

MORINGA OLEIFERA AS AN ADJUNCT TO IRON-FOLIC ACID SUPPLEMENTATION IN RURAL FILIPINO PREGNANT WOMEN: AN OPEN-LABEL PILOT RANDOMIZED CONTROLLED TRIAL OF FEASIBILITY, ADHERENCE, ACCEPTABILITY, AND HEMOGLOBIN CHANGE

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Abstract

Background. Anemia in pregnancy remains a major public health problem, affecting an estimated 36% of pregnant women worldwide in 2019. Daily iron-folic acid (IFA) supplementation is standard antenatal care, yet anemia persists among rural Filipino women. *Moringa oleifera* is locally abundant and has been proposed as an adjunct, but Philippine evidence is limited.

Objectives. To determine whether adjunct *M. oleifera* supplementation can be delivered, adhered to, accepted and tolerated within routine antenatal care, and to generate preliminary estimates of change in hemoglobin, weight and mid-upper arm circumference (MUAC).

Methods. An open-label, pilot two-arm parallel randomized controlled trial with an embedded qualitative component enrolled 20 pregnant women in two barangays of Sindangan, Zamboanga del Norte, allocated 1:1 to routine IFA alone (Group A) or IFA plus a 500 mg *M. oleifera* capsule daily (Group B) for 90 days. Adherence, acceptability, and safety were assessed through journals, a Likert-scale questionnaire, and monthly monitoring; hemoglobin, weight, and MUAC were measured at baseline and monthly. Trial not prospectively registered.

Results. All 20 women received their allocated regimen. Paired hemoglobin data were available for 7 of 10 participants in Group A and 8 of 10 in Group B; the shortfall was due to delivery before the Month 3 blood draw, relocation outside the study area, or incomplete final laboratory follow-up. Mean adherence was 99.4% ($SD \pm 1.6$) in Group A and 99.3% ($SD \pm 1.0$) in Group B; acceptability was 5.00 and 4.96 of 5.00, respectively. No serious adverse events occurred. Hemoglobin rose in both arms (Group A +1.38 g/dL; Group B +1.07

g/dL), with no significant between-group difference (0.31 g/dL, 95% CI -1.24 to 1.86; $p = .674$). Retrospective power was approximately 7%.

Conclusion. Adjunct *M. oleifera* supplementation was feasible, well adhered to, highly acceptable, and tolerated in routine rural antenatal care. The trial was not powered to establish efficacy, and the confidence intervals could not exclude a meaningful benefit or harm. A definitive trial of approximately 148 women per arm would be needed to detect a 0.5 g/dL hemoglobin difference; until then, routine IFA supplementation should remain the primary intervention, with *M. oleifera* considered a promising, locally available complement rather than a replacement.

Keywords: Acceptability; adherence; anemia; hemoglobin; iron-folic acid supplementation; *Moringa oleifera*; pilot randomized controlled trial; pregnancy

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Research Highlights

What is the current knowledge?

- Maternal anemia affects an estimated 36% of pregnant women worldwide, and daily iron–folic acid (IFA) supplementation is the WHO-recommended standard of care.
- Only about a quarter of Filipino women complete the recommended 180-day IFA course, with compliance lowest among the least educated, poorest, and those with fewer antenatal visits.
- Trials from Indonesia and Pakistan suggest *Moringa oleifera* may raise hemoglobin in pregnant women, but doses, preparations, and follow-up periods vary widely and no severe adverse events have been reported.
- No Philippine study has evaluated *Moringa oleifera* as an adjunct to routine IFA supplementation within an antenatal care setting, and none has reported the feasibility, adherence, and acceptability outcomes needed to determine whether such an adjunct could be delivered through a rural health unit.

What is new in this study?

- The first open-label pilot randomized controlled trial in a Philippine antenatal care setting to test *Moringa oleifera* as an adjunct to, rather than a substitute for, routine iron–folic acid supplementation.
- Adherence exceeded 97% in both study arms and acceptability was rated 4.96–5.00 of 5.00, demonstrating that a barangay-based delivery model (SMS reminders, monthly monitoring, and health teaching) can achieve near-complete compliance in a population where national IFA adherence is only about 26%.
- Hemoglobin, weight, and MUAC rose in both groups with no detectable between-group difference (95% CI -1.24 to 1.86 g/dL for hemoglobin); retrospective power was only ~7%, so the trial reports parameters, not efficacy.
- Variance estimates from this pilot yield a concrete sample-size target (~148 participants per arm) for a definitive, blinded, placebo-controlled trial.

INTRODUCTION

Anemia during pregnancy is one of the most widespread nutritional disorders in the world. Global pooled estimates indicate that 36% of pregnant women were anemic in 2019, and iron deficiency accounts for a substantial share of these cases (Stevens et al., 2022; World Health Organization [WHO], 2024; Khurana et al., 2024; Braat et al., 2024). Maternal anemia is associated with increased maternal morbidity, low birth weight, preterm delivery, and impaired fetal growth, which is why WHO recommends daily oral supplementation with 30–60 mg of elemental iron and 400 µg of folic acid throughout pregnancy as part of routine antenatal care (WHO, 2016). A Cochrane review of 60 trials found that preventive iron supplementation substantially reduces maternal anemia at term, and the evidence base has since been reaffirmed (Finkelstein et al., 2024; Peña-Rosas et al., 2015).

In the Philippines, national policy follows the WHO recommendation and prescribes 60 mg of elemental iron with 0.4 mg of folic acid daily for at least 180 days of pregnancy (Felipe-Dimog et al., 2021; Saragih et al., 2022; Skolmowska et al., 2022). National survey data show that anemia among pregnant Filipino women fell from 38.3% in 2008 to 26.6% in 2018, still a problem of moderate public health significance (Food and Nutrition Research Institute [FNRI-DOST], n.d.). Coverage, however, does not equal effect: analysis of the 2017 Philippine National Demographic and Health Survey found that only 25.8% of women complied with the recommended 180-day course, and compliance was lowest among the less educated, the poorest, and those with fewer antenatal visits (Felipe-Dimog et al., 2021). In geographically isolated barangays such as those served by the Sindangan Rural Health Unit in Zamboanga del Norte, limited budget allocations, irregular supply, and constrained dietary diversity further weaken the effect of the standard regimen.

