Effect of gestational and post-partum LNS supplementation on women's anthropometric indices during pregnancy, and at 6 months postpartum

Statistical Analysis Plan (Addendum to "Main" SAP, version 3)

Contents

Version History Log

This table will detail the version history for this document, including the key elements of the changes to the versions.

Version	Date implemented	Details of significant changes
1	17 March, 2015	This is the first version of this SAP. It is intended as an addendum to the main SAP, Version 3. As a result, there are various aspects of the analysis that have been described in the main SAP Version 3 and will not be repeated here. Both the main SAP Version 3 and this current SAP will guide the analysis described in this document.

1. Background

This analysis will involve women who participated in the iLiNS DYAD Study in Ghana (1). In this partially double blind, parallel controlled trial, pregnant women (n =1320, ≤20 weeks gestation) were individually randomized to receive either standard iron (60 mg) + folic acid (400 μg) during pregnancy and placebo (small amount of Ca) in the first six months postpartum (IFA group), or 18 micronutrients including 20 mg iron during pregnancy and 6 months postpartum (MMN group), or SQ-LNS during pregnant and first six months postpartum (LNS group). The LNS group received the same micronutrients as the MMN group, and in addition Ca, P, K and Mg as well as energy (118 kcal/d) and macronutrients.

This SAP describes the analysis of women's anthropometric indices during pregnancy, and BMI at 6 months postpartum

2. Study objectives

To compare, among the three intervention groups, the following indices during pregnancy and at 6 months postpartum:

a) During pregnancy

i. Mean change in weight, mid upper arm circumference (MUAC) and triceps skinfold (TSF) per week from baseline to 36 gw.
ii. Percentage of women whose MUAC and TSF increased (proxy indicators for gain in sub-cutaneous fat) from baseline to 36 gw.
iii. Percentage of women with pregnancy weight gain:
    1) Below the Institute of Medicine (IOM)'s recommended weight-gain ranges (2)
    2) Within the IOM's recommended weight-gain ranges (2)
    3) Above IOM's recommended weight-gain ranges (2).

b) 6 months postpartum

i. Mean weight, MUAC, TSF, and BMI at 6 months postpartum
ii. Percentage of women with:
    1) BMI <18.5 kg/m^2 or 20 kg/m^2 at 6 months postpartum. Note: We will use the 20.0 kg/m^2 cut-off to indicate low BMI in addition to the 18.5 kg/m^2 cut-off, because of concern that the percentage of women with BMI <18.5 kg/m^2 at 6 months post-partum in this population may be low.
    2) BMI >25 kg/m^2 (overweight and obesity) at 6 months postpartum
    3) BMI >30 kg/m^2 (obesity) at 6 months postpartum

3. Hypotheses

a) From baseline to 36 gw, mean increase in anthropometric measures (weight, MUAC and TSF) per week would be greater, or mean decrease in anthropometric measures per week would be less in women in the LNS group than in women in each of the other two groups.
b) From baseline to 36 gw, percentage of women whose MUAC and TSF increased (proxy indicators for gain in sub-cutaneous fat) would be greater in the LNS group than in each of the other two groups.
c) Percentage of women with pregnancy weight gain below the IOM's recommended weight-gain ranges would be lower in the LNS group, and the percentage with pregnancy weight gain within or above the IOM's recommended weight-gain ranges would be higher in the LNS group, compared to each of the other two groups.
d) At 6 months postpartum, mean weight, MUAC, TSF, and BMI would be greater in women in the LNS group than in women in each of the other two groups.
e) At 6 months postpartum, the percentage of women with BMI <18.5 kg/m^2 or BMI <20.0 kg/m^2 would be lower in the LNS group, and the percentage with BMI >25 kg/m^2 (overweight or obese) or BMI >30 kg/m^2 (obese) would be greater in the LNS group, compared to each of the other two groups.

4. Data for analysis

The data for these analyses will be obtained from the Women's Baseline Questionnaire, WBQ (Form W2, completed by field workers once in the home at the time of enrolment), and the Women's Anthropometric Measurements Form, WAQ (Form W3, completed by anthropometrists during visits to the lab by women at enrolment, 36 gw and 6 months postpartum).

