Efficacy of lipid-based nutrient supplements (LNS) for pregnant and lactating women and their infants (iLiNS DYAD-Ghana)

Statistical Analysis Plan

Effect on infant and young child feeding practices (added on 06 May 2014)

Contents

1. Version history

Version number	Version date	Prepared by	Description of the completed editions
01.0	XX.XX.2014	Arimond, Peerson, Okronipa	Original document added 06 May 2014

2. Overview and study objectives

The analysis presented here is nested within a pre-existing iLiNS-DYAD-G analysis plan for primary and other secondary outcomes. Refer to the main analysis plan for: inclusion and exclusion criteria for the trial; data cleaning protocols; procedures for breaking code; and procedures for modifying this protocol.

The main objective of data collection related to IYCF practices is to compare practices across intervention groups. This analysis is motivated by concerns that energy-dense LNS may displace breastfeeding and/or nutrient-dense local foods and/or impede dietary diversification with local foods, thus negatively impacting infant feeding practices and development of infant dietary preferences and habits. Effects on IYCF practices could be mediated either by differing maternal perceptions of sufficiency of breast milk or of different needs for breast milk or local foods for infants receiving supplements and/or by a change in appetite, demand for breastfeeding, or preference for local foods among infants who consume the supplement.

Data on IYCF practices have been gathered on the full study samples, and complement quantitative dietary data, which were collected on sub-samples and at fewer time points.

IYCF practices we will compare across groups include: early breastfeeding practices (early initiation, use of prelacteals); exclusive and predominant breastfeeding for infants under 6 mo of age, continued breastfeeding, frequency of breastfeeding, consumption of nutrient-dense food groups yesterday and last week, food group diversity, consumption of other fortified products, and enrichment of porridges prepared by the caregiver.

Specific objectives of analysis

1.1 Primary objective

To compare infant and young child feeding practices and summary diet quality variables across intervention groups. Since the interventions commenced antenatally, at all time points, comparisons are to assess the effect of the intervention on IYCF practices.

1.2 Secondary objectives

To create summary diet quality variable(s) for potential use in analyses of main outcomes (effect modifiers)

To provide descriptive data on IYCF practices to contextualize results of the trials, and to aid readers in comparing to IYCF in other settings

To provide supporting descriptive data for full samples for manuscripts describing dietary intake of sub-samples, and for triangulating between food frequency and dietary data.

1.3 Exploratory analyses

Exploratory analyses will be described later, in separate SAP or in addenda to this SAP. Note that in the sister trial in Burkina Faso ("iLiNS-ZINC"), there is a pre-planned exploratory analysis: description of child feeding practices and factors associated with these practices including food security and seasonality, and relation with nutritional status (growth, iron status, morbidity).

3. Hypotheses to be tested

Stated qualitatively: Provision of LNS to mothers during pregnancy and early lactation and to infants from 6-18 mo would not impact infant and young child feeding practices. More specifically, provision of LNS would not cause a change in:

- Breastfeeding (timing of initiation, use of prelacteals, exclusive breastfeeding, predominant breastfeeding, prevalence of any breastfeeding at several time points throughout intervention, and reported frequency of breastfeeding the previous day, at several time points)
- Dietary diversity measured as food group diversity at or above the WHO cut-off[1];
- Number of nutrient-dense food groups (animal-source foods, fruits and vegetables)

4. Description of infant and young child feeding practice outcome variables

On the following pages, we present information on construction of outcome variables.

The table shows details on: data sources; variable names and variable construction; treatment of data and criteria for imputing missing values.

[1] WHO (2008) Indicators for assessing infant and young child feeding practices: conclusions of a consensus meeting held 6–8 November 2007 in Washington D.C., USA.

With few exceptions (detailed in the table) no data will be imputed for analyses of IYCF practices as outcomes.

However, in later analyses where longitudinal IYCF practice variables (e.g. indices summed across time points) may be used as potential effect modifiers, data could be imputed to avoid losing substantial numbers (those for whom data from all time points are not available).

Timing of outcomes: Early breastfeeding practices were measured within 1-2 days of birth (recorded on child anthropometry form) and/or on day 8 or later (recorded on "delivery details" form); exclusive and predominant breastfeeding were assessed based on monthly visits at ~1-5 months of age (± 1 week of the planned visit date); continued breastfeeding, frequency of breastfeeding and food groups were usually measured within a week of the infant turning 6, 9, 12, 15 and 18 months of age. In instances where the mother/caregiver travelled, field workers were allowed to complete data collection up to one month from the scheduled date.