Moringa oleifera, known locally as *malunggay*, grows readily throughout the Philippines and is already part of the household diet in most rural communities. Its leaves are dense in iron, calcium, vitamin C, vitamin A, protein, and antioxidant phytochemicals, and leaf preparations have long been used to address malnutrition (Anwar et al., 2007; Arora & Arora, 2021; Falowo et al., 2018; Gopalakrishnan et al., 2016; Yang et al., 2023). Because vitamin C enhances non-heme iron absorption, a leaf preparation supplying both iron and ascorbate is biologically plausible as a complement to a ferrous salt (Hurrell & Egli, 2010; Saini et al., 2016; Stohs & Hartman, 2015). Clinical evidence, however, is thinner than the enthusiasm surrounding the plant. A systematic review and meta-analysis of randomized trials in anemic pregnant women concluded that *Moringa* may raise hemoglobin when given as an adjunct or alternative to iron, but judged the evidence insufficient to establish an optimal dose or preparation (Kalam et al., 2024). Individual trials illustrate substantial heterogeneity: doses, preparations, comparators, and follow-up periods differ widely, so pooled estimates must be interpreted cautiously.

Three gaps motivated the present study. First, almost all available trial evidence comes from Indonesia, South Asia, and sub-Saharan Africa; there is little published evidence from Philippine antenatal programs, where *Moringa* is culturally familiar but not formally integrated into maternal nutrition services. Second, most published studies compare *Moringa* against iron rather than testing it as an addition to the standard of care, which is the question a rural health unit would actually face. Third, and most importantly, the practical questions that determine whether a community program can succeed, namely whether women will take the supplement, whether they find it

acceptable, and whether it is safe alongside ferrous sulfate, have rarely been reported systematically.

Evidence on *M. oleifera* as a maternal nutritional adjunct remains heterogeneous. Reviews describe leaves as sources of minerals, vitamins, protein, and phytochemicals, while emphasizing variation in composition, preparation, and the limited number of well-controlled human trials (Badri et al., 2024; Brar et al., 2022; Gopalakrishnan et al., 2016; Liu et al., 2022; Nurdin & Hadju, 2018; Yang et al., 2023). A recent narrative review of studies conducted during pregnancy and breastfeeding found potentially favorable effects but highlighted uncertainty about dose, duration, and safety evidence (Rotella et al., 2023). Trials from Indonesia and Pakistan have used capsules, powder, extracts, and *Moringa*-containing biscuits, with doses and comparators varying substantially (Hadju et al., 2020; Manggul et al., 2021; Ashfaq et al., 2024; Kalam et al., 2024). This heterogeneity, together with the physiological variation in maternal hemoglobin across pregnancy (Young et al., 2019), supports a staged approach in which feasibility and variance are characterized before a definitive efficacy trial.

A pilot randomized trial is uniquely appropriate here because the principal uncertainties are not yet whether *M. oleifera* is clinically effective, but whether the adjunct can be delivered reliably within routine rural antenatal care and whether the procedures, adherence measurement, acceptability assessment, safety monitoring, retention strategy, and outcome measurement are workable enough to support a definitive trial. Immediate progression to a full-scale efficacy RCT would risk committing substantially more participants and resources before these operational parameters and the variability of the candidate hemoglobin outcome were adequately characterized. Pilot trials are intended to establish feasibility and estimate parameters needed to design a future definitive trial rather than provide confirmatory tests of clinical effectiveness (Cocks & Torgerson, 2013; Eldridge et al., 2016; Montgomery, 2025; Sim & Lewis, 2012; Thabane et al., 2016). This study therefore aimed to evaluate feasibility, adherence, acceptability, safety, and preliminary change in hemoglobin, weight, and MUAC among pregnant women receiving routine iron–folic acid supplementation, while generating variance estimates for a definitive trial.

Specifically, the pilot asked: (1) Can a daily 500 mg *M. oleifera* leaf capsule be delivered alongside routine iron–folic acid supplementation with high adherence, acceptability, and tolerability in a rural antenatal-care setting? (2) What preliminary between-group estimates of change in hemoglobin, body weight, and MUAC, and what outcome variability, can be obtained to inform the design and sample-size planning of a definitive randomized controlled trial? Because the study was designed as a pilot and was not powered for efficacy, these clinical outcome estimates were treated as exploratory rather than confirmatory hypotheses.

METHODS

Design

This was an open-label, pilot two-arm parallel-group randomized controlled trial with an embedded qualitative component, conducted over a 90-day intervention period. Reporting follows the CONSORT 2010 extension for randomized pilot and feasibility trials (Eldridge et al., 2016). The quantitative component assessed change in hemoglobin concentration (the candidate primary outcome of a future definitive trial) together with body weight and mid-upper arm circumference

(MUAC). The qualitative component used participant journals, self-administered questionnaires, and end-of-study interviews to explore adherence and acceptability.

Blinding, allocation concealment, and definitive-trial safeguards. This pilot was intentionally open-label and used manually shuffled coded identifiers without allocation concealment; participants, field staff, and outcome assessors were not blinded. These procedures are appropriate to report as limitations rather than to treat the pilot as a definitive efficacy trial. In the future definitive trial, allocation should be generated by an independent computer-based randomization system and concealed until enrollment through a centralized service or sequentially numbered, opaque, sealed envelopes prepared independently of the enrolling team. A double-blind, placebo-controlled design should be used, with visually and operationally matched placebo capsules so that participants and outcome assessors cannot distinguish *M. oleifera* from placebo; intervention staff and data analysts should also remain blinded where operationally feasible. Randomization should be stratified by gestational-age category and baseline nutritional status to reduce imbalance, with standardized gestational eligibility and outcome-assessment windows.

Environment

The study was conducted in Barangay Dumalogdog and Barangay Labakid, two rural and geographically isolated barangays in the municipality of Sindangan, Zamboanga del Norte, Philippines. Both are served by a single health center under the Sindangan Rural Health Unit, staffed by one barangay health nurse, ten barangay health workers, and two barangay nutrition scholars. These barangays were selected because iron deficiency anemia and maternal undernutrition are recognized local problems, dietary diversity is constrained, and *Moringa* is locally available and culturally familiar. Laboratory work was performed at the Sindangan Rural Health Unit laboratory.

