STATISTICAL ANALYSIS PLAN

A Randomized Controlled Trial in Lombok: Assessing Factors Influencing Adherence to Multiple Micronutrient Supplementation (MMS) Using Digital Tools

SUMMIT INSTITUTE FOR DEVELOPMENT (SUMMIT)

Jl. Sultan Hasanuddin No 137B
Lingkungan Karang Jero, Kelurahan Karang Taliwang, Kota Mataram, Nusa Tenggara Barat, Indonesia

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Statistical Analysis Plan (SAP)

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Author	Summit Institute for Development Jl. Sultan Hassanudin No 137B, Karang Taliwang Mataram, Nusa Tenggara Barat, Postal Code, Indonesia

STATISTICAL ANALYSIS PLAN APPROVAL SIGNATURE PAGE

AUTHOR:

Name: Miftahul Jannah
Position/Title: Data Analyst

Signature **Date: 6 April 2026**

Name: Nurmalita Hartiyana Kusuma Wardani
Position/Title: Project Officer

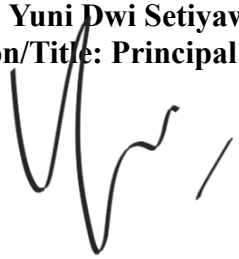
Signature **Date: 6 April 2026**

Name: Ratri Kusuma Wardani
Position/Title: Research Assistant

Signature **Date: 6 April 2026**

APPROVED BY:

Name: Yuni Dwi Setiyawati
Position/Title: Principal Investigator



Signature **Date: 6 April 2026**

Name: Aditiawarman
Position/Title: Senior Research Board

Signature **Date: 6 April 2026**

SAP Revision History
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SAP ROLES

SAP Primary Author: Miftahul Jannah (This is the name of the person directly writing most of the document.)

Senior Statistician: Aditiawarman (This is the name of the person who is the most organizationally senior who would actually read and sign off on and be accountable for the correct approaches being included.)

SAP Contributor (Project Officer): Nurmalita Hartiyana Kusuma Wardani (This is someone on the team who contributed to the SAP but did not do most of the writing nor are they the senior statistician.)

SAP Contributor (Research Assistant): Ratri Kusuma Wardani (This is someone on the team who contributed to the SAP but did not do most of the writing nor are they the senior statistician.)

1. STUDY OVERVIEW

Introduction

Multiple micronutrient supplementation (MMS) during pregnancy has been recommended to improve maternal nutritional status and pregnancy outcomes. However, adherence to supplementation programs among pregnant women remains suboptimal in many settings. Strategies to improve adherence may include both behavioral interventions, such as digital health support, and programmatic modifications, such as changes in supplement packaging that may influence ease of use and storage.

This study evaluates interventions designed to improve adherence to MMS among pregnant women in Lombok, Indonesia. The trial was designed as a 2×2 factorial cluster randomized controlled trial, with Puskesmas (primary health care facilities) serving as the unit of randomization. The factorial design evaluates two intervention components simultaneously: type of care (digital intervention vs. standard care) and type of MMS packaging (blister vs. bottle packaging). Clusters will be randomized to one of four study arms representing the combination of these two factors:

1) Standard care + bottle packaging (control group)
2) Standard care + blister packaging
3) Digital care + bottle packaging
4) Digital care + blister packaging

Eligible pregnant women attending antenatal care services at participating Puskesmas will be screened for eligibility and enrolled after providing informed consent. Participants will be followed from enrollment during pregnancy until delivery. Individual-level data will be collected on participant characteristics, MMS supplementation, adherence indicators, and pregnancy outcomes. The Infants and the mothers will be followed up to 42 days of postpartum.

The purpose of this Statistical Analysis Plan (SAP) is to define the statistical methods that will be used to analyze the trial data. The SAP specifies the analysis populations, outcome definitions, and statistical models that will be used to evaluate the effects of the digital care intervention, MMS packaging type, and their potential interaction on adherence to MMS supplementation and related outcomes.

1.1 Study Objectives

1.1.1 Primary objective

To evaluate the effects of digital care interventions and MMS packaging type on adherence to MMS among pregnant women.

