

Effects of nutritional supplementation and home visiting on growth and development in young children in Madagascar: a cluster-randomised controlled trial



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Summary

Background Evidence from efficacy trials suggests that lipid-based nutrient supplementation (LNS) and home visits can be effective approaches to preventing chronic malnutrition and promoting child development in low-income settings. We tested the integration of these approaches within an existing, large-scale, community-based nutrition programme in Madagascar.

Methods We randomly allocated 125 programme sites to five intervention groups: standard-of-care programme with monthly growth monitoring and nutrition education (T0); T0 plus home visits for intensive nutrition counselling through an added community worker (T1); T1 plus LNS for children aged 6–18 months (T2); T2 plus LNS for pregnant or lactating women (T3); or T1 plus fortnightly home visits to promote and encourage early stimulation (T4). Pregnant women (second or third trimester) and infants younger than 12 months were enrolled in the trial. Primary outcomes were child growth (length-for-age and weight-for-length Z scores) and development at age 18–30 months. Analyses were by intention to treat. The trial was registered with the ISRCTN registry, number ISRCTN14393738.

Findings The study enrolled 3738 mothers: 1248 pregnant women (250 women in each of the T0, T1, T2, and T4 intervention groups and 248 in the T3 intervention group) and 2490 children aged 0–11 months (497 children in T0, 500 in T1, 494 in T2, 499 in T3, and 500 in T4) at baseline who were assessed at 1-year and 2-year intervals. There were no main effects of any of the intervention groups on any measure of anthropometry or any of the child development outcomes in the full sample. However, compared with children in the T0 intervention group, the youngest children (<6 months at baseline) in the T2 and T3 intervention groups who were fully exposed to the child LNS dose had higher length-for-age Z scores (a significant effect of 0.210 SD [95% CI –0.004 to 0.424] for T2 and a borderline effect of 0.216 SD [0.043 to 0.389] for T3) and lower stunting prevalence (–9.0% [95% CI –16.7 to –1.2] for T2 and –8.2% [–15.6 to –0.7] for T3); supplementing mothers conferred no additional benefit.

Interpretation LNS for children for a duration of 12 months only benefited growth when it began at an early age, suggesting the need to supplement infants at age 6 months in a very low-income context. The lack of effect of the early stimulation messages and home visits might be due to little take-up of behaviour-change messages and delivery challenges facing community health workers.

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Introduction

Hundreds of millions of the world's children have poor nutrition and, as a consequence, experience delays in physical and mental health and development.¹ Linear growth faltering (low length-for-age Z score) is associated with poor cognitive, language, and behavioural development; high levels of morbidity and mortality; and negative long-term outcomes including school achievement and adult earnings.² Despite some successes, there is an urgent need for cost-effective, scalable approaches to address entire populations of children who are at risk of poor growth and development.³

Three common strategies used to improve nutritional status in the first 1000 days of life include promotion of

behaviour change to increase dietary quality, fortification of food to improve micronutrient content of staple foods, and nutritional supplementation targeted to vulnerable population groups.^{4,5} Growth monitoring and education strategies are only successful when they involve intensive counselling and strongly emphasise dietary diversity and the promotion and consumption of animal source foods;⁶ the quality of counselling and its intensity are believed to be necessary conditions for growth monitoring programmes to be effective.⁷

Studies examining lipid-based nutrient supplementation (LNS) for pregnant and lactating women, or for very young children, have shown fairly consistent results with small effect sizes. For example, a systematic review⁸ of

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Research in context

Evidence before this study

When this study was conceived in 2012, we reviewed the literature exploring the associations between lipid-based nutritional supplementation (LNS) during pregnancy and infancy and child growth and development outcomes. Although we found no evidence before this study about LNS and child development, new evidence emerged while this study was in place that LNS might be beneficial to child development in Bangladesh, Burkina Faso, and Ghana, but not Malawi. At the time of study design, we used the 2011 *Lancet* Series on Early Child Development to identify articles examining the associations between participating in early stimulation programmes and cognitive development in low-income and middle-income countries. We identified articles that had examined the efficacy of early stimulation programmes in randomised controlled trials in Jamaica, Pakistan, and Bangladesh, and only two studies (Mexico and Colombia) that had examined effects of programmes operating at scale. These last two were within the context of a conditional cash transfer programme.

