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iLiNS DOSE, iLiNS DYAD-G, iLiNS DYAD-M, and RDNS Statistical Analysis Plan: Household Food Security

Background and Objectives

Household food security data were collected at multiple time points during the iLiNS DOSE (Malawi), iLiNS DYAD-G (Ghana), iLiNS DYAD-M (Malawi), and RDNS (Bangladesh) randomized controlled trials. This analysis will assess the effect of each intervention, separately, on perceived household food security as measured by the Household Food Insecurity Access Scale (HFIAS) score. If an effect is found, the analysis will then explore the drivers of the effect.

Description of Interventions

The International Lipid-Based Nutrient Supplements Project (iLiNS Project) conducted randomized controlled trials in Ghana and Malawi designed to test the efficacy of small-quantity lipid-based nutrient supplements (SQ-LNS). The Rang-Din Nutrition Study (RDNS) conducted an effectiveness trial of SQ-LNS in Bangladesh. For each of these trials, data were collected at multiple time-points to assess household food security. In all cases, food security data were collected using the Household Food Insecurity Access Scale survey instrument, developed by FANTA/USAID (Coates et al., 2007), and adapted to the local setting. The randomized treatment groups for each trial are summarized in tables 1-3 below.

Table 1. DOSE Randomized Treatment Groups*

Group	Description
LNS-10gM	10 g sachet of LNS with milk for children from 6-18 months
LNS-20g	20 g sachet of LNS without milk for children from 6-18 months
LNS-20gM	20 g sachet of LNS with milk for children from 6-18 months
LNS-40g	40 g sachet of LNS without milk for children from 6-18 months
LNS-40gM	40 g sachet of LNS with milk for children from 6-18 months
Control	Delayed intervention control

*Randomized at individual level

Table 2. DYAD-G and DYAD-M Randomized Treatment Groups*

Group	Description
IFA	Iron-folic acid capsules for woman during pregnancy
MMN	Multiple micronutrient capsules for women during pregnancy and the first 6 months postpartum
LNS	LNS for women during pregnancy and the first six 6 months postpartum and LNS for their infants from 6-18 months

*Randomized at individual level

Table 3. RDNS Randomized Treatment Groups*

Group	Description
Comprehensive LNS	LNS for women during pregnancy and the first six 6 months postpartum and LNS for their infants from 6-24 months
LNS Child Only	Iron-folic acid for women during pregnancy and the first 3 months postpartum and LNS for their infants from 6-24 months
MNP	Iron-folic acid for women during pregnancy and the first 3 months postpartum and micronutrient powder for their infants from 6-24 months
Control	Iron-folic acid for women during pregnancy and first 3 months postpartum

*Cluster randomized design with clusters being the community health workers' (CHWs) work areas

The scheduled timing of food security data collection for each trial is summarized in Table 4.

Table 4. Schedule of Household Food Security Data Collection[1]

Round	DOSE	DYAD-G	DYAD-M	RDNS
1	Baseline (child 6 mo)*	Baseline*	Baseline*	Baseline
2	Child 12 mo†	Birth†	Birth†	42 days after birth
3	Child 18 mo†	6 mo after birth†	6 mo after birth†	6 mo after birth
4		12 mo after birth†	12 mo after birth†	12 mo after birth
5			18 mo after birth†	18 mo after birth
6				24 mo after birth

*Indicates substantial time-lapse from enrollment to administration of baseline food security data collection for a significant proportion of households.
†Indicates substantial variation in the actual timing of food security data collection relative to scheduled timing of data collection for a significant proportion of households.

Because there was substantial variation in the actual timing of food security data collection visits relative to the scheduled visits at each round for the three iLiNS trials, instead of grouping food security observation by round, this analysis will instead group observations by period, each of which represents a block of time relative to the child's age. [2] This will serve to compare food security observations across households with a similar duration of exposure to the trial. Also, because at each of the iLiNS sites the scheduled baseline round of food security data collection was done post-randomization for many, but not all, households (up to several months post-randomization in some cases), the 'baseline' round will not be used for the DOSE, DYAD-G, or DYAD-M analyses. The baseline round will be retained for the RDNS analysis. The relevant periods are defined, by trial, in Table 5.

[1] This table excludes post-intervention follow-up food security data collection, as those data will not be included in this analysis.
[2] Section A.1 of the appendix includes a description of how the child age brackets that define each period were determined.

Table 5. Periods of Food Security Data Collection

Period	DOSE	DYAD-G	DYAD-M	RDNS
1	Child 11-16 mo	Child 0-5 mo	Child 0-5 mo	Baseline
2	Child >= 16 mo	Child 5-11 mo	Child 5-11 mo	Child 0-5 mo
3		Child >= 11 mo	Child 11 - 16 mo	Child 5-11 mo
4			Child >= 16 mo	Child 11 - 16 mo
5				Child 16-23 mo
6				Child >= 23 mo

Note: Each age bracket includes ages up to but not including the upper bound.

