweight" and include_flag = 1;
run;
```