Variable construction and handling for IYCF practice outcomes

Outcome	Source variable name(s)	Location, variable construction	Criteria for errors, outliers	Criteria for transformation	Use of imputation
Infant breastfeed immediately or within 1 hr (%)	na18long dd26longbfd	**Form C2a (Newborn anthropometry) or if missing or not yet initiated, Form W9 (Delivery details)** Combine information from the variables in the two files into one variable, then construct dichotomous variable: gen bfinitiation=na18long replace bfinitiation=dd26longbfd if bfinitflag==1 replace bfinitiation=dd26longbfd if (na18long==. | na18long>3) gen bfin1hour=. replace bfin1hour=1 if (bfinitiation==0 | bfinitiation==1) replace bfin1hour=0 if (bfinitiation==2 | bfinitiation==3)	None (all illegal codes resolved during data cleaning)	No – dichotomous	No imputation for analysis of outcomes (group comparisons).
Infant breastfed within 24 hr (%)	na18long dd26longbfd	**Same as previous** gen bfin24hour=. replace bfin24hour=1 if (bfinitiation==0 | bfinitiation==1 | bfinitiation==2) replace bfin24hour=0 if (bfinitiation==3)	None (all illegal codes resolved during data cleaning)	No – dichotomous	No imputation for analysis of outcomes (group comparisons).

Outcome	Source variable name(s)	Location, variable construction	Criteria for errors, outliers	Criteria for transformation	Use of imputation
Infant not fed any prelacteal in ~ first week (%)	dd27plnwater dd28sgrwater dd29grpwater[2] dd30fomula dd31milk dd32cocntwter dd33lemon dd34herb dd35fruit dd36koko dd37fluid	**Form W9 (Delivery details)** Information was gathered on the range of fluids/semi-solids listed in variables at left, including Q37 "Any other fluid, drink or food". Classified as not using if all coded "0" and classified as using prelacteals if any of those listed was coded "1".	None (all illegal codes resolved during data cleaning)	No – dichotomous	No imputation for analysis of outcomes (group comparisons).

[2] Several items are "counted" as prelacteals are given in very small quantities (e.g., gripe water and lemon/lime water). The former is sold by the nurses in sealed bottles; the latter is given ritually in drops (from the fruit, and not diluted with water) to newborn infants, primarily to males. Both of these are considered as prelacteals, but for definitions of exclusive breastfeeding, after consultation with the local team, given both the very small volume and the low likelihood of contamination of gripe water, we allow under exclusive breastfeeding. We also allow lemon/lime water, but note this was given in only five instances across all data collection time points (~1-5 mo) used to assess exclusive breastfeeding.

Outcome	**Source variable name(s)**	**Location, variable construction**	**Criteria for errors, outliers**	**Criteria for transformation**	**Use of imputation**
Mean or median # time points w/exclusive breastfeeding Mean or median # time points w/predominant breastfeeding Exclusively breastfed at all 5 time points[3] (%) Predominantly breastfed at all 5 time points[4] (%)	Numerous variables	**Form C5a (Infant FFQ for 1-5 mo)** Variables for exclusive breastfeeding ("ebf") and predominant breastfeeding ("pbf") are constructed from a large number of variables, from a list-based question on liquids/semi-solids, and a guided free recall of all food consumed yesterday. "Other" liquids are also reviewed and coded as either allowed (e.g. medicines) under EBF and/or PBF, or not. After construction of EBF and PBF variables, the source file (at infant-day level) is reshaped to one record per infant, and the four outcomes variables are constructed by summing across time points, then creating a dichotomous variable for "all 5 time points" for EBF and for PBF ("ebfcount", "pbfcount", "ebfall5", and pbfall5")	None (all illegal codes resolved during data cleaning)	# time points: Quasi-continuous and non-normally distributed in full sample. No transformation planned. EBF or PBF at all 5 time points – dichotomous	No imputation for analysis of outcomes (group comparisons).
6 mo: Still breastfed (%) 9 mo: Still breastfed (%) 12 mo: Still breastfed (%) 15 mo: Still breastfed (%) 18 mo: Still breastfed (%)	cqtime cq3brstfeed cq5wean	**Form C5b (Infant FFQ for 6+ mo)** gen stillbf=. replace stillbf=0 if cq3brstfeed==0 & cq5wean==1 replace stillbf=1 if cq3brstfeed==1 | cq5wean==0	None (all illegal codes resolved during data cleaning)	No - dichotomous	Missing data can be coded as "1" (yes) if child is reported to be still breastfed at later time points.

[3] Depending on final sample sizes, we will consider constructing a variable for "exclusively breastfed at at least 4 time points" ("ebf4times"), if this results in substantially less missing data.