Primary Hypotheses

The primary null hypotheses for each trial are as follows:

DOSE

(1) Over the course of the intervention, household food security is not different between the six groups.
(2) Over the course of the intervention, household food security is not different between the control group and the five LNS groups, combined.

DYAD-G

(1) Over the course of the intervention, household food security is not different between the three groups.
(2) Over the course of the intervention, household food security is not different between the IFA and MMN groups, combined, and the LNS group.

DYAD-M

(1) Over the course of the intervention, household food security is not different between the three groups.
(2) Over the course of the intervention, household food security is not different between the IFA and MMN groups, combined, and the LNS group.

RDNS

(1) Over the course of the intervention, household food security is not different between the four groups.
(2) Over the course of the portion of the intervention in which the mother was receiving supplementation, household food security is not different between the comprehensive LNS group and the other three groups (LNS child only, MNP, and control), combined.
(3) Over the course of the portion of the intervention in which the child was receiving supplementation, household food security is not different between the comprehensive LNS group and the LNS child only group, combined, and the MNP and control group, combined.

Description of Variables

Outcome Variables

The HFIAS Score is a continuous measure of the degree of food insecurity in the household and is based on a set of occurrence and frequency of occurrence questions that encompass three domains of food insecurity: (1) anxiety and uncertainty about the household food supply; (2) perceived insufficient quality; and (3) perceived insufficient food intake and its physical consequences (Coates et al., 2007). For each of nine occurrence questions, the survey respondent indicates whether anyone in her household experienced the food insecurity condition in the previous four weeks. If yes, the respondent indicates how frequently it occurred, where 'rarely' = 1-2 times in the past four weeks, 'sometimes' = 3-10 times in the past four weeks, and 'often' = more than 10 times in the past four weeks. The HFIAS Score is then calculated as the simple sum of the frequency-of-occurrence responses, where 'never' = 0 points, 'rarely' = 1 point, 'sometimes' = 2 points, and 'often' = 3 points.

For each trial, the outcome variable is the seasonally-adjusted HFIAS Score by round (hypotheses 1 and 2 for DYAD-G, DYAD-M, and DOSE and hypotheses 1-3 for RDNS) or as a repeated measure (hypotheses 3 and 4 for DYAD-G, DYAD-M, and DOSE and hypotheses 4 and 5 for RDNS). Seasonal adjustment of the HFIAS Score will be accomplished as follows:

$$Adjusted\ HFIAS\ Score_{i,s,p} = HFIAS\ Score_{i,s,p} - \overline{HFIAS\ Score_s} + \overline{HFIAS\ Score_p}$$

Where $Adjusted\ HFIAS\ Score_{i,s,p}$ is the adjusted HFIAS Score for household *i* in season *s* and period *p*. $\overline{HFIAS\ Score_s}$ is the average HFIAS Score among the control group (IFA group in the case of the DYAD trials) in season *s*. And $\overline{HFIAS\ Score_p}$ is the average HFIAS Score among the control group (IFA group for DYAD trials) in period *p*. The seasons are defined in tables 6 - 9 below.[3] Seasons were defined by consulting cropping calendars,[4] the literature, and personal communication with in-country sources. Periods are defined as in Table 5 above.

Table 6. DOSE Seasons of Food Security Data Collection

Season	**Date Range**
Lean 2009_10	November 2009 - March 2010
Harvest 2010	April 2010 - October 2010
Lean 2010_11	November 2010 - March 2011
Harvest 2011	April 2011 - October 2011
Lean 2011_12	November 2011 - March 2012
Harvest 2012*	April 2012 - October 2012

[3] For seasons with less than 30 observations in the IFA/Control group, these observations will be rolled into the adjacent season for calculating the seasonal average (noted in the tables where relevant). The details of this decision are described in section A.2 of the appendix.

[4] Cropping calendars available at: FAO: http://www.fao.org/giews/countrybrief/country.jsp?code=GHA; http://www.fews.net/southern-africa/malawi/food-security-outlook-update/february-2015; http://www.fao.org/giews/countrybrief/country.jsp?code=MWI; http://www.fao.org/giews/countrybrief/country.jsp?code=BGD

*Harvest season 2012 has fewer than 30 observations in the control group so these observations will be rolled into lean Season 2011_12.