Participants

Eligible participants were pregnant women aged 15 to 49 years, between 12 and 39 weeks of gestation (second and third trimesters), residing in the two study barangays, and receiving routine antenatal care from the local health center. Potential participants were identified from the prenatal Target Client List maintained by barangay health workers and nutrition scholars. Women were excluded if they were in the first trimester (to avoid exposure during organogenesis); had a diagnosed condition capable of independently altering hemoglobin, iron metabolism, or nutritional status (e.g., thyroid disorders, diabetes mellitus, hypertension, hyperemesis gravidarum, hematologic disease, or other chronic illness); or had a known allergy or hypersensitivity to herbal supplements, foods, or medications. Before enrollment, each prospective participant obtained medical clearance from the assigned physician certifying stable general condition and fitness to participate.

The sample of 20 participants, 10 per arm, was fixed by the feasibility purpose of the study and by the number of eligible women on the prenatal Target Client List of the two barangays during the enrollment window. No power calculation for a clinical difference was performed, and none was appropriate: a pilot trial is sized to test procedures and estimate parameters, not to test hypotheses about effectiveness (Eldridge et al., 2016). After eligibility screening and informed consent, each

participant was assigned a unique study identification code. Codes generated from the prenatal master list were manually shuffled, and the first ten codes were allocated to Group A (control) and the remaining ten to Group B (intervention). Allocation was completed before data collection began. No allocation concealment mechanism and no blinding of participants, field staff, or outcome assessors were used, a recognized limitation addressed in the Discussion.

Instruments

Data were collected using a Maternal Participant Interview Questionnaire (baseline socio-demographic and obstetric characteristics), a Nutritional and Hematologic Assessment Form (MUAC measurement followed standard anthropometric practice; Ververs et al., 2013) (baseline and follow-up hemoglobin, weight, height, and MUAC), a Participant Self-Administered Questionnaire (follow-up experience, acceptability, and symptom reporting), participant journals and adherence logs (daily supplement intake and missed-dose reasons), and a Dietary Diversity Checklist (baseline and end-of-intervention food variety). Acceptability was assessed in Group B using an eight-item questionnaire on a five-point Likert scale (1 = *strongly disagree* to 5 = *strongly agree*), translated into Bisaya and Tagalog, with an overall score computed as the mean item response and interpreted as: 4.21–5.00 *highly acceptable*; 3.41–4.20 *acceptable*; 2.61–3.40 *neutral*; 1.81–2.60 *less acceptable*; 1.00–1.80 *not acceptable*.

Data Collection Procedure

Group A (control) received the routine standard of care provided by the Rural Health Unit: monthly weighing and anthropometric monitoring, tetanus toxoid immunization, deworming, maternal and nutritional counseling, and daily ferrous sulfate with folic acid. Group B (intervention) received the identical standard of care plus one 500 mg capsule of pure *M. oleifera* leaf powder taken once daily after a meal for 90 days, sourced from a single commercial supplier to keep the preparation uniform; only leaf material was used, excluding root, bark, and flower material associated with uterine stimulation. No independent phytochemical assay (e.g., iron, calcium, or ascorbic acid content per batch) was performed to verify active-ingredient consistency, since raw leaf preparations are known to vary widely in phytochemical concentration; this is noted as a limitation below. Both groups kept a daily journal of supplement intake and missed-dose reasons and received daily SMS reminders; Group B additionally returned used blister foils for objective adherence cross-checking.

All potential participants underwent structured eligibility screening, informed consent, comprehensive clinical screening, and physician medical clearance before enrollment. Safety was monitored through on-site bi-weekly assessment during scheduled mothers'-class sessions or prenatal visits (physical and symptom assessment, adherence review, capsule counts, journal review) and participant self-monitoring (daily symptom journaling). Participants who developed symptoms potentially associated with supplementation underwent increased monitoring frequency, and predefined criteria governed participant-initiated withdrawal, investigator-initiated temporary suspension (e.g., moderate gastrointestinal symptoms, suspected hypersensitivity), and permanent discontinuation (e.g., confirmed allergic reaction, serious adverse event, high-risk pregnancy complication, delivery). Adverse events were classified by severity and causality by the attending physician and reported to the Research Ethics Committee within institutional timelines.

Hemoglobin concentration was obtained from a complete blood count performed at the Sindangan Rural Health Unit laboratory at baseline and at the end of each of the three months; body weight and height were measured with calibrated scales and MUAC with a standard tape.

Data Analysis

Data were encoded in Microsoft Excel and analyzed in Jamovi. Categorical variables are summarized as frequencies and percentages, and continuous variables as means with standard deviations. Normality was assessed with the Shapiro–Wilk test and homogeneity of variance with Levene's test; all outcome variables satisfied both assumptions, so parametric tests were retained. Within-group change from baseline to Month 3 was assessed with paired-samples t-tests, and between-group comparison used independent-samples t-tests applied to individual change scores. Because the number of participants contributing data differed by outcome, analyses were conducted on an available-case basis and the analyzed sample size is reported for every estimate. Consistent with guidance for pilot trials, effect estimates are reported as mean differences with 95% confidence intervals, with p-values presented for completeness rather than as the basis for inference (Eldridge et al., 2016). Qualitative material from journals, questionnaires, and interviews was transcribed and analyzed thematically to interpret the adherence and acceptability findings.

Ethical Considerations

The study was reviewed and approved by Zamboanga City Medical Center Research Ethics Committee (Protocol No. ZCMC-ERB-2026-09; approved March 30, 2026) and the Ateneo de Zamboanga University School of Medicine, and was then conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013) and Republic Act No. 10173, the Philippine Data Privacy Act of 2012 (Republic of the Philippines, 2012). Written informed consent was obtained before enrollment after the study purpose, procedures, duration, foreseeable risks and benefits, compensation, confidentiality safeguards, and voluntary nature of participation were explained. Written informed assent plus parental/guardian consent was obtained for participants younger than 18 years. Participants could withdraw at any time without penalty or loss of access to routine maternal healthcare. No monetary compensation was provided; a modest token of no more than ₱300 per mothers'-class session was provided, while laboratory costs and reasonable transportation expenses were shouldered by the self-funded Principal Investigator regardless of allocation. To comply with the Data Privacy Act, participants were represented in the study dataset by unique study codes rather than personal identifiers; physical records were stored in locked cabinets and digital files on password-protected devices, and reported findings were de-identified and aggregated before dissemination to participants, the local community, and health authorities.