5. Outcome measures

i. Continuous outcome measures:
   a) Mean change in weight, mid upper arm circumference (MUAC) and triceps skinfold (TSF) per week from baseline to 36 gw.
   b) Mean weight, MUAC, TSF, and BMI at 6 months postpartum.

ii. Categorical outcome measures:
   a) Percentage of women whose MUAC and TSF increased (proxy indicators for gain in sub-cutaneous fat) from baseline to 36 gw. An increase in MUAC or TSF from baseline to 36 gw will be defined as MUAC or TSF at 36 gw greater than MUAC or TSF at baseline.
   b) Percentage of women with pregnancy weight gain:
      i. Below the Institute of Medicine (IOM)'s recommended weight-gain ranges (2)

ii. Within the IOM's recommended weight-gain ranges (2)
iii. Above IOM's recommended weight-gain ranges (2).

c) Percentage of women with:
i. BMI <18.5 kg/m^2 or BMI <20 kg/m^2 at 6 months postpartum
ii. BMI >25 kg/m^2 at 6 months postpartum
iii. BMI >30 kg/m^2 at 6 months postpartum

6. Calculation of proxy indicator for pre-pregnancy weight

Because we do not have women's pre-pregnancy weight, (which will be needed to calculate pregnancy weight gain, and subsequently, the percentage of women with pregnancy weight gain below, within or above the IOM's recommended weight-gain ranges (2)), a proxy indicator for pre-pregnancy weight will be calculated as follows, using regression modeling:

a. Determine the best transformation of maternal BMI that achieves normal distribution by regressing BMI with gestational age. This will be done by:
   i. Testing for normality: Test the normality of BMI, log BMI, and inverse BMI and determine/select the transformation that is most normally distributed. In SAS:

```
proc univariate normal data=prepreg normal;
var mombmi logmbmi invmbmi;
histogram mombmi logmbmi invmbmi/normal;
run;
```

   ii. Regressing BMI, log BMI, and inverse BMI with gestational age at enrolment (gaenrol) and examining regression plot. In SAS:

```
symbol1 v=star c=black i=rc;
proc gplot data=prepreg;
plot (mombmi logmbmi invmbmi)*gaenrol;
run;

symbol1 v=star c=black i=rq;
proc gplot data=prepreg;
 plot (mombmi logmbmi invmbmi)*gaenrol;
 run;

symbol1 v=star c=black i=rl;
proc gplot data=prepreg;
 plot (mombmi logmbmi invmbmi)*gaenrol;
 run;
```

b. Using the best transformation as chosen above, we will regress BMI on gestational age, gestational age squared, and gestational age cubed, and save both the predicted value and the residual as separate variables within the data table. In SAS, this is done by the following

command, which saves both the predicted value and the residual (actual – predicted value) in a separate file (named bmi1 in this case) for use later in the analysis.

```
proc glm data=prepreg;
model invmbmi=gaenrol gaenrol*gaenrol gaenrol*gaenrol*gaenrol;
output out=invmbmi1 p=predict r=resid;
run;quit;run;
```

[Also note: for the above transformations, the regression with the highest r-square will be the best model for predicting BMI based on gestational age].

c. We will visually inspect the regression curve above to determine the youngest gestational age before the confidence intervals expands. Ideally this age is young enough that a substantial weight gain has not yet been achieved, yet still fits well along the regression curve. The predicted mean BMI is calculated at the gestational age of interest. Once this "youngest gestational age is determined, we will calculate the mean predicted **invmbmi** at that gestational age. In SAS, given two "youngest GWs" were selected from inspecting the curves, namely 11.0 and 12.0 weeks:

```
proc means data=invmbmi1 maxdec=9 n mean std;
where gaenrol in (11.0,12.0);
class gaenrol;
var predict;
run;
```

d. Create adjusted **invmbmi** values for each of the gestational ages inspected above by adding the residual saved in *step b* above, and then perform the back-transformation (i.e antilog( ) or 1/ **invmbmi** --for the current case). This is done in SAS by the following command, where `adjmombmi11` is the adjusted BMI at 11.0 gestational weeks, **`0.0418188`** is the mean `invmbmi` from step *c* above, and the resid is the residual value as determined by step *b* above.

```
data invmbmi2;
set invmbmi1;
adjmombmi11=1/(0.0418188 + resid);
adjmombmi12=1/(0.0416185 + resid);
run;
```

7. Basis for analysis

Primary analysis will be by intention-to-treat, that is, women will be included in the analysis regardless of the percentage of follow-up days in which the supplement was reportedly consumed. However, to investigate the possible effect of group differences in adherence to treatment, we will perform a per-protocol analysis, which will be restricted to women with adherence ≥ 70%.

8. Statistical software

Analyses will be performed using SAS version 9.4 (SAS Inst., Cary, NC, USA).

9. Outliers

Outliers will be visually inspected by creating box and whisker plots and/or histograms of individual continuous variables, and scatterplots of related variables. Outliers which are clearly impossible or implausible values will be corrected if possible, or recoded to missing if correction is not possible. Outliers which are plausible or possible will be kept.

