Nutritional support for lactating women with or without azithromycin for infants compared to breast-feeding counseling alone in improving the six-month growth outcomes among infants of peri-urban slums in Karachi, Pakistan
(Mumta LW Trial)

Statistical Analysis Plan

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Contents

1. Introduction

This is a community-based, open-label, multiarm randomized controlled trial that will include parallel group assignments with a 1:1:1 allocation ratio in low-income squatter settlements in urban Karachi, Pakistan. The women in the control group (control arm) will receive standard counseling only, whereas the lactating women in the first intervention group (intervention arm 1) will receive two sachets of balanced energy-protein (BEP) supplementation per day from enrollment until the infant reaches six months of age. The lactating women in the second intervention group (intervention arm 2) will receive the same BEP supplementation as those in intervention arm 1 while their babies will also receive a single stat dose (20 mg/kg orally) of Azithromycin at 42 days.

2. Objectives

The primary objective is to compare the efficacy of fortified, balanced energy-protein (BEP) supplements being consumed by lactating women for 6 months (intervention arm 1) with or without a single prophylactic dose of oral azithromycin to the infant at 42 days of age (intervention arm 2) with that of standard exclusive breastfeeding and nutritional counseling alone (control arm) in improving length velocity among infants at 6 months (outcome). The secondary outcome is to compare the impact of the interventions on weight (or growth) velocity, Z-scores, other anthropometry measures of infants, maternal weight changes, breast milk quality, gut microbiota, and key micronutrient levels in both the mother and infant.

3. Study setting and study population

The trial is being conducted in the peri-urban communities of Karachi, Pakistan. The study population includes only lactating women of reproductive ages who have recently delivered and their infants. Lactating women between 13 and 49 years of age and their newborns are the study population.

4. Primary hypothesis

Length velocity at 6 months of infant's age

H_a = Mean difference in length velocity of >0.12cm/month to look at comparisons between multiple arms

H_o = Mean difference in length velocity of ≤ 0.12cm/month to look at comparisons between multiple arms

5. Secondary hypothesis

Growth velocity at 6 months of infant's age

H_a = Mean difference in growth velocity of >0.4 gram/kg/day to look at comparisons between multiple arms

H_o = Mean difference in growth velocity of ≤ 0.4 gram/kg/day to look at comparisons between multiple arms

Length-for-Age Z-score (LAZ) at 6 months of infant's age

H_a = Mean difference in LAZ >0.5 to look at comparisons between multiple arms

H_o = Mean difference in LAZ ≤0.5 to look at comparisons between multiple arms

Weight-for-Length Z-score (WLZ) at 6 months of infant's age

H_a = Mean difference in WLZ >0.5 to look at comparisons between multiple arms

H_o = Mean difference in WAZ ≤0.5 to look at comparisons between multiple arms

Weight-for-Age Z-score of (WAZ) at 6 months of infant's age

H_a = Mean difference in WAZ >0.5 to look at comparisons between multiple arms

H_o = Mean difference in WAZ ≤0.5 to look at comparisons between multiple arms

6. Sample Size

There are limited data available on the impact of BEP on length velocity over the first 6 months of life in infants. However, in one of the studies, the mothers received only perinatal supplement, and the overall increase in length (cm/month) was β =3.289 among the LNS group and β = 3.346 among the MMN group. (1) However, the women in this trial received supplements with smaller doses/energy than the women in our study will receive, and the intervention time was also different, i.e., the perinatal period rather than the infancy period. Another study showed that the difference in length velocity (cm/month) was 0.02 between the MMN and IFA groups over the period of 0-18 months. (2) Therefore, in the absence of clear evidence on the impact of these