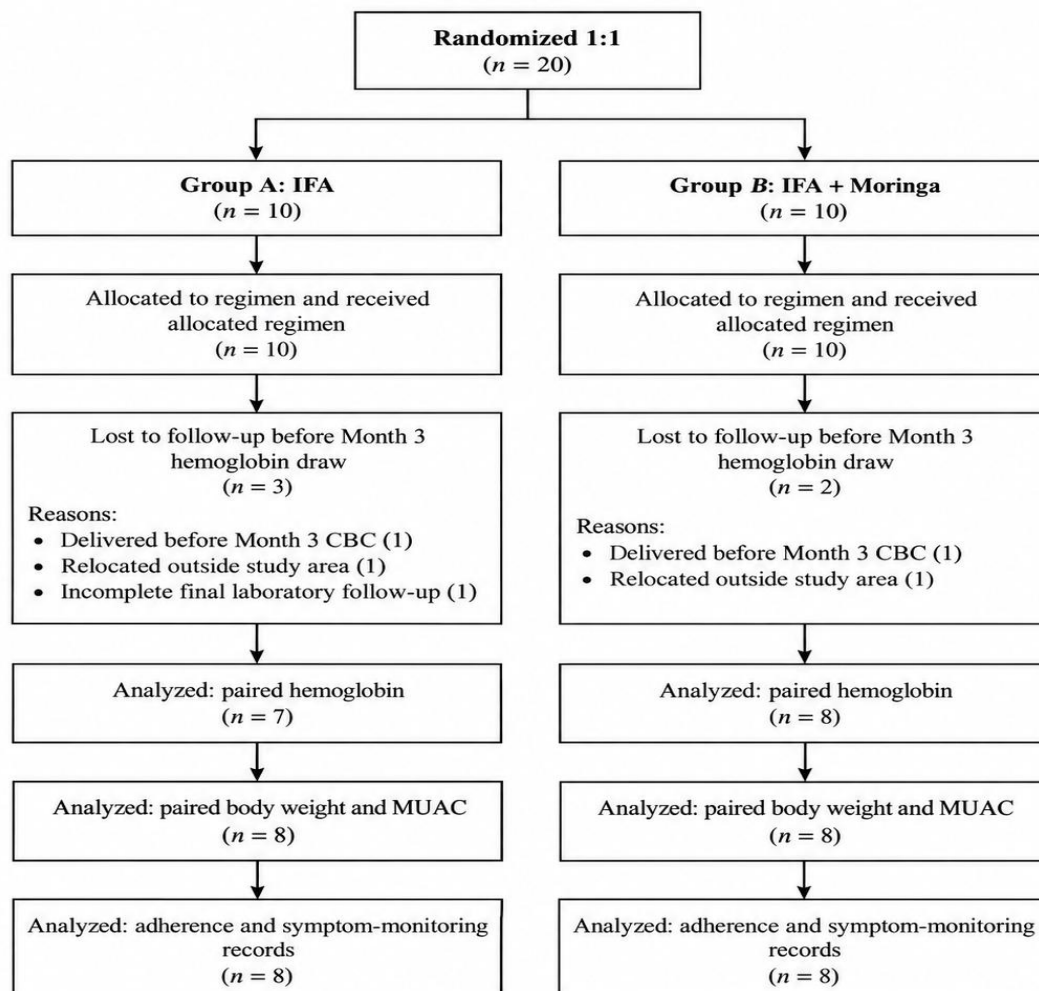
RESULTS

Participant Flow, Recruitment, and Retention

Twenty pregnant women were enrolled and randomized, 10 to each arm, and all 20 received the regimen to which they were allocated. Baseline demographic, obstetric, nutritional, and hematologic data were complete for all twenty participants. Retention was incomplete for endline measurements: in Group A, one participant delivered before the Month 3 complete blood count (CBC) was drawn, one relocated outside the study area, and one did not complete final laboratory follow-up ($n = 7$ for paired hemoglobin); in Group B, one participant delivered before the Month 3 CBC and one relocated ($n = 8$). Paired body weight and MUAC values were available for 8 of 10 participants in each group, and adherence and symptom-monitoring records were available for 8 participants per group. Participant flow followed the CONSORT 2010 extension for randomized pilot and feasibility trials (Figure 1).

Figure 1.

CONSORT 2010 flow diagram of participant enrollment, allocation, follow-up, and analysis



Socio-Demographic and Obstetric Characteristics

The socio-demographic profile of the twenty participants is presented in Table 1. Half were married and half were cohabiting. Educational attainment ranged from elementary to college level, with high school graduates forming the largest group (40.0%). Three-quarters were housewives. Household income was low: 60.0% of participants reported monthly household income below ₱5,000, and none reported more than ₱10,000. Mean participant age was 28.6 years ($SD \pm 7.60$), and the two groups were similar in age (Group A 28.8 ± 7.55 years; Group B 28.5 ± 8.05 years).

Table 1.

Socio-demographic characteristics of participants (N = 20)

Variable	Category	Frequency (n)	Percentage (%)
Civil status	Married	10	50.0
	Cohabiting	10	50.0
Educational attainment	Elementary graduate	5	25.0
	High school graduate	8	40.0
	Senior high school (undergraduate)	1	5.0
	Senior high school graduate	2	10.0
	College graduate	2	10.0
	Out-of-school youth	2	10.0
Occupation	Housewife	15	75.0
	Vegetable seller	3	15.0
	Food service crew	1	5.0
	Office worker	1	5.0
Monthly household income	Below ₱5,000	12	60.0
	₱5,000 – ₱7,000	3	15.0
	₱7,001 – ₱10,000	5	25.0
	Above ₱10,000	0	0.0

Note. Percentages are calculated over the full enrolled sample (N = 20).

Baseline Knowledge, Perceptions, and Acceptance

All participants reported access to health services and were already taking routine iron–folic acid supplementation at enrollment. Awareness of *Moringa* was high before the intervention began, and expectations were largely positive (Table 2). Eighteen of twenty participants (90.0%) had previously heard of *Moringa* supplements, seventeen (85.0%) believed it improves blood health, and seventeen (85.0%) were willing to take it together with ferrous sulfate.