1.1.2 Secondary objective

1) To assess the association between MMS adherence and pregnancy outcomes, comparing intervention and control groups.
2) To further analyze factors influencing adherence to MMS by examining pregnancy birth outcomes.

3) To examine the relationship between MMS adherence and neonatal anthropometric outcomes, including birth weight and birth length.
4) To evaluate the impact of MMS adherence on early infant growth indicators.
5) To evaluate adherence to MMS and calcium when co-administered within routine antenatal care services.
6) To evaluate the cost-effectiveness of the digital MMS intervention to inform MMS program implementation, future policy decisions and potential scale-up strategies in Indonesia.

1.2. Study Hypotheses

1.2.1 Primary Hypotheses

1) Pregnant women receiving digital care interventions will demonstrate significantly higher adherence to Multiple Micronutrient Supplementation (MMS) compared to those receiving standard care.
2) The type of MMS packaging (blister vs. bottle) significantly influences adherence to MMS among pregnant women.

1.2.2 Secondary Hypotheses

1) Higher adherence to MMS is associated with improved pregnancy outcomes compared with lower adherence.
2) Maternal adherence to MMS is associated with improved neonatal anthropometric outcomes, including higher birth weight and greater birth length.
3) Higher maternal adherence to MMS is associated with improved early infant growth indicators during the first months of life.
4) Co-administration of MMS and calcium supplementation during routine antenatal care does not reduce adherence to MMS compared with MMS alone.
5) Digital care interventions designed to improve MMS adherence are cost-effective compared with standard antenatal care approaches.
6) Individual, health system, and intervention-related factors (including digital engagement and packaging type) are significantly associated with MMS adherence among pregnant women.

2. STUDY POPULATION

2.1 Inclusion Criteria

1) Pregnant women in any trimester ≤ 32 weeks gestation
2) Pregnant women stay in the site for the duration of the study

2.2 Exclusion Criteria

1) Lost to follow-up

2) Relocation out of the study area during the study period
3) Death
4) Miscarriage

2.3 Data Acquisition

Study design	The SMART-MMS study is a 2×2 factorial cluster-randomized controlled trial, with puskesmas (community health centers) serving as the unit of randomization. Clusters are allocated to one of four study arms: (1) Standard Care + Bottle, (2) Standard Care + Blister, (3) Digital Care + Bottle, and (4) Digital Care + Blister. The factorial design allows estimation of the independent effects of digital adherence support and packaging format, as well as their interaction. **Design**: 2×2 factorial cluster-randomized controlled trial **Unit of randomization**: Puskesmas (community health center) **Unit of analysis**: pregnant women **Number of arms**: 4
Data source	Data will be collected as part of the trial through primary data collection conducted at participating Puskesmas. Information will be obtained at enrollment and during follow-up visits throughout pregnancy using standardized data collection instruments administered by trained study staff. Data sources will include maternal and child health records (Buku KIA) documented during Posyandu visits, data collected during home visits, and electronic case report forms captured through the KoboCollect platform. Additionally, relevant data will be extracted from existing government legacy health information systems to complement the primary data collected during the study.
Data transfer method	Data collected at the study sites will be compiled into the study database and transferred to the statistical analysis team through secure electronic transfer after completion of data cleaning and verification procedures. The dataset used for statistical analysis will correspond to the final cleaned dataset.

	Data collected through electronic forms using the KoboCollect platform will be synchronized to the KoboToolbox server and subsequently transferred to a secure cloud environment hosted on the Google Cloud Platform (GCP) for centralized storage and management. Data extraction and processing for analysis will be conducted within the GCP environment. For data management and analysis activities—including data cleaning, recoding, and dataset merging—authorized analysts may access the database through a secure remote desktop environment using statistical software such as SAS.
Data storage	The dataset used for statistical analysis will be stored in a secure cloud-based storage environment hosted on the Google Cloud Platform (GCP). Data management processes, including data validation, merging, and structured query operations (e.g., SQL queries), will be conducted within the GCP environment to ensure data security and integrity. Access to the data will be restricted to authorized study personnel in accordance with data protection and study governance procedures.