Added value of this study

This cluster-randomised controlled trial evaluated the effects of delivering LNS and early stimulation to children during the first 1000 days of life by integrating new intervention strategies into an existing community-based programme, which provides growth monitoring, nutrition education, and health referrals for treatment. The existing programme, which is implemented

by the Madagascar Government, is a key component of the country's nutrition and food security strategy and is already operating at scale, covering around 7000 sites across Madagascar. In addition to primary outcomes (anthropometrics and child development), we recorded information across a range of measures along the pathways of impact. Results will directly inform future programme design and scale-up and are expected to be generalisable to other low-income settings where the prevalence of stunting is high.

Implications of all the available evidence

Our results support the potential for LNS to be used effectively to increase linear growth and decrease stunting as a preventive component of a nutrition package in low-income settings such as Madagascar, provided that the supplementation starts at 6 months of age. However, the additional cost of supplementing mothers during pregnancy and lactation might not be warranted. Our results also show that intensive counselling can be effective in shifting feeding behaviours, but it might not be sufficient by itself to address nutritional deficiencies over and above group messaging in a context of high poverty and food insecurity. Finally, challenges remain to improving early child development in this context, including barriers to message delivery (eg, distance to travel to homes or security of the front-line worker) as well as to caregivers' adoption of new early stimulation behaviours (eg, from competing demands on time and financial resources).

four LNS trials among pregnant women in Bangladesh, Burkina Faso, Ghana, and Malawi concluded that there was evidence of a small positive effect of LNS during pregnancy on birthweight and birth length, a lower risk of small for gestational age, and reduced newborn stunting (length-for-age Z score <-2). Preventive LNS among 6–24-month-old children in Kenya, Bangladesh, Burkina Faso, Malawi, Zimbabwe, Mali, and Haiti has shown positive, albeit modest, effects on linear growth.⁹ In the Bangladesh study,¹⁰ there was no difference between the mother-and-child LNS group compared with the child-only LNS group by 24 months of age, despite the small improvements in birthweight and birth length in the mother-and-child LNS group. In two studies^{11,12} integrating LNS into water and sanitation interventions, there were some modest but significant effects on growth.

Thus far, few studies have examined effects of LNS on child development outcomes and the available data are conflicting. In Malawi, children given LNS from 6 months to 18 months of age had no difference in age of achievement of motor or language developmental milestones¹³ or other child development measures.¹⁴ However, in a study¹⁵ in Bangladesh evaluating prenatal and postnatal LNS and micronutrient powders, LNS had positive effects on motor and language development but

no effects on personal-social behaviour or executive function.¹⁵ Similarly, a trial in Burkina Faso also reported significant benefits of LNS on children's motor, language, and personal-social development,¹⁶ and two other trials in Ghana found significant beneficial effects of LNS on children's development.¹⁷ In Bangladesh, LNS showed benefits to child development independently or when combined with water and sanitation interventions¹⁸ but these findings were not apparent in a similar study in Kenya.¹⁹

Home-visiting programmes during infancy and early childhood have generally shown consistent benefits for child growth and development, but the benefits are not always sustained into later childhood. A large home-visiting programme in Pakistan in children aged 2–5 months to 24 months of age, for example, utilised community health workers and showed improved child development outcomes.²⁰ A scaled-up programme in several Caribbean islands delivered parenting support messages about early stimulation within primary care clinics and showed benefits to child development.²¹ Two studies have used the existing structure of a country's conditional cash transfer programme to deliver messages about early stimulation, through group sessions or home visiting; in Mexico, there were benefits

to child development of exposure to a scaled-up, group-based programme promoting early stimulation,²² whereas in Colombia, there were benefits in the short term that faded 2 years after the home-visiting programme had ended.²³

The overall aim of the MAHAY study (meaning “smart” or “skilled” in Malagasy) was to determine whether selected intervention packages could significantly alter the pattern of severe growth faltering and delays in child development among young children in Madagascar. The prevalence of stunting in Madagascar is almost 50%¹ and stunted children have consistently shown deficits in developmental outcomes such as language and cognition.²⁴ A community-based nutrition programme delivered through a public sector platform has been operating at scale since 1999, and the programme provides growth monitoring, nutrition education, cooking demonstrations, and health referrals. In spite of intense government commitment to these problems, the existing programme has only shown small effects on weight-for-age in young children and little to no effect on children’s length-for-age.²⁵ Given the high prevalence of moderate and severe stunting in Madagascar, the rationale for providing supplementation to both children and pregnant or lactating women was strong, particularly when combined with an improved behaviour change intervention in the form of individualised counselling.^{26,27}

Our primary objectives were to determine whether there were benefits of intensive counselling or LNS for child nutritional status and development over and above the existing nutrition education and child growth-monitoring programme, examine the optimal timing and composition of interventions to promote growth and development by comparing intervention groups to each other in terms of effectiveness, and to identify benefits of integrating an early childhood stimulation programme into the existing nutrition programme for improved child development.