10. Analytical methods

a. Background characteristics of women, by original group assignment, will be presented as means ±SD (continuous variables) or frequencies (binary variables) (**Table 1**).

b. At 36 gw and 6 months postpartum, we will calculate overall mean (±SD) values and percentages of outcome variables. We will compare treatment groups using general linear model (continuous outcomes) and logistic regression model (binary), with Tukey-Kramer adjustment for multiple comparisons. Along with the treatment group comparisons, we will calculate pairwise mean differences (continuous outcomes) and relative risks (binary outcomes) with their 95% CI and p-values. Relative risks will be calculated using Poisson regression (3). Treatment comparisons will be performed twice, first without any covariate adjustments, and then with adjustment for covariates (see below) significantly associated ($p<0.10$) with the outcome in a bivariate analysis.

c. For continuous outcome variables that are not normally distributed, the group means (± SD or SE), group percentages, and pair-wise mean differences and relative risks with their 95% CI will be calculated using untransformed data to allow for easy interpretation of results, while the p-values for group or pair-wise comparisons will be generated using logarithmically transformed data. Results of the analysis of continuous and binary outcomes will be presented as shown in **Table 2** and **Table 3.**

d. Where appropriate, we will analyze changes in the prevalence of binary outcomes from enrolment using mixed model logistic regression (SAS PROC GLIMMIX), but if the mixed model logistic regression fails to converge because of sparse data, we will use generalized estimating equations model (SAS PROC GENMOD).

e. We will evaluate the potential effect modification by pre-specified background variables (see below). Where an effect modification is significant (alpha <0.10), we will perform stratified/subgroup analysis by including an interaction term between treatment and the effect modifier in the ANCOVA or logistic regression model. Each effect modifier will be

considered separately in the models to avoid collinearity. Results of sub-group analyses will be presented as shown in **Table 4**.

11. Potential covariates

Baseline variables to be included in the ANCOVA or logistic regression models as covariates will be derived from the list below. Only variables that show a statistically significant association with an outcome (P<0.10) will be included in the final model.

1) BMI (continuous)
2) Primiparity (binary)
3) Season at enrolment (binary)
4) Anemia (binary)
5) Gestational age (continuous)
6) Age (continuous)
7) Assets index (continuous)
8) Housing index (continuous)
9) HH food insecurity index (continuous)

12. Potential effect modifiers

Potential effect modifiers to be examined are listed below. For significant effect modifiers, sub-group analyses will be based on $<10^{th}$ percentile value versus $< 90^{th}$ percentile for continuous effect modifiers, and "yes or no" for binary effect modifiers.

1. BMI (continuous)
2. Primiparity (binary)
3. Season (binary)
4. Anemia (binary)
5. Gestational age (continuous)
6. Age (continuous)
7. Assets index (continuous)
8. Housing index (continuous)
9. HH food insecurity index (continuous)

TABLE 1
Background characteristics of women who completed the study at 6 months postpartum, by original group assignment[1]

Background characteristics	**IFA (n = xxx)**	**MMN (n = xxx)**	**LNS (n = xxx)**
Age, y	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
Formal education, y	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
Body Mass Index, kg/m^2	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
Low BMI, n/N (%)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
Gestational age at enrolment, weeks	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
Assets index[2]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
Housing index[2]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
HFIA Score[2]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]	xx.x ± xx.x [xxx]
Married or co-habiting, n/N (%)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
Primiparous women, n/N(%)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
Tested positive for malaria, n/N (%)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)

[1] IFA= Iron-Folic Acid group; LNS=Lipid-based Nutrient Supplement for pregnant and lactating women group. MMN=Multiple Micronutrients group. HFIA is Household Food Insecurity Access Score. Values are Mean ± SD or Number of participants (%).

[2] Proxy indicators for household socioeconomic status and food insecurity. Assets index is a composite of household ownership of assets such as radio, television, refrigerator, cell phone, and stove. Housing index is a composite of drinking water supply, sanitation facilities, wall material, flooring material, roofing material, and lighting source. HFIA score is a continuous measure of the degree of food insecurity based on a set of questions that encompass three domains of food insecurity: (i) anxiety and uncertainty about the household food supply, (ii) insufficient quality, and (iii) insufficient food intake and its physical consequences (4).