interventions, we hypothesized the effect size to be 0.12 cm/month. This is also based on learning through field experience; when severely malnourished lactating women (MUAC < 19.0 cm) were provided with chickpea-based ready-to-eat supplements (100 gm/day for 3 months), the difference was 0.06 cm/month at 3 months of age between these women and women who did not receive any supplements (unpublished data that was used purely for implementation and was not included in a study).
The null hypothesis for this trial is that the mean difference in length velocity between an infant of a lactating woman receiving standard breastfeeding counseling with BEP alone (Intervention arm 1) for 6 months or in combination with a single prophylactic dose of azithromycin at 42 days of age (Intervention arm 2) and an infant of a lactating woman receiving standard breastfeeding counseling alone (control arm) is equal or less than 0.12 cm/month (primary outcome). Due to the absence of evidence of such interventions on length velocity, we based this hypothesis on our local experience and field data from our field sites. The alternate hypothesis for this trial is that an infant of a lactating woman receiving BEP alone for 6 months or in combination with a single prophylactic dose of azithromycin at 42 days of age has a mean length velocity is greater than 0.12 cm/month that of an infant of a lactating woman not receiving an intervention at 6 months. The sample size takes multiple comparisons into account and is based on the primary outcome of length velocity with an effect size of difference of 0.12 cm per month between the arms (i.e., 0.72 cm difference at 6 months), a 1-sided test, power of 80% and an alpha of 0.025 to account for multiple comparisons (the lower alpha – Bonferroni correction was used). A drop-out rate of 14% (i.e., 10% loss to follow up and infant mortality rate of 4%) is assumed in the study, so the minimum total sample size required is 957 (319 lactating women in each arm).

7. Eligibility criteria

Inclusion Criteria

a) Lactating women with a mid-upper-arm-circumference (MUAC) of < 23.0 cm
b) Infants with a live birth outcome, captured within 168 hours (0-6 days)
c) Individuals with the intention to stay in the catchment area for entire duration of trial after enrollment
d) Individuals with the intention to exclusively breastfeed child for at least 6 months of age
e) Individuals who have provided voluntary written informed consent

Exclusion Criteria

a) Newborns with a birth weight of less than 1500 grams
b) Newborns with a known congenital anomaly or other severe illness based on the study physician's assessment before enrollment.
c) Lactating women with known allergies to peanut, lentils, chickpea or dairy products
d) Individuals who were previously enrolled in the trial

8. Blinding

The outcome assessors will be blinded, responsible only for the anthropometry measurements, and will be assigned a schedule that does not overlap with those of the follow-up teams. All investigators will also be blinded to group allocation throughout the period of the study. Furthermore, a statistician will independently perform the interim analysis for the Data Safety and monitoring board (DSMB) blinded by arm. Furthermore, the data analyst who will perform the final analysis will be blinded, and the code will eventually be revealed after the blinded results are shared with DSMB and investigators in a final review meeting. This is an unblinded study so SAEs may be related to use of BEP, unlikely to be blinded.

9. Treatment allocation

Stratified block randomization with blocks of sizes 3, 6, and 9 is used. Sequence generation will be performed by an independent statistician using a random selection method before the beginning of the trial. Self-adhesive, pre-coded sticky labels with unique identification numbers will be applied to sealed opaque envelopes containing the coded randomization identification number and intervention name to ensure that the

randomization process and allocation are blinded. Baseline information regarding nutrition and exclusive breastfeeding will be recorded. Anthropometry measurements of both the mother and newborn will be performed. The allocation ratio is 1:1:1.

10. Outcomes variables

10.1. Primary growth outcome*

- **'Length velocity (cm/month) of infant'** at 6 months is define as = (Length at 6-month visit – Length at baseline)/ (Date of visit of visit at 6-month – Date of enrollment) *30.4. (3)

10.2. Secondary growth outcomes*

- **'Growth velocity (gm/kg/day) of infant'** at 6 months is define as per Patel Exponential method = [1000 x ln (Weight at 6-month visit – Weight at baseline)] / (Date of visit of visit at 6-month – Date of enrollment). (4)

- **'Weight gain (gm/month) of infant'** at 6 months is define as = (weight at 6-month visit – weight at baseline)/ (Date of visit of visit at 6-month – Date of enrollment) *30.4.