Table 2.

Baseline knowledge, perceptions, and acceptance of Moringa oleifera supplementation (N = 20)

Indicator	Frequency (n)	Percentage (%)
Had heard of <i>Moringa/malunggay</i> before enrollment	18	90.0
Believed <i>Moringa</i> helps improve blood health	17	85.0
Believed <i>Moringa</i> is safe for pregnant women	16	80.0
Willing to take <i>Moringa</i> alongside ferrous sulfate	17	85.0
Previously consumed <i>Moringa</i> as food	19	95.0
Aware of possible side effects	10	50.0

Note. Responses were obtained before allocation and before the start of supplementation.

Baseline Comparability of the Two Groups

Baseline clinical characteristics are compared in Table 3. Age and baseline hemoglobin were similar between groups, while body weight and pre-pregnancy BMI also showed no appreciable differences. Baseline MUAC was higher in Group A than in Group B by 2.3 cm ($t(18) = 2.110$, $p = .049$), indicating an imbalance that should be considered when interpreting nutritional outcomes. Gestational age at enrollment was also similar between groups (Group A: 24.67 ± 2.78 weeks; Group B: 26.20 ± 2.62 weeks; $t = -1.267$, $p = .221$). With only ten participants per arm, these baseline comparisons are descriptive checks of randomization balance rather than evidence that the groups are statistically identical.

Table 3.

Baseline clinical characteristics by study group (n = 10 per group)

Characteristics	Group A: IFA Mean $\pm$ SD	Group B: IFA + <i>Moringa</i> Mean $\pm$ SD	<i>t</i>	<i>p</i> -value
Age (years)	28.8 $\pm$ 7.55	28.5 $\pm$ 8.05	0.086	.933
Gestational age at enrollment (weeks)	24.67 $\pm$ 2.78	26.20 $\pm$ 2.62	-1.267	.221
Hemoglobin (g/dL)	10.9 $\pm$ 0.61	11.3 $\pm$ 1.11	-0.871	.395
Body weight (kg)	56.0 $\pm$ 4.60	56.2 $\pm$ 7.19	-0.085	.933
Pre-pregnancy BMI (kg/m ²)	23.4 $\pm$ 3.10	23.1 $\pm$ 3.85	0.194	.848
MUAC (cm)	28.7 $\pm$ 2.10	26.4 $\pm$ 2.75	2.110	.049

Note. Independent-samples *t*-tests, *df* = 18. IFA = iron–folic acid; BMI = body mass index. Age values are reported from the submitted aggregate data (Group A 28.8 $\pm$ 7.55 years; Group B 28.5 $\pm$ 8.05 years; *t* = 0.086, *p* = .933). Gestational age at enrollment was 24.67 $\pm$ 2.78 weeks in Group A and 26.20 $\pm$ 2.62 weeks in Group B (*t* = -1.267, *p* = .221). Baseline comparisons are descriptive balance checks given the small sample size; the baseline MUAC imbalance should be kept in view when interpreting nutritional outcomes.

Change Within Each Group After 90 Days

Within-group changes are shown in Table 4. Both groups gained weight and MUAC over the 90-day period, as would be expected during the second and third trimesters. Hemoglobin rose in both groups: in Group A the increase of 1.38 g/dL was statistically significant, while in Group B the increase of 1.07 g/dL was not, although the two estimates overlap substantially and their confidence intervals are wide.

Table 4.

Change from baseline to Month 3 within each study group

Group and variable	Baseline Mean $\pm$ SD $\pm$	Month 3 Mean $\pm$ SD $\pm$	Mean change (95% CI)	<i>t</i> (df)	<i>p</i>
Group A: IFA alone					
Hemoglobin (g/dL), <i>n</i> = 7	10.7 $\pm$ 0.564	12.1 $\pm$ 0.844	+1.38 (0.23 to 2.53)	2.94 (6)	.026
Body weight (kg), <i>n</i> = 8	56.1 $\pm$ 5.13	63.0 $\pm$ 4.32	+6.92 (5.29 to 8.56)	10.00 (7)	< .001
MUAC (cm), <i>n</i> = 8	28.9 $\pm$ 2.54	31.0 $\pm$ 2.65	+2.06 (0.87 to 3.25)	4.08 (7)	.005
Group B: IFA + <i>Moringa</i>					
Hemoglobin (g/dL), <i>n</i> = 8	11.0 $\pm$ 1.01	12.1 $\pm$ 1.79	+1.07 (−0.20 to 2.34)	1.99 (7)	.086
Body weight (kg), <i>n</i> = 8	55.8 $\pm$ 8.04	62.3 $\pm$ 6.53	+6.49 (4.15 to 8.83)	6.55 (7)	< .001
MUAC (cm), <i>n</i> = 8	26.1 $\pm$ 2.80	27.9 $\pm$ 2.80	+1.77 (1.12 to 2.42)	6.39 (7)	< .001

Note. Paired-samples t-tests on participants with both baseline and Month 3 measurements for the variable concerned. MUAC = mid-upper arm circumference. Within-group change is not attributable to the supplement alone, since both groups received iron–folic acid and both were advancing in gestation.

Comparison Between the Two Groups

The central question of the pilot was whether the observed change estimates could inform a future definitive trial. The between-group hemoglobin difference was 0.31 g/dL in favor of Group A (Table 5), with a 95% CI of −1.24 to 1.86 g/dL and *p* = .674. This *p*-value is presented as an exploratory variance-generating result, not as a definitive test of clinical efficacy. The confidence interval is more informative for planning because it illustrates the substantial uncertainty around the effect estimate. The data remain compatible with a moderate advantage for *Moringa*, no meaningful difference, or a moderate advantage for IFA alone. The same exploratory interpretation applies to the weight and MUAC comparisons.

Table 5.