[4] As above, for exclusive breastfeeding ("pbf4times").

Outcome	**Source variable name(s)**	**Location, variable construction**	**Criteria for errors, outliers**	**Criteria for transformation**	**Use of imputation**
6 mo: Breastfed 6+ times yesterday (%) 9 mo: Breastfed 6+ times yesterday (%) 12 mo: Breastfed 6+ times yesterday (%) 15 mo: Breastfed 6+ times yesterday (%) 18 mo: Breastfed 6+ times yesterday (%)	cqtime cq3brstfeed cq4bfeed	**Form C5b (Infant FFQ for 6+ mo)** gen bfyesterday=. replace bfyesterday=0 if cq3brstfeed==0 replace bfyesterday=cq4bfeed if cq3brstfeed==1 gen bf_6=. replace bf_6=0 if bfyesterday<4 replace bf_6=1 if bfyesterday==4	As above	No - dichotomous	No imputation for analysis of outcomes (group comparisons).
6 mo: 4+ food groups yesterday (WHO) (%) 9 mo: 4+ food groups yesterday (WHO) (%) 12 mo: 4+ food groups yesterday (WHO) (%) 15 mo: 4+ food groups yesterday (WHO) (%) 18 mo: 4+ food groups yesterday (WHO) (%)	cqtime cq8kkoko cq10amaize cq10cgari cq10lbeans cq8bfomu cq8cmilk cq8gmktea cq8imkcocoa cq8jyogurt cq10mmilk cq10hliver cq10ibeef cq10kfish cq10qsnail cq10jegg cq10bcarrot cq10dkontom cq10emango cq10fbana cq10gtomato	**Form C5b (Infant FFQ for 6+ mo)** For each of the 7 WHO food groups, a dichotomous variable is constructed, and coded "1" if any of the constituent groups=1; "0" if all are "0", missing if all are missing or combination of missing and 0. Constructed variables are: starch24, legume24, dairy24, flesh24, eggs24, vitafood24, othfrveg24 These new variables are summed to construct "dd24", a quasi-continuous variable ranging from 0 to 7. A dichotomous variable is constructed for the WHO minimum diversity indicator, coded "0" if dd24<4, "1" if dd24 is 4, 5, 6 or 7, and missing if missing: dd24GE4	None (all illegal codes resolved during data cleaning)	dd24: Quasi-continuous and non-normally distributed in full sample. No transformation planned. Dd24GE4:No transformation; dichotomous	No imputation of constructed variable for analysis of outcomes (group comparisons). Some of the source variables are imputed. There was little missing data, but for liquid/food groups consumed by <2% of children, missing values are imputed to "0".

Outcome	**Source variable name(s)**	**Location, variable construction**	**Criteria for errors, outliers**	**Criteria for transformation**	**Use of imputation**
6 mo: Number of ASF food groups yesterday 9 mo: Number of ASF food groups yesterday 12 mo: Number of ASF food groups yesterday 15 mo: Number of ASF food groups yesterday 18 mo: Number of ASF food groups yesterday 6 mo: No ASF yesterday (%) 9 mo: No ASF yesterday (%) 12 mo: No ASF yesterday (%) 15 mo: No ASF yesterday (%) 18 mo: No ASF yesterday (%)	cqtime cq8bfomu cq8cmilk cq8gmktea cq8imkcocoa cq8jyogurt cq10mmilk cq10hliver cq10ibeef cq10jegg cq10kfish cq10qsnail	**Form C5b (Infant FFQ for 6+ mo)** Five dairy-containing fluids, along with dairy on the "solids" page, are coded into a new summary variable for any dairy yesterday "dairy24".[5] A count variable ("asf24sum") is created summing dairy24 and organ meats, flesh foods, eggs and fish. A point is given for insects/small protein only if flesh foods = 0. Range is 0 to 5. A dichotomous ASF variable, for any ASF yesterday: "asf24yn". Coded "1" if dairy24 or any of organ, flesh, eggs, fish or insects/small protein=1. Coded "0" if all are 0. Coded missing if all missing or combination of missing & 0.	None (all illegal codes resolved during data cleaning)	asf24sum: Quasi-continuous and non-normally distributed in full sample. No transformation planned. asf24yn:No transformation; dichotomous	There was very little missing data. For variables with prevalence of intake <2%, missing data recoded to "0" (tea w/ or w/o milk, organ meats, insect/small protein) For all other ASF variables prevalence is ≥3% & there is no imputation.