- **'LAZ, WAZ and WLZ of infant'** at 6 months is define as per WHO z-anthro 2006 guidelines and standard queries. Change in

- **Stunting** at 6-month is define as <-2 SD length for age z score

- **Wasting** at 6-month is define as <-2 SD weight for length z score

- **Underweight** at 6-month is define as <-2 SD weight for age z score

- **'Gain in infant MUAC (cm/month)'**, at 6 months is define as = (MUAC at 6-month visit – MUAC at baseline)/ (Date of visit of visit at 6-month – Date of enrollment) *30.4

- **'Gain in infant head circumference (cm/month)'**, at 6 months is define as = (head circumference at 6-month visit – head circumference at baseline)/ (Date of visit of visit at 6-month – Date of enrollment) *30.4

- **'Maternal weight change Kg/month',** at 6 months is define as = (Maternal weight at 6-month visit – Maternal weight at baseline)/ (Date of visit of visit at 6-month – Date of enrollment) *30.4

- **'Gain in Maternal MUAC (cm/month)'**, at 6 months is define as = (MUAC at 6-month visit – MUAC at baseline)/ (Date of visit of visit at 6-month – Date of enrollment) *30.4

*All measurements were taken at baseline, then day 27, 56, 89, 114, 143 and 177-179 of infant's age. we allow a window until next follow-up is appeared.

10.3. Outcomes related to biomarkers of mother-infant dyad at day 40-42 and 56+

- **Maternal anemia,** categorized as mild: Hb 11.0-11.9 g/dl, moderate: Hb 8.0-10.9 g/dl, and severe: Hb <8.0 g/dl. (5)
- **Maternal iron deficiency,** define by Ferritin <15 ng/mL (6) and (separately) Soluble transferrin receptor (sTfR) (IQR will be calculated)
- **Infant anemia,** categorized as mild: Hb -11.0-11.9 g/L, moderate: Hb 7.0-10.9 g/dl, and severe: Hb < 7.0 g/dl. (7)

- **Infant iron deficiency,** define by Ferritin <12ng/mL (6) and (separately) Soluble transferrin receptor (sTfR) (IQR will be calculated)
- **Maternal C-reactive protein (CRP) (mg/l)**, IQR will be calculated
- **Maternal alpha1-acid glycoprotein (AGP),** IQR will be calculated
- Specific hypothesis driven analysis pertaining to breastmilk analysis – refer to plan of analysis developed with IMiC team at Azad Lab
- Specific hypothesis driven analysis pertaining to stool biomarker analysis – refer to plan of analysis developed with team at Stanford university.

10.4. Outcome related to serious adverse events

Adverse and serious adverse event reporting and categorization

- Vomiting: Persistent vomiting or projectile vomiting in an infant reported by mother, within duration of 6 months (Observed or reported).
- Poor feeding/suck: If an infant develops poor feeding/suck or is unable to feed within duration of 6 months (Observed or reported).
- Necrotizing Enterocolitis: Abdominal distention/tenderness, bowel movements, signs of infection such as apnea (stop breathing), and lethargy within duration of 6 months (Observed or reported).
- Diarrhea: Loose stool in an infant reported by mother, lead to severe dehydration, within duration of 6 months (Observed or reported).
- Respiratory: Respiratory distress: Fast breathing (60 or more breathes per minutes) and/or severe chest in drawing and/or baby turn bluish, within duration of 6 months (Observed or reported).
- Rash: An appearance of itchy, red, painful, and irritated skin, visible by health worker or reported by family, within duration of 6 months (Observed or reported).

Serious Adverse Event

Any adverse event will be labeled as a "Serious Adverse Event" (SAE) if it leads to:

a. Intravenous therapy
b. Hospitalization
c. Life threatening situation
d. Death

This is defined per clinician's assessment

Definition of mortality

Infant Mortality	Any infant death under one year of age.[4] An agreement was reached to also capture cause of death[5], date of death, and time of death (if death is within 7 days of birth).
Neonatal mortality	Deaths among live births during the first 28 completed days of life (0-27 days). Rate (per 1000 live births) Numerator: # deaths <28 days Denominator: # live births
Maternal Mortality	Maternal death from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes), during pregnancy and childbirth, or within 42 days of termination of pregnancy.