Table 7. DYAD-G Seasons of Food Security Data Collection

Season	**Date Range**
Lean 2010	March 2010 - July 2010
Harvest 2010_11	August 2010 - February 2011
Lean 2011	March 2011- July 2011
Harvest 2011_12	August 2011 - February 2012
Lean 2012	March 2012 - July 2012
Harvest 2012_13	August 2012 - February 2013
Lean 2013	March 2013 - July 2013

Table 8. DYAD-M Seasons of Food Security Data Collection

Season	**Date Range**
Harvest 2011	April 2011 - October 2011
Lean 2011_12	November 2011 - March 2012
Harvest 2012	April 2012 - October 2012
Lean 2012_13	November 2012 - March 2013
Harvest 2013	April 2013 - October 2013
Lean 2013_14	November 2013 - March 2014
Harvest 2014*	April 2014 - October 2014

*Harvest season 2014 has fewer than 30 observations in the IFA group, so these observations will be rolled into lean season 2013_14.

Table 9. RDNS Seasons of Food Security Data Collection

Season	**Date Range**
Monga 2011	September 2011 - November 2011
First Harvest 2011_12	December 2011 - February 2012
Little Monga 2012	March 2012 - May 2012
Second Harvest 2012	June 2012 - August 2012
Monga 2012	September 2012 - November 2012
First Harvest 2012_13	December 2012 - February 2013
Little Monga 2013	March 2013 - May 2013
Second Harvest 2013	June 2013 - August 2013
Monga 2013	September 2013 - November 2013
First Harvest 2013_14	December 2013 - February 2014
Little Monga 2014	March 2014 - May 2014
Second Harvest 2014	June 2014 - August 2014
Monga 2014	September 2014 - November 2014
First Harvest 2014_15	December 2014 - February 2015
Little Monga 2015	March 2015 - May 2015

Covariates

The following variables will be included as baseline covariate controls in all regression models:

- Maternal age
- Maternal education
- Maternal BMI
- Maternal marital status
- Maternal ethnicity (DOSE, DYAD-M, RDNS)
- Main language spoken at home (DYAD-G)
- Primiparity
- Asset Index
- Small livestock score
- Household distance to market
- Stage during food security questionnaire administration
- Season during food security questionnaire administration
- Baseline HFIAS Score (RDNS[5])
- Cluster (RDNS)

Effect Modifiers

The following variables will be assessed for potential effect modification:

- Maternal age
- Maternal education
- Maternal BMI
- Maternal marital status
- Maternal ethnicity (DOSE, DYAD-M, RDNS)
- Main language spoken at home (DYAD-G)
- Primiparity
- Asset Index
- Small livestock score
- Household distance to market
- Stage during food security questionnaire administration
- Season during food security questionnaire administration
- Baseline HFIAS Score (RDNS)

[5] In most cases in the iLiNS DOSE, DYAD-G, and DYAD-M trials, the 'baseline' round of food security enumeration took place after the receipt of first supplement (sometimes a few days after the receipt of first supplement and sometimes many months after receiving the assigned supplement). Because the 'baseline' round includes both households surveyed prior to the receipt of first supplement and households surveyed after the receipt of supplement, the 'baseline' round will not be included as a covariate control for these trials.

Analysis Principles

The analysis will be by intent-to-treat. That is, by-group analysis will be according to the group assignment regardless of any protocol violations. Households with missed food security visits will be included in the analysis for all time points where data are available, and the sample size will be clearly reported for each regression analysis/time point. Missing data (food security data and covariates) will not be imputed.

Households for whom a food security visit occurred so far off schedule such there are two observations for the same household in one period (for example, the food security visit that was scheduled to occur when the child was approximately six months of age didn't occur until the child was 11 or 12 months of age, and then another food security visit occurred when the child was 12 or 13 months so that both observations fall into the same stage), the visit closest to when the visit was scheduled during that period will be retained and the other observation dropped from the analysis.

For households for which the date of birth of the child is not available (miscarriages, stillbirths), period will be assigned based on the scheduled timing of each visit.

All tests will be two-sided at the 10% level of significance.

Analysis of the Effect of the Intervention

To account for the cluster randomized design of the RDNS trial, standard errors in all models will be clustered at the 'cluster' level for the RDNS analysis.

Repeated Measures Analysis

The null hypotheses of no difference between groups over time will be tested using linear mixed models with baseline covariate controls and cluster-robust standard errors. If the null hypothesis of no difference between groups is rejected, post-hoc pairwise comparisons of group means using the Tukey-Kramer adjustment for multiple comparisons will then be performed, where applicable. Linear mixed models with an interaction between group and period will be used to assess differences in the effect of group over time. Statistically significant interactions between group and period ($p<.10$) will be further examined using cross sectional analysis of each period. In particular, the null hypotheses of no difference between groups at each period will be tested using OLS regression with baseline covariate controls and cluster-robust standard errors.

Effect modification by other baseline covariates will be similarly assessed by including an interaction term in the mixed models. Significant interactions ($p < 0.10$) will be further examined with stratified analyses, estimation of separate regression lines, or estimation of adjusted means at certain values of the effect modifier, in order to understand the nature of the effect modification.