3. OUTCOME AND EXPOSURE

3.1 Primary Outcome

Primary Outcome			
1.	Adherence to MMS	Mean proportion of recommended MMS tablets consumed from enrollment until delivery	The primary outcome is the level of adherence to MMS supplementation among pregnant women enrolled in the study. Adherence reflects the extent to which participants consumed the MMS tablets distributed through the study during the follow-up period of pregnancy.

			Adherence will be assessed based on the proportion of MMS tablets consumed relative to the number of tablets expected to be taken during the observation period. The primary outcome will be derived from the following variables collected during the study: - Number of MMS tablets distributed to the participant - Number of MMS tablets remaining or reported as unused - Self-reported supplement intake (if applicable) - MMS distribution and monitoring records maintained by study staff and health workers at participating Puskesmas These data will be collected through study monitoring forms and antenatal care records during routine follow-up visits. Adherence will be calculated as: $$Adherence(\%) = \frac{\text{Number of MMS tablets consumed}}{\text{Number of MMS tablets expected to be taken}} \times 100$$ where: - Tablets consumed = tablets distributed − tablets remaining (or missed doses reported). - Expected tablets = number of days between first MMS distribution and end of follow-up multiplied by the recommended daily dose. Depending on the planned analysis, adherence may be analyzed as: - a continuous variable (percentage of MMS adherence)

3.2 Secondary Outcomes

Secondary Outcomes

1.	Pregnancy and Birth outcome	Gestational Age at Birth	Gestational age (GA) will be calculated in completed weeks based on first-trimester ultrasound where available (preferred), or last menstrual period if ultrasound is unavailable. Mean GA at delivery will be reported.
		Preterm Birth	Proportion of live births occurring at <37 completed weeks of gestation.
		Very and Extremely Preterm Birth	Proportion of pregnancies delivered before these gestational age: at <34 weeks, <32 weeks, and <28
		Post-term Birth	Proportion of live births occurring at >42 completed weeks of gestation.
		Stillbirth	Proportion of pregnancies resulting in fetal death ≥28 weeks of gestation occurring before or during labor and before complete expulsion or extraction.
		Perinatal Mortality	Stillbirth (≥28 weeks gestation) or death of a liveborn infant within 7 completed days of birth.
		Neonatal Mortality	Death of a liveborn infant within 28 completed days of birth.
		Early Neonatal Mortality	Death within 7 completed days of birth.
		Late Neonatal Mortality	Death occurs after 7 days but within 28 days of birth.
2.	Neonatal Anthropometric Outcomes	Birth Weight	Mean birth weight (grams), measured within 1 hour of birth using calibrated mechanical or digital scales.
		Low Birth Weight (LBW)	Proportion of infants with birth weight <2500 g (≤2500 g if scale increments are 100 g).
		Small for Gestational Age (SGA, 3rd Centile)	Proportion of infants with birth weight <3rd centile of INTERGROWTH-21st standards by gestational age and sex.

		Large for Gestational Age (LGA, 90th Centile)	Proportion of infants with birth weight >90th centile of INTERGROWTH-21st standards by gestational age and sex.
		Birth Length	Mean birth length (cm).
		Short for Gestational Age (10th Centile)	Proportion of infants with birth length <10th centile of INTERGROWTH-21st standards by gestational age and sex.
		Short for Gestational Age (3rd Centile)	Proportion of infants with birth length <3rd centile of INTERGROWTH-21st standards by gestational age and sex.
		Head Circumference	Mean head circumference at birth (cm).
		Infant Sex	Proportion of male and female live births.
3.	Infant growth	Length-for-age z-score (LAZ)	Mean length-for-age z-score (LAZ)
		Weight-for-Length Z-score (WLZ)	Mean weight-for-age z-score (WAZ)
		Weight-for-Age Z-score (WAZ)	Mean weight-for-length z-score (WLZ)
		Stunting	Proportion of infants with LAZ < −2 at 1 months.
		Wasting	Proportion of infants with WLZ < −2 at 6 months.
		Underweight	Proportion of infants with WAZ < −2 at 6 months.
4.	Cost effectiveness	The total cost required for each treatment group divided by The number of pregnant women who adhere with supplementation	$Cost\ effectiveness$: $\frac{Total\ Cost}{Number\ of\ Adherence}$