10.5. Co-variates definition

Variable	Definition	Source
Preterm birth (PTB)	Live birth <37 completed weeks (and very preterm birth: live birth <32 completed weeks)	Baseline

Preterm delivery	Any birth outcome ≥22 and <37 completed weeks based on LMP or Ultrasound data, whichever is available.	Baseline
Gravidity	Self-reported number of time woman got pregnant, including the enrolled child	Baseline
Parity	Number of live births (plus stillbirths)	Baseline
Prelacteal feeding (<72 hours)	Infant receives any liquids of foods other than breast milk, vitamins, minerals, or medicines identified at baseline (e.g., honey, ghee, boiled water, goat's milk, ritual fluids).	Baseline
Exclusive breastfeeding	Infant receives breast milk and nothing else except vitamins, minerals, or medicines (e.g., ORS, drops, or syrups). Breast milk can be breast or bottle fed and from mother or wet nurse.	Follow-ups
Predominant breastfeeding	Infant receives breast milk as the predominant source of nourishment. Infant may also receive other liquids (water, fruit-juice, water-based drinks, ritual fluids) or vitamins, minerals or medicines. Infant may NOT receive non-human milk or food-based fluids.	Follow-ups
Partial breastfeeding	Infant receives breast milk and infant formula or non-human milk (also may receive any other liquids).	Follow-ups
No breastfeeding	Infant receives no breast milk.	Follow-ups
Solid or semi-solid feeding	Infant receives solid, semi-solid, or soft foods.	Follow-ups
Age at introduction of solid foods	Age at which caregivers begin to provide solid, semi-solid, or soft foods.	Follow-ups
Early initiation of breastfeeding	Infant was breastfed within 1 hour of birth (includes infants who die beyond one hour of birth).	Baseline
Exclusive breastfeeding duration	Total time that infant was exclusively breastfed (in weeks) [could also assess breastfeeding duration past introduction of complementary food]	Follow-ups
Adherence to intervention	Mean percent of assigned supplement that was consumed (out of total eligible and supplementation time)	Follow-ups
Total time on supplement	Total time BEP supplement consumed during lactation (days)	Follow-ups
Kcals per day (from supplement)	Mean kcals consumed per day from supplement	Follow-ups
Protein per day (from supplement)	Mean protein (g) consumed per day from supplement	Follow-ups
Kcals per day (dietary intake)	Mean kcals consumed per day in maternal diet (not including BEP supplement)	Follow-ups
Carbohydrates per day (dietary intake)	Mean carbohydrate (g) consumed per day in maternal diet (not including BEP supplement)	Follow-ups

Protein per day (dietary intake)	Mean protein (g) consumed per day in maternal diet (not including BEP supplement)	Follow-ups
Fat per day (dietary intake)	Mean fat (g) consumed per day in maternal diet (not including BEP supplement)	Follow-ups
Mode of delivery	1. Vaginal 2. Assisted vaginal (forceps or vacuum) 3. Elective C-section 4. Emergency C-section	Baseline
C-section indication	1. Obstructed/prolonged labor 2. Fetal presentation (e.g. breech) 3. Cord prolapse 4. Fetal intolerance of labor 5. Maternal hypertension/pre-eclampsia, eclampsia 6. Prior c-section (repeat) 7. Elective (planned) 8. Other _____	Baseline
Onset of labor	1. Spontaneous – contractions started on their own 2. Induced – intervention used to start contractions 3. None – c-section without start of labor	Baseline
Rupture of membranes (ROM)	1. Spontaneous – membranes ruptured on their own 2. Artificial – intervention used to rupture membranes	Baseline
PROM (premature rupture of membranes)	Spontaneous rupture of membranes before onset of labor	Baseline
PPROM (preterm premature rupture of membranes)	Spontaneous rupture of membranes before onset of labor at < 37 completed weeks	Baseline
Spontaneous preterm birth	Birth before 37 completed weeks (37 0/7 weeks) after spontaneous labor	Baseline
Labor augmentation	Anything done to help labor progress (e.g. oxytocin, artificial ROM)	Baseline
Obstructed labor (proxy)	Any maneuvers or instruments (e.g. forceps) were needed to help deliver the baby OR c-section due to obstructed/prolonged labor	Baseline

11. Procedure for data cleaning

Data is being collected on the tablets and sync live on server. The data analyst verifies or check through queries using Stata syntax on weekly basis and where required we asked repeat home visits until next due follow-up schedule. Forms are designed to reduce outliers by placing restricted ranges built in which shows errors if range exceed normal limits. Mostly variables are visualized by Box plot, histograms and scatter plot for distribution and detect errors.