Methods

Study design and participants

Details on the study methods and rationale have been published previously.²⁸ In brief, the study was a five-group, cluster-randomised controlled trial of enhanced variants to the existing national nutrition programme, the Programme National de la Nutrition Communautaire. All pregnant women and women with children aged 0–2 years living in the programme site catchment area are eligible to participate. The programme and variants, which included intensive counselling and provision of nutritional supplementation, were implemented from September–October, 2014, over a 2-year period by the Madagascar Government (the National Nutrition Office) with co-financing from the World Bank. Data were collected by an independent survey firm, ProESSECAL, in 125 study sites at three timepoints: a baseline survey administered before the launch of the interventions (June–August, 2014), and two follow-up surveys administered 1 year after baseline

(September–October, 2015) and 2 years after baseline (September–November, 2016). Programme and survey timelines are shown in the appendix (p 1). Study protocols were reviewed and approved by the local Ethics Committee in Madagascar and the Institutional Review Board at the University of California, Davis. Mothers provided verbal consent before study enrolment. The study protocol has been already published.²⁸

Randomisation and masking

The sampling frame was 1476 active government nutrition programme sites as of January, 2014, in five regions of south and southeast Madagascar (Amaron’i Mania, Androy, Atsimo Atsinanana, Haute Matsiatra, and Vatovavy-Fitovinany; see appendix p 2 for the geographical distribution of sites). These regions have some of the highest prevalence of child stunting in Madagascar and were selected as part of a World Bank emergency loan to restore and preserve basic service delivery after the economic and political crisis of 2009–12.

A sample size of 25 sites per intervention group and 30 households per site was estimated to be sufficient to detect an effect size of 0·3 SD for each pairwise comparison of groups, assuming an intracluster correlation of 0·1, $\alpha=0\cdot05$, and statistical power of 80%, unconditional on covariates.²⁸ The intracluster correlation was based on previous studies of child development in Madagascar using direct assessments. Our total target sample was therefore 125 sites, stratified by region, and 3750 households. Site sampling was done by the research team using administrative data.

Local non-governmental organisations (NGOs) were responsible for providing programme supervision. To minimise contamination of intervention by supervisors, these NGOs were randomly sampled with one site per NGO supervisor, and stratified by region, whenever possible. This reduced the sampling frame to 261 sites. Next, a random generator was used to block-randomise five sites per intervention group per region into the current standard programme (T0; control group) or to one of four enhanced intervention groups: intensive nutrition counselling (T1); intensive nutrition counselling plus LNS to children aged 6–18 months (T2); intensive nutrition counselling plus LNS to pregnant women, lactating mothers of children aged 0–5 months, and to children aged 6–18 months (T3); and intensive nutrition counselling and home visiting for early stimulation of children aged 6–30 months (T4). The final sample of 125 sites was balanced across intervention groups along average underweight prevalence and size of the target population per site, based on existing programme monitoring data.

Programme sites cover an average of two to three small communities, with a target population of about 100 children aged 0–2 years. In each study site, an up-to-date registry of government-programme-eligible women and children maintained by the local

See Online for appendix

community health worker was used as a sampling frame to select households eligible for enrolment in the trial. 30 households were randomly sampled per site, stratified by children's age at baseline: ten households with a pregnant woman in her second or third trimester and eligible for LNS (cohort A); ten households with a child aged 0–5 months whose mother was eligible for LNS (cohort B); and ten households with a child aged 6–11 months (cohort C) eligible for a minimum of 6 months of LNS (11-month-olds) and a maximum of 12 months of LNS and 24 months of early stimulation (6-month-olds) during the 2-year study. If the site registry did not have a sufficient number of pregnant women or children in the target age groups, a household listing exercise was done in the site catchment area to draw the remaining sample.