[5] The decision about which items to "count" in the dairy score was made after several discussions with the local team. Specifically, we discussed tea with milk, cocoa/Milo with milk, and yogurt. Although the dairy content and amount consumed will vary, typically these drinks are given with substantial dairy content. The decision was made to code three items positively as part of the dairy group. Any errors should not be differential across intervention groups.

Outcome	**Source variable name(s)**	**Location, variable construction**	**Criteria for errors, outliers**	**Criteria for transformation**	**Use of imputation**
6 mo: Number of fruit/veg groups yesterday 9 mo: Number of fruit/veg groups yesterday 12 mo: Number of fruit/veg groups yesterday 15 mo: Number of fruit/veg groups yesterday 18 mo: Number of fruit/veg groups yesterday 6 mo: No fruits/vegetables yesterday (%) 9 mo: No fruits/vegetables yesterday (%) 12 mo: No fruits/vegetables yesterday (%) 15 mo: No fruits/vegetables yesterday (%) 18 mo: No fruits/vegetables yesterday (%)	cqtime cq10bcarrot cq10dkontom cq10emango cq10fbana cq10gtomato	**Form C5b (Infant FFQ for 6+ mo)** A count variable ("frveg24sum") is created summing vitamin A-rich yellow/orange vegetables, dark green leafy vegetables, vitamin A-rich fruits, other fruits, and other vegetables. Range is 0 to 5. A dichotomous variable is constructed: "frveg24yn". Coded "1" if any of the groups above were consumed yesterday. Coded "0" if all are 0. Coded missing if all missing or combination of missing & 0.	None (all illegal codes resolved during data cleaning)	frveg24sum: Quasi-continuous and non-normally distributed in full sample. No transformation planned. frveg24yn:No transformation; dichotomous	There was very little missing data. For all variables prevalence is ≥2% & there is no imputation.
6 mo: ASF score (out of 28) 9 mo: ASF score (out of 28) 12 mo: ASF score (out of 28) 15 mo: ASF score (out of 28) 18 mo: ASF score (out of 28)	cqtime cq12hmeat cq12jfish cq12iegg cq12lmilk	**Form C5b (Infant FFQ for 6+ mo)** The 4 ASF variables are summed into a score, "asf7sum". Range is 0 to 28. Missing if any are missing (in syntax, these variables were first renamed to names used in Malawi data set, so syntax from Malawi could be cut/pasted in).	Ghana form had a row for "other"; when infant formula was written in, number of days of dairy was recoded accordingly.	Quasi-continuous and non-normally distributed in full sample. No transformation planned.	No imputation for analysis of outcomes (group comparisons).

Outcome	**Source variable name(s)**	**Location, variable construction**	**Criteria for errors, outliers**	**Criteria for transformation**	**Use of imputation**
6 mo: Lowest ASF tertile[6] (%) 9 mo: Lowest ASF tertile (%) 12 mo: Lowest ASF tertile (%) 15 mo: Lowest ASF tertile (%) 18 mo: Lowest ASF tertile (%)	cqtime cq12hmeat cq12jfish cq12iegg cq12lmilk	**Form C5b (Infant FFQ for 6+ mo)** Categorical variables "asf7T6" "asf7T9" "asf7T12" etc. are constructed by creating tertiles of "asf7sum" based on the entire sample (all groups) at each visit/child age (T=6, 9, 12, 15, and 18 mo). The variable is coded 1-3 for lowest to highest tertile. Dichotomous variables are also generated, "i6_asfT1 – i6_asfT3" (and similarly for each "T") and coded 0 if no and 1 if yes for the indicated tertile. E.g. if a score is in the lowest tertile for a child age 6 mo, i6_asfT1=1 and if not, i6_asfT1=0.	Ghana form had a row for "other"; when infant formula was written in, number of days of dairy was recoded accordingly.	No, constructed variables are categorical or dichotomous.	No imputation for analysis of outcomes (group comparisons).
6 mo: Fruit/vegetable score (out of 35) 9 mo: Fruit/vegetable score (out of 35) 12 mo: Fruit/vegetable score (out of 35) 15 mo: Fruit/vegetable score (out of 35) 18 mo: Fruit/vegetable score (out of 35)	cqtime cq12bcarrot cq12dleav cq12emongo cq12fbana cq12gtomato	**Form C5b (Infant FFQ for 6+ mo)** The 5 fruit/vegetable variables are summed into a score, "frveg7sum". Range is 0 to 35. Missing if any are missing (in syntax, these variables were first renamed to names used in Malawi data set, so syntax from Malawi could be cut/pasted in).	None (all illegal codes resolved during data cleaning).	Quasi-continuous and non-normally distributed in full sample. No transformation planned.	No imputation for analysis of outcomes (group comparisons).