12. Statistical plan and analysis goal

The primary analysis will be by intention-to-treat (ITT) perform for those who had anthropometry at 6 months. All analyses will be done using Stata software version 16. The WHO 2009 Child Growth Standards will be used for age-sex standardization of child length, weight, head circumferences, MUAC and weight-for-height. Descriptive analysis of each arm will be conducted, and percentages or continuous data with SD will be reported.

The baseline characteristics will be assessed by arm. Outcomes of mean length velocity, growth velocity, weight gain, z scores and change in z score from 0-6 month will be compared using one way analysis of variance (ANOVA). Tukey's test will be used for multiple comparisons. As determined *a priori* the analysis will be adjusted for the birth weight and length of infant, maternal MUAC at enrollment, maternal age, gravida, maternal body mass index and gender of child using general linear model (GLM). Mixed model analysis will be used to compare change in outcome per month in the intervention arm compared to the control arm. Using repeated measures ANOVA, the analysis will report beta coefficients and 95% CI. The coefficients represents the rate of change in outcome per month. For covariate adjustment, an unadjusted and stepwise adjusted model will be run. Trajectories will be plotted for mean length and weight by age for each arm, and monthly z scores were also be plotted.

13. Potential sub-group analysis

The following variables will be considered for sub-group analysis for primary and secondary outcomes:

1. Birth weight i.e. <2500 gm and => 2500 gm
2. Maternal MUAC at enrolment i.e. < 21.0 cm and =>21.0 cm
3. Maternal age i.e. <30 years and => 30 years
4. Gravidity i.e. <3 and =>3
5. Maternal BMI i.e. <18.5 kg/m^2 and =>18.5 kg/m^2
6. Gender of child

14. Missing Data

We will treat missing data as it is, no imputation will be applied. We discussed that due to growth flattering during this age, imputation maybe unreliable.

15. Interim analysis

Data Safety and Monitoring Board of the trial will request an independent statistician to run interim analysis when 50% of the enrollment will complete the 6 months follow-ups in the trial. The analysis will be coded, and the findings will on difference in primary, secondary outcomes and Serious Adverse Events will be shared to DSMB in blinded coding. The DSMB will review results from the interim data analysis and will determine whether stopping boundaries have been crossed. Additional interim analyses may be completed and reviewed by the DSMB, per the advisement of the DSMB chair. The DSMB may, at its own discretion, ask the interim analysis to be done earlier or additional interim analyses to be completed on an ad hoc basis. Based on the trial safety monitoring and interim analysis, the following may be the key decision/s of DSMB pertaining to the trial:

i. No action needed; trial continues as planned.
ii. Early stopping due, for example, to clear benefit or harm of an intervention/s, uselessness, or external evidence.
iii. Extending recruitment (based on actual control arm response rates being different to predicted rather than on emerging differences) or extending follow-up.
iv. Stopping an arm of the multi-arm trial.
v. Sanctioning and/or proposing protocol changes

While stopping rules will be utilized to help the DSMB to assess the justification of trial continuation, the DSMB will take into account the balance of risks and benefits as well as consistency with external evidence. Thus, the DSMB recommendation to continue or discontinue will not be based on any single issue or value in any of the analyses, but a comprehensive analysis considering multiple issues around the trial.

The DSMB may recommend termination or modification of the study if:

i. In an interim analysis, there is strong evidence of a benefit (increases length velocity and/or secondary outcome) from the study intervention (O'Brien Fleming rule, $p<0.05$).

ii. In an interim analysis, there is strong evidence of harm (incidence of SAEs) from the study intervention. For harm assessment, no fixed statistical rules will be applied, but the DSMB will holistically consider point estimates and confidence intervals for SAE incidence differences, p-values from appropriate statistical tests and other relevant factors, when determining its recommendation about study continuation or discontinuation.

16. Background characteristics of participants

The background characteristics involved during screening, recruitment, or enrolment prior to taking any intervention will be considered baseline characteristics. Maternal and infant anthropometry at birth (baseline, within 0-6 days of birth) and then on monthly basis until 6 months of age. Every month, 24 hours food recall data will be collected from every enrolled LW participant. The number of times each participant will be contacted for outcome assessment is summarized in table 3. Moreover, frequencies and percentages will be used to summarize categorical data and mean and SD for continuous variables will be calculated.