Drivers of the Effect

If statistically significant differences in food security by group are found either by period (cross sectional analysis) or over time (repeated measures analysis), exploratory analyses will then be performed to try to understand what is driving the effect. This will be accomplished as follows[6]:

1. Use logistic regressions and/or mixed model logistic regressions to assess difference by group for each of the nine HFIAS occurrence questions (i.e., dichotomous variable indicating whether or not the household experienced the particular food insecurity condition in the past four weeks). Assess effect modification using interaction terms with statistically significant effect modifiers identified in the main analysis.

2. Use logistic regressions and/or mixed model logistic regressions to assess difference by group in 'coping strategies' (i.e., dichotomous variable indicating whether or not the household employed a particular strategy to deal with food insecurity in the past four weeks). Assess effect modification using interaction terms with statistically significant effect modifiers identified in the main analysis.

3. Using appropriate regression models, assess difference by group in child diet variables as well as selected KAP and maternal diet (if available) variables related to food consumption patterns, perceived sufficiency/deficiency in food availability and quality, perception of child growth, maternal role in food purchasing decisions, etc.

[6] Because the analysis exploring the drivers of the effect will focus on individual questions that are primarily dichotomous choice, these data will not be seasonally adjusted.

References

Coates, Jennifer, Anne Swindale, and Paula Bilinsky. 2007. Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access: Indicator Guide. Washington, DC: Food and Nutrition Technical Assistance Project (FANTA), Academy for Educational Development.

Appendix

A.1 Periods of Food Security Data Collection

This section of the appendix describes how the age brackets that define the 'periods' of food security data collection were determined. Food security data collection took place a month or more off schedule for many households in the DOSE, DYAD-M, and DYAD-G samples (and to a much lesser extent in the RDNS sample). As a result, the distributions of the age of the index children by round are wide and overlap across rounds at the tails (that is, for example, **round 3** might have occurred when the index child was 10 months old for some households and for other household **round 4** occurred when the child was 10 months old). In order to make clear the age range of children at each time point as well as to ensure we compare (within-trial comparisons) food security scores across households who have been exposed to the intervention for a similar duration, instead of using the usual longitudinal marker of 'round' as coded in the data, periods are defined based on index child age. The age ranges included in each period of food security data collection were determined by looking at the distribution of child age around each scheduled time point of data collection (that is, for each round) and identifying an age range that captured the majority of the observations in the scheduled round and prevented overlap in child age across rounds.

The tables of two-way tabulations below show round (as coded in the data) by period (as defined by child age). In most cases, round corresponds to period. However, there are several cases in each site in which food security data collection occurred so far off schedule that round and period do not correspond (note that a round of data cleaning focused on date of food security data collection will be performed which may eliminate some of the cases in which round and period do not correspond).

DOSE

	Period	
Round	Child 11-16	Child >= 16
2	1,129	5
3	13	974

DYAD-M

	Period			
round	Child 0-5	Child 5-11	Child 11-16	Child >= 16
2	734	1	3	2
3	1	622	14	1
4	0	1	659	4
5	0	5	4	660

DYAD-G

	Period		
Round	Child 0-5	Child 5-11	Child >= 11
2	1,110	1	0
3	1	1,049	5
4	0	2	983

RDNS

	Period					
Round	Pregnancy	Child 0-5	Child 5-11	Child 11-16	Child 16-23	Child >=23
1	4,006	0	1	0	0	0
2	1	3,671	8	0	0	0
3	0	1	3,535	0	0	0
4	0	0	0	3,447	0	0
5	0	0	0	3	3,420	0
6	0	0	0	0	0	3,440

A.2 Seasonal Adjustment

This section of the appendix provides details that were considered when deciding to roll observations from seasons with less than 30 observations in the IFA/Control group into the adjacent season for calculating the seasonal average (relevant for the final season of DOSE and final season of DYAD-M).

For the case of DOSE, Harvest 2012 was the final season in which food security data were collected. In this season, which spans from April – October of 2012, food security data were only collected in the first two months of the season (during April and May). During those two months, food security data were collected from 106 households, 15 of which were in the control group. We decided that a sample of 15 was too few observations from which to calculate the seasonal average. Moreover, since all observations in this final season were collected during the first two months of the season, we decided it would not be appropriate to use the seasonal average from the previous year (Harvest 2011, from April – Oct 2011) as the adjustment for the final season. Given these considerations, we decided to include the 15 observations from April and May of 2012 in calculating the seasonal adjustment for the previous season (Nov 2011 – March 2012) and then apply that at adjustment to all observations from Nov 2011 – May 2012.

For DYAD-M, the last season of food security data collection was Harvest 2014 (April – Oct 2014). Here, the final food security data were collected from two households in April 2014. Neither of these households were in the IFA group. Therefore, we decided to apply the seasonal adjustment from the previous season (lean season 2013-2014) to these two observations.