[6] Due to heavy lumping on "0" at 6 month visit, the lowest ASF "tertile" includes 58% of infants.

Outcome	**Source variable name(s)**	**Location, variable construction**	**Criteria for errors, outliers**	**Criteria for transformation**	**Use of imputation**
6 mo: Lowest fruit/veg tertile[7] (%) 9 mo: Lowest fruit/veg tertile (%) 12 mo: Lowest fruit/veg tertile (%) 15 mo: Lowest fruit/veg tertile (%) 18 mo: Lowest fruit/veg tertile (%)	cqtime cq12bcarrot cq12dleav cq12emongo cq12fbana cq12gtomato	**Form C5b (Infant FFQ for 6+ mo)** Categorical variables "frveg7T6" "frveg7T9" "frveg7T12" etc. are constructed by creating tertiles of "frveg7sum" based on the entire sample (all groups) at each visit/child age (T=6, 9, 12, 15, and 18 mo). The variable is coded 1-3 for lowest to highest tertile. Dichotomous variables are also generated, "i6_frvegT1 – i6_frvegT3" (and similarly for each "T") and coded 0 if no and 1 if yes for the indicated tertile. E.g. if a score is in the lowest tertile for a child age 6 mo, i6_frvegT1=1 and if not, i6_frvegT1=0.	None (all illegal codes resolved during data cleaning).	No, constructed variables are categorical or dichotomous.	No imputation for analysis of outcomes (group comparisons).

[7] Due to heavy lumping on "0" at 6 month visit, the lowest fruit/vegetable "tertile" includes 76% of infants.

5. Approach to analysis and exclusions specific to this analysis

All tests will be two-sided, at 5% level of significance.

Since varying numbers of observations are available depending on the time point (i.e., there were a substantial number of missed visits), sample sizes by group will be reported for each time point. If specific outcome variables are missing for more than 10% of infants (with denominator being total records available for the time point) we will report the number of observations used per specific outcome analysis.

Analysis will be by intention-to-treat. Data on subjects who were lost to follow-up (either temporarily or permanently) will be included in the analysis for all time points where data are available.

Outcomes are divided temporally into 3 groups: neonatal (initiation of breastfeeding and use of prelacteals); early lactation (exclusive and predominant breastfeeding at data collection time points 1-5 mo); later practices (continued breastfeeding, frequency of breastfeeding, and food group diversity measured several ways, at data collection time point of 6, 9, 12, 15 and 18 mo).

In addition, data available in the DYAD-Ghana trial are divided into three "periods" based on their relationship to an error in allocation of treatments. Women in "period 1" received the same supplement throughout pregnancy, though it was not the intended supplement (reversal of MMN and IFA groups); women in "period 2" received different supplements at different time points during pregnancy; women in "period 3" received the correct supplement throughout pregnancy and lactation. At no point was LNS confused with the two tablets (IFA and MMN).

6. Statistical methods

5.1 Software

All analyses will be done using SAS version 9.3 (SAS Inst. Cary, NC, USA) or Stata version 10.1 or higher (StataCorp, TX, USA).

5.2 Sample size and attrition

Sample sizes by group will be presented for each time point (**Table 1 and Figure 1**), and differential attrition will be assessed with chi-square tests at each time point.

5.3 Background characteristics

Selected background characteristics (measured at baseline) will be examined by group for baseline and endline samples (**Table 2**).

5.4 Analysis of the effect of the intervention

General comments:

a. The hypothesis stated in section 3 is a non-equivalence hypothesis. However, the study was not powered for IYCF practices outcomes and we are severely underpowered for equivalence analyses, particularly for dichotomous outcomes (such as prevalence of continued breastfeeding at any time point). Therefore the more traditional approach in the nutrition literature of analyzing for significant differences will be followed in the first instance. This limitation will be clearly explained in the discussion section of any publication.

a. For quasi-continuous variables, we will supplement this with an equivalence approach to hypothesis testing, to help inform conclusions from this analysis.