17. Sample figures and tables

Figure 1 | Screening, Randomization, and Analysis

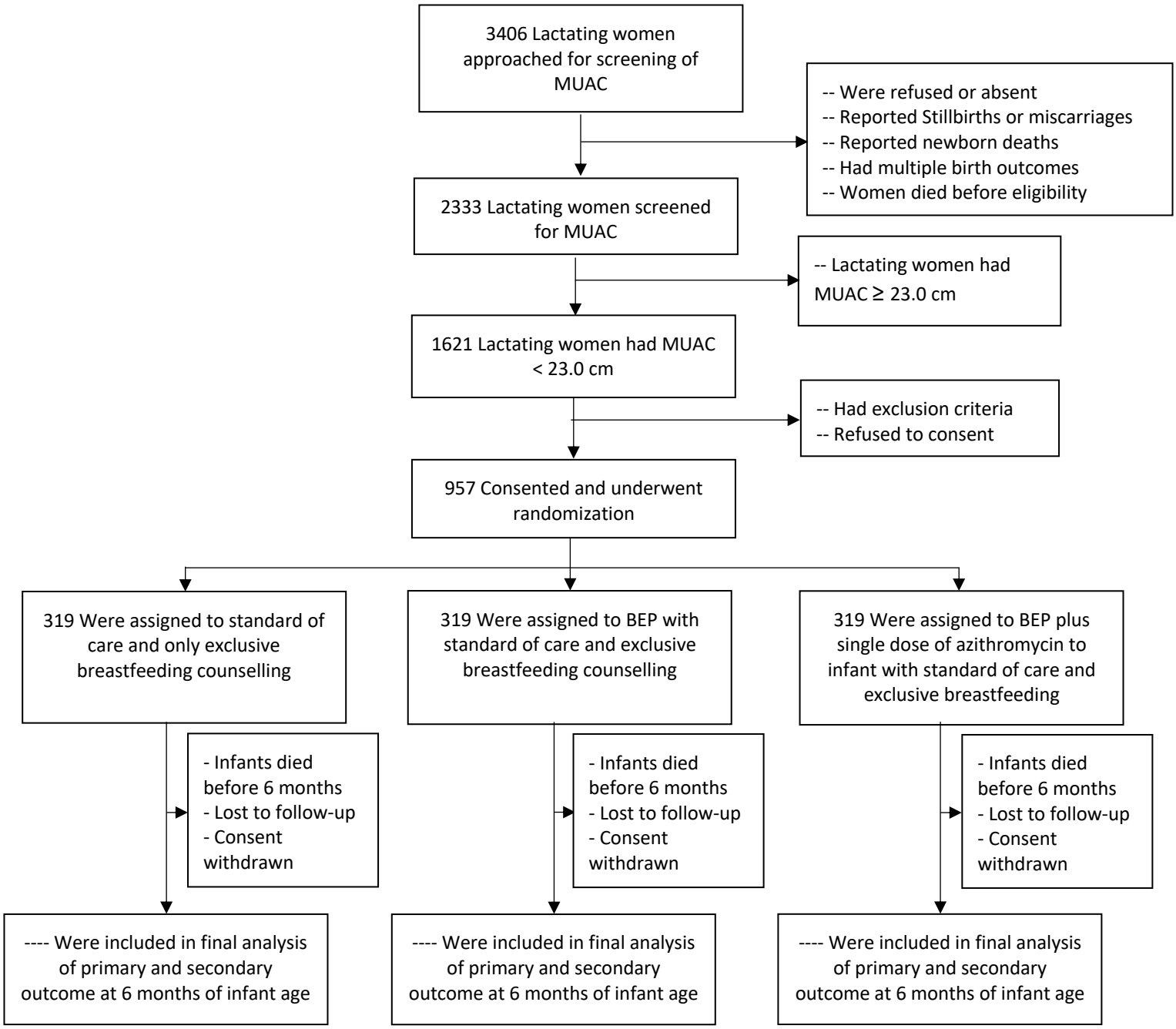


Table 2 | Baseline characteristics

Characteristics	Standard of care and only exclusive breastfeeding counselling (N=319)	BEP with standard of care and exclusive breastfeeding counselling (N=319)	BEP plus single dose of azithromycin to infant with standard of care and exclusive breastfeeding (N=319)
Maternal characteristics			
Age – Mean (years)			
Nutrition status - Mean			
Weight (kg)			
Body mass index (kg/m2)			
Mid-upper-arm-circumference (cm)			
Education – no./total no. (%)			
No formal education			
Primary			
Secondary			
Intermediate			
Undergraduate or above			
Obstetric history - Mean			
Gravidity			
Parity			
Initiation of breastfeeding soon after birth – no./total no. (%)			
Colostrum given			
Breastfeeding started within one hour of birth			
Prelacteal feeding given			
Household characteristics - Mean			
Household density**			
Material used for the floor of the house – no./total no. (%)			
Cement			
Natural/mud			