		consumption in each treatment group.	
5	Calcium adherence	Mean Proportion of Recommended Calcium and MMS Consumed from Enrollment Until Delivery	Adherence will be defined as the proportion of recommended daily doses consumed from week 20 until delivery. Dose consumption will be measured using digital tracking data (QR code scans), self-reports, and/or supplement counts where applicable. The outcome will be expressed as mean adherence proportion (%) per participant.

3.3 Exposure

Independent Variables			
1.	Individual Characteristic	Age	Maternal age will be calculated as the difference between the date of interview/enrollment and date of birth (DOB), expressed in completed years.
		Occupation	Occupational status will be categorized based on the participant's primary employment at the time of enrollment
		Education status	Highest level of formal education completed
		Marital status	Marital status at the time of enrollment
		Number of pregnancy	Number of pregnancies (gravidity) will be defined as the total number of times the participant has been pregnant, including the current pregnancy, regardless of pregnancy outcome.
		Number of children	Number of living children will be defined as the total number of live-born children at the time of enrollment
2	ANC 12 components Standard Care	Antenatal Care (ANC) Visit Frequency	Mean number of ANC visits attended per participant during pregnancy, and proportion of women attending ≥6 ANC visits from enrollment through delivery, following the national recommendation.

		Antenatal Care (ANC) Completeness	Proportion of pregnant women who complete the recommended minimum of six ANC visits from enrollment through delivery, including at least one visit in the first trimester, two visits in the second trimester, and three visits in the third trimester. Completeness will also include receipt of standardized ANC services ("12T" package), consisting of anthropometric assessment, blood pressure measurement, nutritional status assessment (MUAC), uterine fundal height measurement, fetal presentation and fetal heart rate assessment, tetanus-diphtheria immunization screening, provision of ≥90 iron-folic acid tablets, recommended laboratory testing (including hemoglobin and triple elimination testing for HIV, syphilis, and hepatitis B), counseling, limited obstetric ultrasound (first and third trimester), and mental health screening, following the national guideline.
		Antenatal Care (ANC) Timeliness	Proportion of women initiating ANC in the first trimester (≤14 completed weeks of gestation) and attending ANC visits according to the recommended trimester distribution (1 visit in first trimester, 2 visits in second trimester, 3 visits in third trimester). Timeliness will also include completion of first-trimester ultrasound screening and third-trimester ultrasound as recommended.
3.	Maternal Biomedical Status	Maternal Hemoglobin (Hb)	Mean maternal hemoglobin concentration (g/dL) measured in the first and third trimester.
		Maternal Anemia (Third Trimester)	Proportion of women with hemoglobin <11.0 g/dL during the first and third trimester.

		Maternal weight gain	Maternal weight gain during pregnancy
4.	Socioeconomic Status	Wealth Index	Household socioeconomic status will be assessed using a composite wealth index derived through principal component analysis of household assets, housing materials, water and sanitation facilities, energy source, crowding, livestock ownership, and income. The first principal component will be retained to generate standardized SES scores, which will be categorized into tertiles or quintiles for analysis.

4. STATISTICAL ANALYSIS PLAN

4.1 Sample Size Calculation

This study applies a two-stage randomized design, consisting of (1) a cluster-randomized controlled trial (RCT) for MMS adherence, and (2) cluster nested randomization for calcium supplementation in posyandu level. The sample size calculation is based on the supplement distribution design, the likelihood that not all pregnant women will complete the program, the annual birth rate, and statistical calculations ensuring the results will be meaningful. Taking these factors into account, it is estimated that approximately **10,012 pregnant women** need to participate in the MMS program. Detailed calculations for sample size are as follows:

Table 2. Key parameter in sample size calculation

Parameter	Value	Source/Note
Randomization Unit	Cluster (Puskesmas) for MMS adherence; Individual (pregnant woman) for calcium dose	Two-stage randomization design: Stage 1 cluster-level, Stage 2 posyandu level
Effect Size	10% difference in MMS adherence (0.80 vs 0.90)	Based on expected adherence improvement with digital support (8)
Alpha (Type I Error)	0.05	Standard threshold for 95% confidence interval
Power (1–β)	0.80	To detect a significant adherence difference

Loss to Follow-Up (Attrition Rate)	32%	Based on previous SUMMIT Trial in Lombok
Intraclass Correlation Coefficient (ICC)	0.03	Estimated within expected range (0.01–0.05) for community-based studies
Average cluster size (n)	114.5	Average number of first-trimester pregnant women per cluster
Design Effect (DE)	4.41	DE = 1 + (n – 1) × ICC
Adjusted Design Effect (Adj DE)	4.28	Adj DE = DE / (1 + ICC)
Unadjusted sample size per group	397	Calculated using Lemeshow formula for two proportions (P_1 = 0.80; P_2 = 0.90)
Adjusted sample size per group (after DE)	1,702	397 × 4.28
Adjusted sample size per group (after attrition)	2,503	1,702 / (1 – 0.32)
Total sample size	10,012	2,503 × 4 groups (Bottle Intervention, Blister Intervention, Bottle Control, Blister Control)
Sub Sample Calcium	900 Calcium Carbonate (500 mg) and no calcium	Nested Cluster randomization by posyandu

Unadjusted Sample Size Calculation

Sample size calculation for proportion comparison, we will use the following formula (Lemeshow)

$$n = \frac{2\left\{Z_{1-\frac{\alpha}{2}}\sqrt{2P(1-P)}+Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}\right\}^2}{(P_1-P_2)^2}$$

n = unadjusted minimum sample

$Z_{1-\frac{\alpha}{2}}$ = Z value with confident interval 95% (1,96)

$Z_{1-\beta}$ = Z value with power 80% (0,84)

P $= \frac{(P_1+P_2)}{2} = 0.85$

P_1 = Proportion in group 1 = 0.80

P_2 = Proportion in group 2 = 0.90

Unadjusted sample size per group as follow:

$$n = \frac{2\left\{1.96\sqrt{2\times0.85\times0.15}+0.84\sqrt{0.80\times0.2+0.9\times0.1}\right\}^2}{(0.1)^2}$$

n=397.47

Design Effect

Due to the clustering effect, it is necessary to account for the fact that individuals within the same cluster tend to have similar (homogeneous) characteristics compared to individuals from different clusters. This clustering effect is represented by the Design Effect (DE). The formula for calculating the design effect is as follows:

$$DE = 1 + (n-1) \times ICC$$

ICC = Intracluster correlation coefficient, measures the correlation between individuals within the same cluster compared to individuals in different clusters. It represents the degree of similarity or homogeneity among individuals within a cluster. The ICC can be calculated from previous studies, if available. If no prior data is accessible, the ICC is typically estimated to fall within the range of 0.01 to 0.05. For this study, the ICC will be set at **0.03**.

n = Number of interquartile range of pregnant women in first trimester 114.5

$$DE = 1 + (n-1)\times ICC$$

$$DE = 1 + (114.5 - 1)\times 0.03$$

$$DE = 4.41$$

Adjusted Design Effect

$$Adj\ DE = \frac{DE}{1+ICC}$$

$$Adj\ DE = \frac{4.41}{1+0.03}$$

Adj DE = 4.28

Number of Sample per Group

$$n_{group} = N \times DE$$

$$= 397.47 \times 4.28 = 1{,}702$$

Adjusted Sample per Group

The Attrition Rate (AR) is set at 0.32, based on previous MMS studies conducted in Lombok. This rate accounts for participants who are lost to follow-up, drop out, relocate, die, experience abortion, or stillbirth during the study period.

$$n_{adj} = \frac{n_{group}}{1 - AR}$$

$$n = \frac{1{,}702}{1-0.32}$$

n= 2,503

This study includes 4 groups (bottle intervention, blister intervention, bottle control, blister control). Thus, the total sample size for this study will be 2,503×4=**10,012**

Calcium (Sub-sample)

The total sample size for the calcium sub-study will be 900 pregnant women, equally allocated between intervention and control groups.