Analysis of the effect of the intervention will follow these steps:

b. A set of pre-specified potential covariates will be examined through reviewing correlations and collinearity (e.g. using "collin" command in Stata). Variables with VIF > 10 will be assessed and a reduced set of variables will be retained, such that all VIF are < 10.

c. We will test the null hypothesis of no difference among the three treatment groups using ANCOVA or logistic regression, and controlling for the pre-specified covariates (most of which are also potential effect modifiers, see below).

d. For all analyses, if the global null hypothesis is rejected at 0.05 level, then we will perform post-hoc pairwise comparisons of all three groups using appropriate adjustments for multiple comparisons and Scheffe's test to examine other contrasts of interest.

e. If the IFA and MMN groups are not different for a specific outcome, we will test differences between LNS and non-LNS groups (IFA and MMN, grouped together), using all data from periods 1-3.

f. The effects of potential effect modifiers will be assessed with an interaction term in the ANCOVA or logistic regression model. Each interaction will be assessed separately.

g. Significant interactions ($p < 0.05$) will be further examined with stratified analyses, estimation of separate regression lines, or estimation of adjusted means at key points of the covariate, in order to understand the nature of the effect modification.

h. For quasi-continuous outcomes (number of time points with exclusive or predominant breastfeeding; number of fruit/vegetable groups consumed yesterday; number of animal-source food groups consumed yesterday, and fruit/vegetable and animal-source food scores for last week) equivalence will be assessed based on defined margins. Margins for breastfeeding and food groups yesterday will be ±1.0 (one more or fewer time points exclusively or predominantly breastfed; one more or one fewer fruit vegetable group yesterday; one more or one fewer animal-source food group yesterday). For scores for last week, the margin will be ±5 points for the fruit/vegetable scores and ±4 for animal-source foods (~= a difference of one group/day in each).

i. We will assess equivalence in the context of ANCOVA models, controlling for the same pre-specified covariates as noted above. Equivalence will be determined to exist if the 90% confidence interval for the difference between the means is entirely contained within the negative and the positive values of the equivalence margin.

j. Confidence intervals will be adjusted for multiple comparisons.

k. For each equivalence outcome, if results are inconclusive, the IFA and MMN groups will be combined and 2-group comparisons will be made, to improve power to detect differences.

5.5 Covariates in main effects models

In theory, a variety of community-, household-, maternal-, and child-level characteristics could affect child feeding practices independently of the intervention. Data are available for the covariates listed below. All covariates are as measured at baseline, with the exception of child age. Since child age at each visit can vary, child age at time of measure will be included in models.

Before making final decisions on inclusion of covariates, completeness of data for the covariates will be considered and covariates will be excluded if loss of sample size is judged too large.

- Month of food group recall measurement
- Characteristics of households
    - Baseline HH food security (HFIA score)
    - Baseline HH asset score
    - Baseline small livestock score

  - Baseline HH housing quality score
  - Number of underfives in the HH, assessed at baseline
- Maternal education
- Child's characteristics
  - Child age
  - Child sex

5.6 List of potential effect modifiers to be examined

Similarly most of the covariates identified above could interact with the provision of LNS to produce differential effects on feeding practices, and will be evaluated for their potential to interact with intervention group.

5.7 Future exploratory (path) analyses

There are a number of potential effect modifiers not yet available, but which could interact with provision of LNS to produce differential effects. These may be included in later exploratory analyses:

- Household
  - Proxy for income (expenditures)
  - Grandmother lives on compound/with the child
- Maternal
  - Index for responsive feeding (composite from KAP)
  - Maternal decision-making power (composite from KAP)
  - Maternal depression
- Child
  - Birthweight
  - Weight gain from 0-5 months (for later outcomes)
  - Morbidity
  - Appetite

7. Design of tables and figures

See following pages for a list of tables and example figures that will be examined by the manuscript writing group:

Table 1. Number of observations and missing visits, by intervention group and by time point

Table 2. Background characteristics of study participants, baseline and endline samples, by intervention group

Table 3. Breastfeeding practices, by intervention group

Table 4. Infant diet quality yesterday: food group diversity and nutrient-dense food groups by intervention group

Table 5. Infant diet quality last week: nutrient-dense food groups, by intervention group

Example figures (final set of figures to be determined):

Figure 1. Participant flow

Figure 2. Early feeding practices (neonatal, and up to 6 mo) by intervention group

Figure 3. IYCF practices at 6-18 months, dichotomous outcomes, by intervention group

Figure 4. IYCF practices at 6-19 months, food group diversity scores, by intervention group

Figures 5ff Possibly, illustrations of adjusted CI and equivalence margins for scores

Table 1. Number of observations and missing visits, by time point (FFQ)[a]

Age[a]	Neonatal outcomes			EBF & PBF 1-5 mo			6 mo outcomes			9 mo outcomes			12 mo outcomes			15 mo outcomes			18 mo outcomes		
Group	IFA	MMN	LNS	IFA	MMN	LNS	IFA	MMN	LNS	IFA	MMN	LNS	IFA	MMN	LNS	IFA	MMN	LNS	IFA	MMN	LNS
Number permanently lost to follow-up																					
Number missing[c]																					
% missing																					
Number of visits completed																					
Total[d]																					

[a] FFQ=food frequency questionnaire; EBF=exclusive breastfeeding; PBF=predominant breastfeeding; IFA=iron folic acid group (standard care); MMN=multiple micronutrient group; LNS=lipid-based nutrient supplement group.