Wood			
Tiles			
Material used for the wall of the house – no./total no. (%)			
Cement			
Natural/mud			
Wood			
Tiles			
Temporary sheet			
Source of drinking water – no./total no. (%)			
Piped			
Community tap water			
Water tanker			
Bottle			
Boring			
Filtered Water			
Infant characteristics			

Demographic characteristics – no./total no. (%)
Age (Hours)
Gender
Male
Female
Anthropometric measures – Mean
Length (cm)
Weight (kg)
Mid-upper-arm-circumference (cm)
Head circumference (cm)
Length-for-age z-score
Weight-for-age z-score
Weight-for-length z-score
Nutritional status – no./total no. (%)
Wasting§
Stunting¶
Underweight‖

* Plus–minus values are means ±SD.

** Calculated as number of people per room at household.

§ Stunting was defined as a height-for-age z score lower than −2 SD.

¶ Wasting was defined as a weight-for-height z score lower than −2 SD.

‖ Underweight was defined as a weight-for-age z score lower than −2 SD.

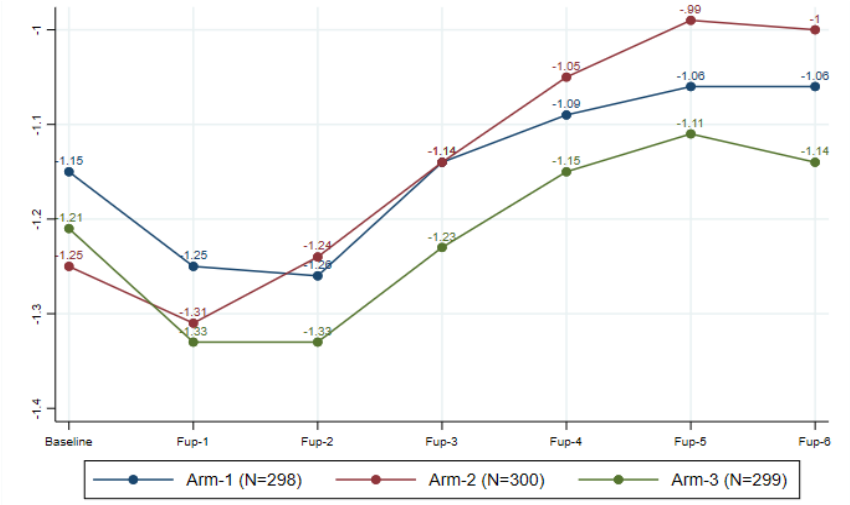
Table 3 | Outcomes at 6 months in the Intention-to-treat analysis*