Between-group comparison of change from baseline to Month 3

Variable	Group A: IFA Mean change ± SD	Group B: IFA + Moringa Mean change ± SD	Difference (95% CI)	t (df)	p- value
Hemoglobin (g/dL)	+1.38 ± 1.24 (n = 7)	+1.07 ± 1.52 (n = 8)	0.31 (−1.24 to 1.86)	0.431 (13)	.674
Body weight (kg)	+6.92 ± 1.96 (n = 8)	+6.49 ± 2.80 (n = 8)	0.44 (−2.16 to 3.03)	0.362 (14)	.723
MUAC (cm)	+2.06 ± 1.43 (n = 8)	+1.77 ± 0.79 (n = 8)	0.29 (−0.96 to 1.54)	0.499 (14)	.626

Note. Independent-samples *t*-tests on individual change scores. A positive difference favors Group A. The hemoglobin comparison ($p = .674$) is an exploratory variance-generating estimate for planning a future definitive trial, not a confirmatory efficacy test. Given the analyzed sample sizes, retrospective power to detect a difference of the observed magnitude in hemoglobin was approximately 7%.

Adherence

Adherence to the assigned supplementation regimen was consistently high among participants who completed the 90-day intervention in both study groups (Table 6). Group A demonstrated mean adherence of 99.4% ($SD \pm 1.6$), median 100.0%; Group B demonstrated mean adherence of 99.3% ($SD \pm 1.0$), median 100.0%. Minimum adherence recorded was 95.6% in Group A and 97.8% in Group B; maximum reached 100.0% in both groups. Monthly journal entries, pill logs, and blister-foil returns showed consistent agreement, and no participant discontinued supplementation because the regimen was perceived as burdensome.

Table 6.

Adherence to the assigned supplementation regimen over 90 days

Group	n	Mean ± SD (%)	Median (%)	Minimum (%)	Maximum (%)
Group A: IFA alone	8	99.4 ± 1.6	100.0	95.6	100.0
Group B: IFA + Moringa	8	99.3 ± 1.0	100.0	97.8	100.0

Note. Two participants in each group were excluded because their records were incomplete following delivery, relocation, or loss to follow-up before completing the 90-day intervention. Adherence is expressed as the percentage of prescribed doses taken.

Acceptability

Acceptability was assessed among the eight participants who completed the 90-day intervention in both groups (Table 7). Group A reported a perfect acceptability score, mean 5.00 ($SD \pm 0.00$),

median 5.00, range 5.00–5.00, indicating unanimous acceptance of routine iron–folic acid supplementation. Group B likewise demonstrated very high acceptability, mean 4.96 ($SD \pm 0.12$), median 5.00, range 4.67–5.00. Both supplementation regimens were therefore highly acceptable, with only minimal variability observed among those receiving adjunct *Moringa oleifera*.

Table 7.

Acceptability of the assigned supplementation regimen over 90 days

Group	<i>n</i>	Mean $\pm$ <i>SD</i>	Median	Minimum	Maximum
Group A: IFA alone	8	5.00 $\pm$ 0.00	5.00	5.00	5.00
Group B: IFA + <i>Moringa</i>	8	4.96 $\pm$ 0.12	5.00	4.67	5.00

Note. Two participants in each group were excluded because they did not complete the 90-day intervention. Higher scores indicate greater acceptability (5-point Likert scale).

Safety and Reported Symptoms

No serious adverse event occurred in either group during the 90-day period, and no participant permanently discontinued supplementation because of an adverse reaction (Table 8). Six of eight participants in Group B reported no symptoms at all; one reported mild diarrhea and one mild constipation, both confined to the first month. In Group A, seven of eight participants with complete symptom monitoring reported no symptoms, and one reported mild nausea and vomiting during the second month. All events were mild, transient, managed by clinical observation and follow-up, and resolved without sequelae.

Table 8.

Symptoms and adverse events reported during the 90-day intervention

Reported symptom or adverse event	Group A: IFA (<i>n</i> = 8)	Group B: IFA + <i>Moringa</i> (<i>n</i> = 8)
No adverse event reported	7 (87.5%)	6 (75.0%)
Mild diarrhea (Month 1 only)	0 (0.0%)	1 (12.5%)
Mild constipation (Month 1 only)	0 (0.0%)	1 (12.5%)
Mild nausea and vomiting (Month 2 only)	1 (12.5%)	0 (0.0%)
Serious adverse event	0 (0.0%)	0 (0.0%)

Note. Percentages are calculated among participants who completed the 90-day intervention and had complete symptom-monitoring data. Two participants in each group were excluded for the reasons stated above.

DISCUSSION

This pilot trial set out to answer a practical question before an efficacy question: can a daily *M. oleifera* capsule be added to routine iron–folic acid supplementation inside an ordinary rural antenatal program, and will women take it? On that question the answer is unambiguous. Every woman who was randomized received her allocated regimen, mean adherence exceeded 97% in both arms, acceptability was rated 5.00 of 5.00 in Group A and 4.96 of 5.00 in Group B, and no serious adverse event occurred. Hemoglobin, body weight, and MUAC all improved within both groups over the 90-day period. Between the groups, however, no difference in the magnitude of improvement was detected for any outcome, and the point estimate for hemoglobin change in fact slightly favored iron–folic acid alone.

The temptation is to read the between-group results as evidence that *Moringa* adds nothing. That reading is not supported by these data. A statistical test answers a narrow question: is the observed difference larger than what sampling variation would readily produce, given this sample size? With 7 and 8 participants contributing paired hemoglobin values, retrospective power to detect a difference of the size observed was approximately 7%; non-significance is therefore close to uninformative about efficacy. This is the expected and accepted property of a pilot trial, which is why the CONSORT extension for pilot and feasibility trials advises reporting estimates with confidence intervals rather than framing conclusions around hypothesis tests (Eldridge et al., 2016). The 95% CI for the between-group difference in hemoglobin change runs from -1.24 to 1.86 g/dL; a difference of that magnitude in favor of *Moringa* would be clinically substantial, and the data cannot rule it out, nor can they rule out a comparable difference in the opposite direction. The honest conclusion is that this trial did not measure the effect precisely enough to say anything about it, a statement about the study's resolution rather than about the supplement.