Mothers or children who died before the final assessment were not replaced. Children who had permanently moved outside the programme site catchment area before final assessment were replaced with a randomly drawn child from the site within the same age range. Children and their households who returned to the site between the baseline and final assessment were re-interviewed.

Due to the nature of the interventions, masking of participants and community health workers was not possible. Data analysts were not blinded to intervention group assignment due to differences in survey information (eg, number of community health workers at a site or women's receipt of LNS).

Procedures

In all groups, a community health worker was elected in each community in the programme site catchment area. Community health workers provided monthly standard-of-care health and nutrition services, including growth monitoring activities for infants and young children, cooking demonstrations, community mobilisation, and nutrition and hygiene education. In the control group (T0), only these activities were provided.

In all sites randomly assigned to interventions T1–T4, an additional community health worker was hired to be fully dedicated to home visits. All pregnant women and children aged 0–24 months registered at these sites were eligible to receive the home visits. Additional community health workers had at least lower secondary education, lived within the site, and received 10 days of intensive training after the administration of the baseline survey and refresher training, with special emphasis on listening and communication skills, problem solving for exclusive breastfeeding, introduction of complementary feeding, and food security. The counselling model was based on a theory of change using constructs from an integrated behavioural model.²⁹ The additional community health worker was instructed to do home visits for all children in the site catchment area up to 2 years of age, with one visit during pregnancy, monthly visits during the first 8 months of age, bimonthly visits from

9 to 12 months of age, and quarterly visits from 12 to 24 months of age.

In the T2 intervention group, 20 g of LNS were provided to all children aged 6–18 months in the community. In T3, 40 g sachets of LNS were provided to all pregnant and lactating women (within the first 6 months postpartum) and 20 g of LNS to all children aged 6–18 months in the community. The composition of the two supplements is provided in the appendix (p 4). Weekly supplies of LNS were distributed to eligible mothers and children at the programme site by the additional community health worker. Mothers were instructed to mix 10 g sachets of supplement into their children's typical food twice per day. Throughout the project, LNS distribution logs were used to monitor the fidelity of implementation of the LNS delivery. Compliance was monitored by the NGO supervisors. Empty sachets had to be returned to the additional community health worker to avoid reselling.

The T4 intervention group (ie, integrated counselling on nutrition and early stimulation) included home visits to children aged 6–30 months. For this intervention, the additional community health worker provided bi-weekly stimulation messaging home visits in addition to the nutrition counselling home visits. To ensure sufficient intensity of the cognitive stimulation component, and considering the workload of the additional community health worker, only households enrolled in the baseline survey were considered eligible to receive the stimulation messaging home visits. The structured curriculum on early stimulation was adapted from the Reach Up and Learn Early Childhood Parenting programme, first implemented in Jamaica.³⁰ In addition to the basic and refresher training received by all community health workers, the additional workers for intervention T4 received theoretical and practical training on early stimulation at the onset of the intervention and at 6-month intervals. Additionally, a team of early childhood development coaches provided a week of on-site support at the onset of the programme and after 6 months of implementation.

As previously described, there were three child age cohorts at baseline, ranging from –6 months (ie, second or third trimester) to younger than 12 months. After the first year of programme implementation, target children would be aged 6 months to younger than 24 months, and after the second year at study end, they would be aged 18 months to younger than 36 months. Due to their differing ages at the start of the trial, varying age eligibility by intervention group (figure 1), and timing of the data collection, children experienced different exposure durations to the interventions. The T0 intervention covered children during pregnancy up to 24 months of age. As this programme was operational before the start of the trial, all children sampled for the study were exposed to the T0 intervention from pregnancy onward.

Women and children were eligible for intensive nutrition counselling (T1–T4) during pregnancy up to

24 months of age. However, counselling began for cohort C (the oldest) when they were at least 6 months old and stopped 12–18 months later, whereas cohort A (the youngest) was eligible for the maximum duration of counselling during their first 1000 days of life (figure 1). In T2, LNS was delivered when children were 6–18 months. Children in cohorts A and B (–6 months to <6 months at baseline) were eligible to receive the full 12 months of supplementation. However, children in cohort C (6 months to <12 months) received LNS for 12 months or less and stopped receiving supplements a year or more before the study end survey. In T3, LNS was additionally provided to mothers during pregnancy and lactation. Only cohort A maximally benefited from the maternal supplements, whereas cohort B benefited for 6 months and cohort C not at all. Finally, in T4, the intervention was provided for children aged 6–30 months. In this last intervention group, cohort C maximally benefited, whereas cohort A did not have the opportunity to be fully exposed to the intervention before the study end survey.