Participants will be divided as follows:

Table 3. Subsample calcium allocation

Type of Group	Calcium subsample	Number of Sample
Intervention	MMS + Calcium Carbonate (500 mg elemental)	450
Control	MMS + No Calcium	450

The intervention group will receive multiple micronutrient supplements (MMS) in combination with 500 mg of calcium daily, while the control group will receive MMS alone without additional calcium supplementation.

This sub-sample size was determined based on the adherence evidence reported on multidoses regiment (32), which demonstrated higher adherence with once-daily dosing compared to multiple daily dosing regimen

4.2 Randomisation, Stratification, Blinding, and Replacement of participants

In the first stage, randomization is conducted at the puskesmas level, with a total of 60 puskesmas allocated into four intervention arms. The randomization process utilizes data management tools to generate randomization numbers, followed by stratification based on median, upper, and lower values of pregnancy rates to ensure balanced distribution across population characteristics. Following this process, the 60 puskesmas are assigned to four distinct intervention clusters: 1) Digital-Bottle (MMS provided in bottles, with adherence supported through a digital reminder and monitoring tool), 2) Digital-Blister (MMS provided in blister packs, with digital adherence support), 3) Non-Digital-Bottle (MMS in bottles without digital support, standard counselling only), 4) Non-Digital-Blister (MMS in blister packs without digital support). Puskesmas are randomly assigned in 1:1:1:1 ratio to these four MMS arms. The randomization schema is designed to be reproducible and minimize bias, providing a transparent framework for the assignment of interventions to each puskesmas cluster. This second-stage randomization is implemented to ensure balanced allocation of calcium supplementation across all four MMS arms from Stage 1. In other words, within each MMS intervention arm, posyandu are proportionally and randomly assigned to calcium or no-calcium groups to maintain comparability and avoid systematic imbalance across treatment combinations.

4.3 Data Preprocessing

Prior to analysis, data will undergo preprocessing procedures including data cleaning, validation of variable ranges, and consistency checks across datasets. Derived variables will be created as required for the analysis, including calculation of MMS adherence proportions, gestational age at delivery, infant anthropometric z-scores based on standardized growth references, etc.

4.4 Handling Missing Data

The extent and patterns of missing data will be examined for all key variables. If the proportion of missing data is small, complete-case analysis will be used. If missingness exceeds a predefined threshold, multiple imputation methods may be considered under the assumption that data are missing at random.

4.5 Descriptive Analysis of Baseline Characteristics

Baseline characteristics of participants will be summarized for each of the four study arms. This section will include:

1) Maternal sociodemographic characteristics
2) Baseline health indicators
3) Pregnancy characteristics
4) Pregnancy outcomes

Balance across arms will be assessed descriptively. Baseline characteristics will be summarized by study arm using mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables, and frequency and percentage for categorical variables. No formal statistical testing of baseline differences will be conducted. Participant flow will be reported in accordance with consort guidelines for cluster randomized trials.

4.6 Primary Outcome Analysis

The primary objective is to evaluate the effect of digital interventions on adherence to multiple micronutrient supplementation among pregnant women. Adherence will be expressed as the proportion of recommended doses consumed during the observation period.

The primary analysis will use Generalized Linear Mixed Models (GLMM) to account for the hierarchical structure of the data, where participants are nested within Puskesmas. A random intercept for Puskesmas will be included to account for clustering due to the cluster randomized design. Because the study follows a 2×2 factorial design, the model will include fixed effects for digital intervention (digital vs. standard care) and supplement packaging (blister vs. bottle). The choice of distribution for the GLMM will depend on the distributional characteristics of the adherence outcome:

- If the adherence proportion is approximately symmetric and normally distributed, a Gaussian GLMM with identity link will be used.
- If the adherence outcome is bounded between 0 and 1 and exhibits skewness typical of proportion data, a Beta GLMM with logit link will be considered.
- adherence may also be categorized (e.g., $\geq$ 80% adherence vs. $<$ 80%) and will be analyzed using a binomial GLMM with logit link, with a random intercept for Puskesmas.