Three considerations bear on the hemoglobin results, each arguing for caution rather than pessimism. First, the comparator is already effective: both arms received daily iron and folic acid, which reduces anemia at term by a large margin in pooled trial evidence (Peña-Rosas et al., 2015; Finkelstein et al., 2024), so any adjunct is being asked to improve on a regimen that already works. Second, within-group hemoglobin change during the second and third trimesters is confounded by gestational physiology: plasma volume expands by roughly half over the course of pregnancy, more rapidly than red cell mass, producing physiological hemodilution and its subsequent partial recovery in the third trimester (Soma-Pillay et al., 2016); variation in gestational age at enrollment across participants further complicates the within-group comparison, and stratified randomization by gestational-age category is recommended for future trials. Third, dose and preparation matter: participants received 500 mg of leaf powder daily, a quarter of the dose used in the South Sulawesi trial that reported maternal benefit (Hadju et al., 2020), and the non-heme iron in *Moringa* leaf is embedded in a matrix containing phytate and polyphenols that inhibit its absorption even as the leaf's ascorbate content works in the opposite direction (Hurrell & Egli, 2010); taking the capsule after a meal, as instructed here to improve tolerability, may also have reduced absorption relative to fasting administration.

Both groups gained weight and MUAC significantly, and the between-group differences were small and imprecise, for the same reasons that apply to hemoglobin: gestational weight gain and increasing arm circumference are expected during the second and third trimesters and cannot be attributed to either supplement from a within-group comparison alone. The baseline imbalance in

MUAC (Group A 28.9 cm, Group B 26.1 cm, $p = .049$) deserves explicit acknowledgement: with ten participants per arm, chance imbalance on some baseline variable is close to inevitable, and a definitive trial should stratify allocation on baseline nutritional status or adjust the analysis for baseline value.

The adherence and acceptability findings are the most robust results in this study and the ones a maternal nutrition program would act on. Mean adherence above 97% is unusually high against the national contrast of only about 26% completion of the recommended 180-day IFA course, concentrated among women of lower education, fewer antenatal visits, and lower household income, a profile that closely matches this study's participants (Felipe-Dimog et al., 2021), 60% of whom reported monthly household income below ₱5,000. That women in this profile achieved near-complete adherence suggests the result is a property of the delivery model (an existing barangay antenatal structure, daily SMS reminders, monthly face-to-face review, and health teaching) rather than of the participants, and the same package could plausibly raise adherence to routine IFA itself. High acceptability is easier to interpret here than in many supplement trials: 90% of participants already knew of *Moringa* and 85% were willing to take it before the intervention began, so acceptance did not have to be created, and the capsule form avoided the taste and preparation objections that attach to fresh leaves or powders mixed into food. This reflects a capsule preparation in a community where *Moringa* is already culturally embedded, and enrolled volunteers are a self-selected group whose enthusiasm may exceed that of the general antenatal population.

No serious adverse events were observed, and the three mild gastrointestinal events reported were transient and self-limiting. The single episode of nausea and vomiting occurred in the iron-only arm, consistent with the established gastrointestinal profile of ferrous sulfate (Tolkien et al., 2015). The favorable tolerability observed is consistent with meta-analytic findings that *Moringa* supplementation in anemic pregnant women produced no severe adverse events across included trials, and is likely to have been helped by the decision to use leaf-only capsules (Kalam et al., 2024), excluding root, bark, and flower material associated with uterine stimulation. These reassurances apply to 500 mg daily for 90 days from the second trimester onward and should not be extended to higher doses, first-trimester use, or whole-plant preparations. The small sample size and limited follow-up of this pilot nonetheless limit the precision of these safety findings, and larger, adequately powered trials are needed to confirm them.

The study has several genuine strengths: it is randomized, uncommon among community-based *Moringa* studies, many of which are quasi-experimental; adherence was measured objectively through three converging sources rather than self-report alone; the intervention was standardized to a single commercial source and plant part; outcome measurement used laboratory-based complete blood counts; safety monitoring was structured and prospective; and the trial was embedded entirely within routine antenatal services, so the feasibility findings describe conditions a rural health unit would actually encounter.

The limitations are substantial and should be stated plainly. First, sample size and power: only 20 participants were enrolled, and attrition reduced the paired hemoglobin analysis to 7 participants in Group A and 8 in Group B. The study therefore had negligible power to detect clinically relevant differences, and no efficacy conclusion, positive or negative, can be drawn. Second, the intervention tracking window was only 90 days, which is short relative to the duration of a full-term pregnancy; this limits assessment of sustained maternal effects and prevents meaningful conclusions about outcomes near delivery or postpartum. Third, attrition and missing data occurred because some participants delivered before the Month 3 blood count, relocated, or did not complete final laboratory follow-up; available-case analyses therefore depend on an untestable assumption

about missingness. Fourth, there was no blinding and no placebo control: participants, field staff, and outcome assessors knew the allocation, making adherence, acceptability, and symptom reporting vulnerable to expectation effects. Fifth, allocation concealment was absent because randomization used manually shuffled coded identifiers. Sixth, baseline MUAC imbalance and variable gestational age at enrollment limit interpretation of within-group change. Seventh, potential selection bias is important: recruitment was confined to two rural barangays, participants were identified through the local antenatal-care system, and volunteers may have been especially receptive to *Moringa*, limiting generalizability to less-engaged rural populations. Eighth, uncontrolled dietary intake is possible because *Moringa* is a common household vegetable in the study barangays, so control-group participants may have consumed it as food. Ninth, only one dose and one commercial leaf-powder preparation were tested. Tenth, this trial was not prospectively registered; although acceptable for a small-scale exploratory pilot, any future definitive trial must be prospectively registered (e.g., on ClinicalTrials.gov or an equivalent WHO primary registry) to comply with ICMJE standards. Eleventh, no quantitative feasibility stop/go thresholds (e.g., a minimum adherence or retention rate) were predefined before enrollment; future pilots should specify such thresholds a priori to support an objective progression decision. Additionally, the embedded qualitative data, participant journals, self-administered questionnaires, and end-of-study interviews, informed the interpretation of adherence and acceptability but are not presented here as separate thematic findings subsection; a fuller qualitative report, including specific barriers and facilitators to use, is warranted in future publications from this dataset. Finally, hemoglobin alone does not distinguish iron deficiency from other causes of anemia, and an iron-status marker such as ferritin was not available.