Table 2

Comparison of continuous outcomes from enrolment to 36 gw, and 6 months postpartum, by group, and pairwise-differences between groups

	IFA [xxx]	MMN [xxx]	LNS [xxx]	P-value	Comparison of IFA and MMN		Comparison of IFA and LNS		Comparison of MMN and LNS	
					Difference in means or medians (95 % CI)	p	Difference in means or medians (95 % CI)	p	Difference in means or medians (95 % CI)	p
Mean gain/wk from baseline to 36 gw										
Weight, kg	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx
MUAC, cm	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx
TSF, mm	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx
Mean at 6 months postpartum										
Weight, kg	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx
MUAC, cm	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx
TSF, mm	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx	x.xx (x.x, x.x)	x.xxx

Table 3

Comparison of binary outcomes by group, and pair-wise relative risks

Binary variables	IFA[2] [xxx]	MMN[2] [xxx]	LNS[2] [xxx]	P[3]	Comparison of IFA and MMN[4]		Comparison of IFA and LNS[4]		Comparison of MMN and LNS[4]	
					RR (95 % CI)	p	RR (95 % CI)	p	RR (95 % CI)	p
Increased (baseline to 36 gw)										
MUAC	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
TSF	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
IOM's recommended weight-gain ranges										
Below	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Within	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Above	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
BMI at 6 mo postpartum										
<20 kg/m^2	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
>25 kg/m^2	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
>30 kg/m^2	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	0.xx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx

Table 4

Subgroup analysis of anthropometric indices[1]

Outcome variable	IFA[2]	MMN[2]	LNS[2]	P[3]	Comparison of MMN and IFA (n = 349)		Comparison of LNS and IFA (n = 354)		Comparison of LNS and MMN (n = 354)	
					Mean difference or RR	p	Mean difference or RR	p	Mean difference or RR	p
Mean change in weight/week										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Mean change in MUAC/week										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Mean change in TSF/week										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Mean wt, MUAC, TSF at 6 months postpartum										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% with increased MUAC										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% with increased TSF										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% below IOM recommended ranges										
Effect modifier				x.xxx		.		.		.

Effect of LNS supplementation on food intake patterns, pregnancy weight gain, and BMI

Outcome variable	IFA[2]	MMN[2]	LNS[2]	P[3]	Comparison of MMN and IFA (n = 349)		Comparison of LNS and IFA (n = 354)		Comparison of LNS and MMN (n = 354)	
					Mean difference or RR	p	Mean difference or RR	p	Mean difference or RR	p
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% below IOM recommended ranges										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% within IOM recommended ranges										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% above IOM recommended ranges										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% with BMI <20 at 6 mo postpartum										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
% with BMI >25 at 6 mo postpartum										
Effect modifier				x.xxx		.		.		.
Sub-group #1	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx
Sub-group #2	x.x ± x.x [x]	x.x ± x.x [x]	x.x ± x.x [x]	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx	x.xx (x.xx, x.xx)	x.xxx

Effect of LNS supplementation on food intake patterns, pregnancy weight gain, and BMI

[1]IFA= Iron-Folic Acid group received 60 mg iron plus 400 µg folic acid; MMN=Multiple Micronutrients group received 1-2 RDAs of 18 vitamins and minerals (including 20 mg iron); LNS=Lipid-based nutrient supplement (LNS) group received LNS with same micronutrients as the MMN group, plus another four minerals (Ca, P, K and Mg) as well as macronutrients. All three supplements were intended for daily consumption.

[2]Data are means ± SE for continuous effect modifiers, or means ± SE [n] for binary effect modifiers.

[3]P-values with asterisks are for interaction. P-values without asterisks compare all three groups in each stratum

References

1. Adu-Afarwuah S, Lartey A, Okronipa H, et al. Lipid-based nutrient supplement increases the birth size of infants of primiparous women in Ghana. Am J Clin Nutr 2015;AJCN. First published ahead of print February 11, 2015 as doi: 10.3945/ajcn.114.091546.
2. Institute of Medicine. Nutrition during pregnancy, weight gain and nutrient supplements. Report of the Subcommittee on Nutritional Status and Weight Gain during Pregnancy, Subcommittee on Dietary Intake and Nutrient Supplements during Pregnancy, Committee on Nutritional Status during Pregnancy and Lactation, Food and Nutrition Board. Washington, DC: National Academy Press, 1990:1–233.
3. Spiegelman D, Hertzmark E. Easy SAS calculations for risk or prevalence ratios and differences. Am J Epidemiol 2005;162(3):199-200.
4. Coates J, Swindale A, Bilinsky P. Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access: Indicator Guide (V.3). Washington, D.C.: Food and Nutrition Technical Assistance Project, Academy for Educational Development. At: http://www.fao.org/fileadmin/user_upload/eufao-fsi4dm/doc-training/hfias.pdf (accessed 12 August 2013). 2007.