[b] Age for neonatal outcomes was ≤7 d.

[c] For most outcomes, this is the number of missed visits at a given time point. For EBF and PBF it is the number for whom any of five visits (1 mo – 5 mo) were missed, because the outcomes were constructed by combining data from the 5 time points.

[d] Total number of children who should have been in data set at this time point (excluding permanent loss to follow-up).

Table 2. Background characteristics of study participants

	N	(missing)	IFA[a]	MMN	LNS	All	P-value[b]
HFIA score at baseline							
Baseline sample							
Endline sample							
HH asset score at baseline							
Baseline sample							
Endline sample							
HH housing quality score at baseline							
Baseline sample							
Endline sample							
HH livestock assets score at baseline							
Baseline sample							
Endline sample							
Number of underfives in the HH at baseline							
Baseline sample							
Endline sample							
Maternal education (in y)							
Baseline sample							
Endline sample							
Child age at baseline (in mo)							
Baseline sample							
Endline sample							
Child sex (% female)							
Baseline sample							
Endline sample							

[a] IFA=iron folic acid group (standard care); MMN=multiple micronutrient group; LNS=lipid-based nutrient supplement group.

[b] Comparison between intervention groups at each time point; p-value for ANOVA (continuous and quasi-continuous variables) or chi-square test (categorical variables).

Table 3. Breastfeeding practices, by intervention group

	N[a]	(missing)	IFA[b]	MMN	LNS	All	P-value[c]
Infant breastfeed immediately or within 1 hr of birth (%)							
Infant breastfed within 24 hr of birth (%)							
Infant not fed any prelacteal in ~ first week of life (%)							
At 1-5 mo: Mean or median # time points with exclusive breastfeeding							
At 1-5 mo: Mean or median # time points w/predominant breastfeeding							
Exclusively breastfed at all 5 time points (%)							
Predominantly breastfed at all 5 time points (%)							
Frequency of breastfeeding yesterday[d]							
At ~ 6 mo (%)							
None							
6+ times							
At ~ 9 mo (%)							
None							
6+ times							
At ~ 12 mo (%)							
None							
6+ times							
At ~ 15 mo (%)							
None							
6+ times							
At ~ 18 mo (%)							
None							
6+ times							

[a] Number of infants not permanently lost to follow-up at each age/time point.

[b] IFA=iron folic acid group (standard care); MMN=multiple micronutrient group; LNS=lipid-based nutrient supplement group.

[c] Values presented are unadjusted means (SD) or medians (I-Q ranges) and prevalences. Decision on presenting means or medians will be made after examination of distributions. Statistical tests are for adjusted analyses; analysis of covariance and logistic regression, controlling for

[d] Respondents were asked if the baby was breastfed yesterday and if so they were read the following options: Only at night; only 1 or 2 times during the day; about 3 to 5 times during the day; at least 6 times during the day.

Table 4. Infant diet quality yesterday: food group diversity and nutrient-dense food groups

	N[a]	(missing)	IFA[b]	MMN	LNS	All	P-value[c]
Food groups consumed by the infant yesterday[d]							
At ~ 6 mo (%)							
4+ food groups (WHO indicator[e], %)							
No ASF[f] (%)							
Mean or median # ASF groups (of 5)[g]							
No fruits/vegetables (%)							
Mean or median # fruit/vegetable groups (of 5)[h]							
At ~ 9 mo (%)							
4+ food groups (WHO indicator, %)							
No ASF (%)							
Mean or median # ASF groups (of 5)							
No fruits/vegetables (%)							
Mean or median # fruit/vegetable groups (of 5)							
At ~ 12 mo (%)							
4+ food groups (WHO indicator, %)							
No ASF (%)							
Mean or median # ASF groups (of 5)							
No fruits/vegetables (%)							
Mean or median # fruit/vegetable groups (of 5)							
At ~ 15 mo (%)							
4+ food groups (WHO indicator, %)							
No ASF (%)							
Mean or median # ASF groups (of 5)							
No fruits/vegetables (%)							
Mean or median # fruit/vegetable groups (of 5)							
At ~ 18 mo (%)							
4+ food groups (WHO indicator, %)							
No ASF (%)							
Mean or median # ASF groups (of 5)							
No fruits/vegetables (%)							

Mean or median # fruit/vegetable groups (of 5)

[a] Number of infants not permanently lost to follow-up at each age/time point.