Outcomes	Standard of care and only exclusive breastfeeding counselling	BEP with standard of care and exclusive breastfeeding counselling	BEP plus single dose of azithromycin to infant with standard of care and exclusive breastfeeding	Pairwise comparison Δ ± SD	p-value
	N=	N=	N=		
Primary outcomes - Mean					
Length velocity of infant (cm/mon)					
Secondary outcomes					
Infant related					
Growth – Mean					
Growth velocity (gm/kg/day)					
Mid-upper-arm-circumference (cm)					
Head circumference (cm)					
Length-for-age z-score					
Weight-for-age z-score					
Weight-for-length z-score					
Head circumference-for-age z-score					
Nutritional status - no./total no. (%)					
Wasting					
Stunting					
Underweight					
Adverse event - no./total no. (%)					
Infant deaths					
Hospitalization					
Injectable therapy					
Maternal related					
Nutritional status - Mean					
Maternal weight gain (kg)					
Mid-upper-arm-circumference (cm)					
Body mass index (kg/m2)					
Adverse event - no./total no. (%)					
Infant deaths					
Hospitalization					
Injectable therapy					

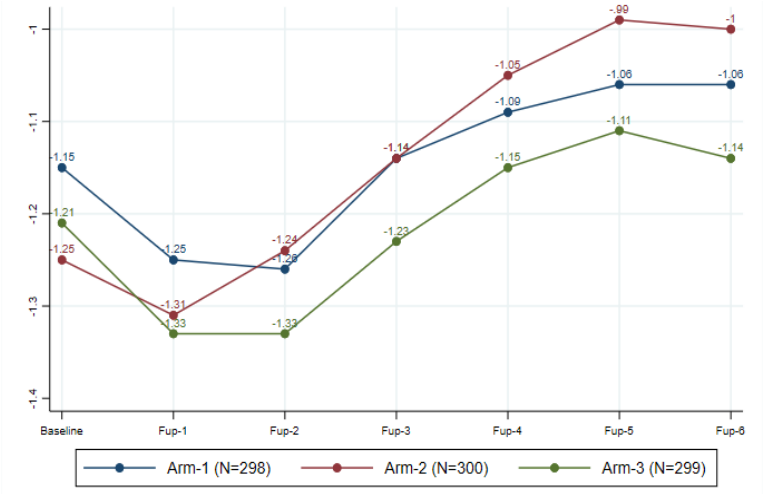
* Plus–minus values are means ±SD.

Figure 2 | Monthly trends for z-scores

2a | Monthly mean length-for-age z-scores



2b | Monthly mean weight-for-age z-scores



2c | Monthly mean weight-for-length z-scores

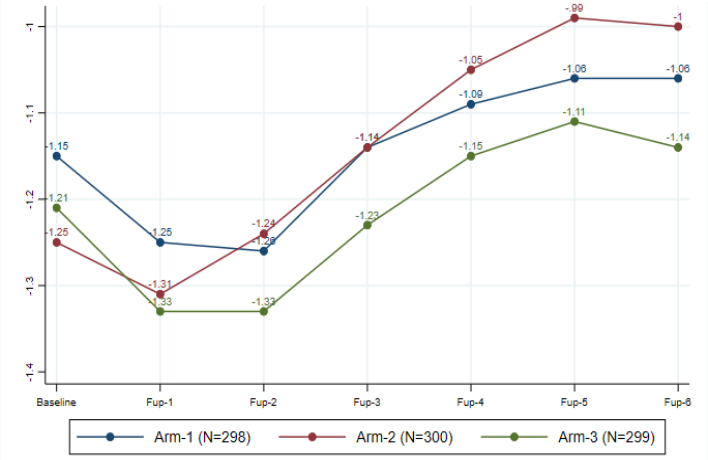


Table 4 | Subgroup analysis

Indicator		**1**	**2**	**3**	**Δ**	**p-value**	**1**	**2**	**3**	**Δ**	**p-value**	**1**	**2**	**3**	**Δ**	**p-value**	**1**	**2**	**3**	**Δ**	**p-value**	**1**	**2**	**3**	**Δ**	**p-value**	**1**	**2**	**3**	**Δ**	**p-value**
Subgroups		Mean length velocity (cm/mon)					Weigh gain (gram/month)					Mean MUAC					Mean length-for-age z-score					Mean weight-for-length z-score					Mean weight-for-length z-score				
Maternal MUAC	< 21.0 cm																														
	=>21.0 cm																														
Maternal BMI	<18.5																														
	=>18.5																														
Birth weight	<2500 gm																														
	=> 2500 gm																														
Maternal age	<30 years																														
	=> 30 years																														
Gravidity	<3																														
	=>3																														
Gender	Male																														
	Female																														

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