Model diagnostics and distributional assessment will be conducted prior to finalizing the model specification. Effect estimates will be reported with 95% confidence intervals, and statistical significance will be assessed using two-sided tests with a significance level of 0.05.

4.7 Secondary Outcome Analysis

Outcome	Outcome Type	Statistical Model	Effect Measure
Gestational Age at Birth	Continuous	Poisson regression with robust variance	Relative Risk (RR) with 95% CI
Preterm Birth, Post-term Birth, Very and Extremely Preterm Birth	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI
Stillbirth, Perinatal Mortality, Neonatal Mortality, Early Neonatal	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI

Mortality, Late Neonatal Mortality			
Birth Weight	Continuous	Linear mixed-effects model	Adjusted mean difference with 95% CI
Low Birth Weight (LBW), Small for Gestational Age (SGA, 3rd Centile), Large for Gestational Age (LGA, 90th Centile)	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI
Birth Length	Continuous	Linear mixed-effects model	Adjusted mean difference with 95% CI
Short for Gestational Age (10th Centile), Short for Gestational Age (3rd Centile)	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI
Head circumference	Continuous	Linear mixed-effects model	Adjusted mean difference with 95% CI
Infant sex	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI
Length-for-age z-score (LAZ)	Continuous	Linear mixed-effects model	Adjusted mean difference with 95% CI
Weight-for-Length Z-score (WLZ)	Continuous	Linear mixed-effects model	Adjusted mean difference with 95% CI
Weight-for-Age Z-score (WAZ)	Continuous	Linear mixed-effects model	Adjusted mean difference with 95% CI
Stunting	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI

Wasting	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI
Underweight	Binary	Mixed-effects logistic regression	Adjusted Odds Ratio (aOR) with 95% CI
Cost Effectiveness		Descriptive analysis	
Calcium Adherence	Continuous / Binary	Generalized linear mixed model	Mean difference / aOR with 95% CI

All secondary outcome analyses will include MMS adherence as the primary exposure variable. Individual characteristics, receipt of ANC 12T standard care, maternal biomedical status, and socioeconomic status will be included as covariates for adjustment.

4.8 STATISTICAL PACKAGE

All analyses and tabulations will be performed using SAS Version 9.4 or higher on a PC platform, R Version 4.5 or higher may be used for statistical graphics and statistical inferences, and STATA version 17 for other inferential analysis.

5. SCHEDULE OF EVENTS

To make following the sequence of events and timing of patient assessments, the schedule of events from the protocol should be reproduced here. It may be necessary to insert other statistical events into the schedule i

Events	*Month*											
	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*
Enrollment												
Monitoring												
Interim Analysis												
Final Analysis												
Study Termination												

Declarations

Ethics Approval and Consent to Participate

This Statistical Analysis Plan (SAP) does not involve direct interaction with human participants or access to identifiable personal data. Ethical approval and informed consent are therefore not applicable. The SAP is developed based on the study protocol, which has obtained the necessary ethical approvals.

Consent for Publication

Not applicable.

Availability of Data and Materials

No primary data were generated or analyzed as part of this SAP. The document outlines the planned statistical analyses for the study. All relevant methodological details are included within the manuscript.

Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Authors' Contributions

- ***Author 1:*** *Conceptualization, Methodology, Formal Analysis, Investigation, Project Administration, Software, Visualization, Writing – Original Draft Preparation*

- ***Author 2:*** *Conceptualization, formal analysis Supervision, Writing – Original Draft Preparation, project administration. Project field supervision*

- ***Author 3:*** *Conceptualization, Formal Analysis, Supervision, Validation,Writing – Review & Editing, project administration*

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Not applicable.

Research Data for This Article

This article does not report results from data analysis. No datasets were generated or analyzed as part of this Statistical Analysis Plan. Therefore, no data are available for sharing.