[b] IFA=iron folic acid group (standard care); MMN=multiple micronutrient group; LNS=lipid-based nutrient supplement group.

[c] Values presented are unadjusted means (SD) or medians (I-Q ranges) and prevalences. Decision on presenting means or medians will be made after examination of distributions. Statistical tests are for adjusted analyses; analysis of covariance and logistic regression, controlling for

[d] Respondents were asked (yes/no) if the infant was given any of a list of fluids and semi-solids yesterday, and solid food consumption was determined using an open, guided recall of the previous day (qualitative 24-hour recall). Foods reported in the recall were circled and coded into groups.

[e] The WHO indicator sums seven food groups and a score of 4 or more of 7 is associated with higher nutrient density (WHO, 200X); the food groups are: 1) grains, roots and tubers; 2) legumes and nuts; 3) dairy products; 4) flesh foods; 5) eggs; 6) vitamin-A rich fruits and vegetables; and 7) other fruits and vegetables.

[f] ASF=animal-source food.

[g] The 5 ASF groups are: 1) organ meats; 2) other meat/poultry; 3) fish; 4) eggs; and 5) dairy.

[h] The 5 fruit and vegetables groups are: 1) vitamin A-rich orange/yellow vegetables; 2) dark green leafy vegetables; 3) other vegetables; 4) vitamin A-rich fruits; and 5) other fruits.

Table 5. Infant diet quality last week: nutrient-dense food groups, by intervention group

	N[a]	(missing)	IFA[b]	MMN	LNS	All	P-value[c]
Food groups consumed by infant in the last 7 days[d]							
At ~ 6 mo (%)							
Mean or median ASF[e] score (of 28)[f]							
Lowest ASF tertile (%)[g]							
Mean or median fruit/vegetable score (of 35)[h]							
Lowest fruit/vegetable tertile (%)							
At ~ 9 mo (%)							
Mean or median ASF score (of 28)							
Lowest ASF tertile (%)							
Mean or median fruit/vegetable score (of 35)							
Lowest fruit/vegetable tertile (%)							
At ~ 12 mo (%)							
Mean or median ASF score (of 28)							
Lowest ASF tertile (%)							
Mean or median fruit/vegetable score (of 35)							
Lowest fruit/vegetable tertile (%)							
At ~ 15 mo (%)							
Mean or median ASF score (of 28)							
Lowest ASF tertile (%)							
Mean or median fruit/vegetable score (of 35[i]							
Lowest fruit/vegetable tertile (%)							
At ~ 18 mo (%)							
Mean or median ASF score (of 28)							
Lowest ASF tertile (%)							
Mean or median fruit/vegetable score (of 35)							
Lowest fruit/vegetable tertile (%)							

[a] Number of infants not permanently lost to follow-up at each age/time point.

[b] IFA=iron folic acid group (standard care); MMN=multiple micronutrient group; LNS=lipid-based nutrient supplement group.

[c] Values presented are unadjusted means (SD) or medians (I-Q ranges) and prevalences. Decision on presenting means or medians will be made after examination of distributions. Statistical tests are for adjusted analyses; analysis of covariance and logistic regression, controlling

[d] Respondents were asked how many days in the last seven days the infant was given any of a list of foods. Foods were read to the respondent in groups. The respondent was also instructed to consider ingredients of mixed dishes.

[e] ASF=animal-source food.

[f] The ASF score equals the sum, across four animal-source food groups, of the number of days in the last seven days the respondent reported the infant consumed a food in the group. The four groups are: 1) meat/poultry; 2) fish; 3) eggs; and 4) dairy. Scores could range from 0 to 28.

[g] Tertiles are based on the full sample at each time point. The table shows the percent of children in each intervention group falling into the lowest tertile for an ASF score and for a fruit/vegetable score.

[h] The fruit/vegetable score equals the sum, across five fruit and vegetable food groups, of the number of days in the last seven days the respondent reported that the child consumed a food in the group. The five groups are: 1) vitamin A-rich yellow/orange vegetables; 2) dark green leafy vegetables; 3) vitamin A-rich fruits; 4) other fruits; 5) other vegetables. Scores could range from 0 to 35.

Figure 1.
Figure 1 will present a detailed participant flow chart (CONSORT diagram). The Figure will include numbers and reasons for permanent and temporary loss-to-follow-up at each time point where outcomes are evaluated.

Additional Figures: To be determined; see list of possible figures above.