A pilot trial earns its place by making the next trial designable, and this one does. The pooled standard deviation of hemoglobin change observed here was 1.40 g/dL; using that estimate, a two-arm parallel trial with 80% power at a two-sided alpha of .05 would require approximately 123 participants per arm to detect a difference of 0.5 g/dL, or 55 per arm for 0.75 g/dL, and allowing 20% for the attrition observed in this pilot, roughly 148 and 66 participants per arm respectively. Detecting the 0.31 g/dL difference actually observed would require about 320 per arm, a useful indication that a difference of that size is probably not worth powering a community trial to find. Beyond sample size, this pilot points to five concrete design changes for a definitive trial: use a placebo capsule and blind participants and outcome assessors; conceal allocation using sealed opaque envelopes or a remote randomization service, stratified by trimester and baseline nutritional status; enroll at a standardized gestational window; test a higher daily dose, since 500 mg is at the low end of what published trials have used; and measure ferritin or another iron-status marker alongside hemoglobin, together with birth weight as a clinically meaningful endpoint. Retention should also be strengthened by scheduling the endline blood count before the expected date of delivery rather than at a fixed 90 days, the single largest source of data loss in this study. These calculations are presented as planning estimates rather than as evidence of efficacy (Cocks & Torgerson, 2013; Montgomery, 2025; Sim & Lewis, 2012).

Two conclusions are available to program managers now. Routine iron–folic acid supplementation remains the intervention of record for preventing maternal anemia, and nothing in these data displaces it; *M. oleifera* should be regarded as a possible complement and not a substitute. The supervision package used here (existing barangay structures plus SMS reminders plus monthly contact plus health teaching) produced adherence far above the national norm, and given that incomplete IFA adherence is a documented weakness of the Philippine program, that package may be the more immediately valuable finding of this trial.

CONCLUSION

Adding a daily 500 mg *M. oleifera* leaf capsule to routine iron–folic acid supplementation was feasible, well tolerated, and highly acceptable to pregnant women receiving antenatal care in two rural barangays of Sindangan, Zamboanga del Norte. Adherence exceeded 97% in both study arms, acceptability was rated 5.00 of 5.00 in Group A and 4.96 of 5.00 in Group B, and no serious adverse event occurred over 90 days of supplementation. Hemoglobin, body weight, and MUAC improved in both groups, but no difference between the groups was detected for any outcome. Because the analyzed sample was small and attrition further reduced it, the trial had approximately 7% power for the observed hemoglobin difference, and the confidence intervals around the between-group estimates remain wide enough to include both a clinically meaningful benefit and a clinically meaningful harm. This pilot study is therefore insufficient to establish either the clinical efficacy or the ineffectiveness of *Moringa oleifera* supplementation; the small sample size and limited number of participants available for the hemoglobin analysis prevented the study from estimating its effect with useful precision.

What the study does establish is that the intervention can be delivered within existing barangay antenatal services and that women will take it. Combined with the variance estimates reported here, this provides the basis for an adequately powered, blinded, and placebo-controlled trial of approximately 148 participants per arm, using a higher daily dose, a standardized gestational enrollment window, and an iron-status marker alongside hemoglobin. Until such a trial is completed, routine iron–folic acid supplementation should remain the primary intervention for preventing iron deficiency anemia in pregnancy, with *M. oleifera* considered a promising and locally available complement rather than a replacement.

RECOMMENDATIONS

For healthcare providers, routine iron–folic acid supplementation should continue to be promoted as the standard prenatal nutritional intervention, reinforced with maternal nutrition education and adherence counseling during antenatal care; adjunctive *Moringa oleifera* supplementation may be considered as a complementary option where appropriate, provided standardized, quality-assured leaf-based preparations are used.

For the Sindangan Rural Health Unit and local government units, pilot implementation of community-based nutrition education programs highlighting locally available nutrient-rich food sources, including *Moringa oleifera*, may be considered while continuing to prioritize routine iron–folic acid supplementation in accordance with national maternal health guidelines.

For future researchers, larger sample sizes, multiple study sites, and longer follow-up periods are needed to improve statistical power and evaluate long-term clinical effects; stratified randomization by gestational-age category at enrollment is recommended to balance gestational stage between groups. Future investigations may include additional maternal and neonatal outcomes such as birth weight, gestational age at delivery, maternal iron stores, ferritin levels, dietary intake, postpartum

recovery, and infant health outcomes, and should evaluate different dosages, durations, and formulations of *Moringa oleifera* while maintaining rigorous safety monitoring.

For policymakers, the current evidence remains preliminary because of the pilot nature of this study; wider integration of *Moringa oleifera* supplementation into routine maternal nutrition programs should await evidence from larger, adequately powered randomized controlled trials.

List of Abbreviations

BMI – Body Mass Index
CBC – Complete Blood Count
CI – Confidence Interval
CONSORT – Consolidated Standards of Reporting Trials
IFA – Iron-Folic Acid
MUAC – Mid-Upper Arm Circumference
REC – Research Ethics Committee
RCT – Randomized Controlled Trial
SAE – Serious Adverse Event
SD – Standard Deviation
SMS – Short Message Service
WHO – World Health Organization

Declarations

Ethical approval and consent to participate

This study was reviewed and approved by Zamboanga City Medical Center Research Ethics Committee (Protocol No. ZCMC-ERB-2026-09; approved March 30, 2026) and Ateneo de Zamboanga University School of Medicine. Written informed consent was obtained from all participants before enrollment; written informed assent plus parental/guardian consent was obtained for participants under 18 years of age. All procedures were conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013) and Republic Act No. 10173, the Philippine Data Privacy Act of 2012 (Republic of the Philippines, 2012).

Trial registration

Not prospectively registered.

Consent for publication

Not applicable. This manuscript does not contain identifiable individual participant data, images, or case details; all reported results are aggregated and de-identified.

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

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Declaration of Generative AI and AI-assisted Technologies

ChatGPT and QuillBot were used to assist with grammar and spelling checks, rephrasing, and summarizing of literature during manuscript preparation. AI tools were not used to generate, fabricate, manipulate, or analyze study data or results. All AI-assisted outputs were reviewed and verified by the authors, who retain full responsibility for the manuscript.

Competing Interests

None declared.

Author Contributions

Author Contributions and ICMJE Authorship. Author 1 contributed to the conception and design of the study, acquisition and analysis of data, interpretation of findings, and drafting of the manuscript. Author 2 contributed to study supervision, methodological review, interpretation of findings, and critical revision of the manuscript. Both authors reviewed and approved the final version for publication and agree to be accountable for all aspects of the work, including investigating and resolving questions concerning its accuracy or integrity. Both authors therefore affirm that they meet all four ICMJE authorship criteria.

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