Data were collected prospectively with five tablet-based questionnaires administered at the three timepoints (appendix pp 5–7). A household questionnaire with detailed sections on household demographics, housing, and water and sanitation conditions was administered to the household head or, in their absence, to the most informed household member. A mother and primary caregiver questionnaire was administered to pregnant women and primary caregivers of target children, including (but not limited to) questions on prenatal care, knowledge about nutrition and hygiene, and programme participation in T1–T4 activities. A child questionnaire administered to all primary caregivers included primary outcome information (see below). Finally, community health worker and site questionnaires were administered at each timepoint to compare key site-level characteristics across intervention groups. All questionnaires and the timing of the data collection are available in the appendix (pp 5–8).

Outcomes

Child length-for-age and weight-for-length Z scores were the primary nutritional outcomes. Length and weight were measured in duplicate at each survey wave using techniques described for the WHO Multicenter Growth Reference Study.³¹ Calculation of continuous nutritional status Z scores for age were completed using the computer software, Anthro (version 7.0), and growth standards, both issued by WHO.³²

Children's development was also a primary outcome and was assessed at each survey wave using the Ages and Stages Questionnaire: Inventory version (ASQ-I), a comprehensive caregiver-report assessment of child development.³³ ASQ-I is a continuous scale version of the more widely used ASQ-3 screening tool, which is subject to ceiling effects when assessing normally developing

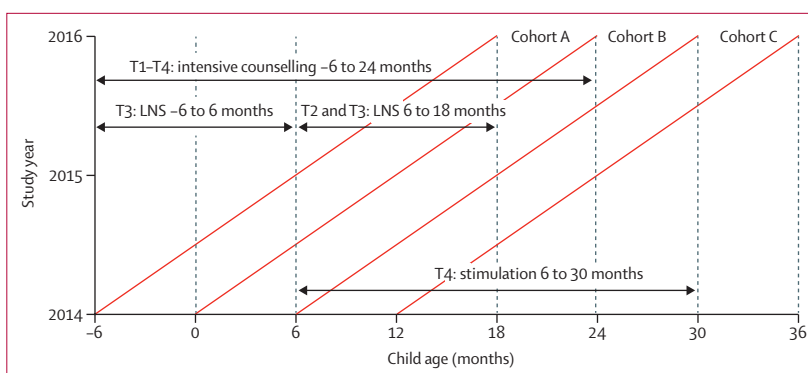


Figure 1: Duration of exposure and eligibility by cohort, age, and intervention group

Figure shows the overlap between age at measurement for the different cohorts at different survey years (2014: baseline, 2015: 1-year follow-up, 2016: study end). Cohorts A (second or third trimester), B (0–5 months of age), and C (6–11 months of age) are the age groups that were used to stratify the sample at baseline. LNS=lipid-based nutrient supplementation.

children.³⁴ The ASQ-I subscales measure skills in communication, gross motor, fine motor, personal-social, and problem-solving domains. ASQ-I subscale and total scores were converted to internally age-adjusted Z scores in 1-month age increments.

Secondary outcomes were child weight-for-age Z scores (continuous) and binary indicators for stunted and severely stunted, which were calculated at –2 SD and –3 SD below the median length-for-age Z score, respectively, of healthy same-age and same-sex children.

Intermediate child-level measures were a continuous measure of caregiver-reported child morbidity (ie, a cumulative number of occurrences of child fever, cough, or diarrhoea in the previous 7 days), four binary indicators of different food group consumption (intake in the previous 24 h of dairy; meat, fish, and eggs; vitamin A-rich foods; and at least four food groups), and a continuous score for diet diversity (number of food groups consumed from a 24-h dietary recall). Mother-level measures included six continuous measures of caregiver knowledge of child development, care, and feeding practices (such as breastfeeding history and status and timing of complementary feeding), hygiene practices (eg, washes hands before meal preparation), maternal dietary diversity in a 24-h period (as measured by the Minimum Diet Diversity for Women module),³⁵ household food security (using the Food and Agriculture Organization's Household Food Insecurity Scale),³⁶ and home stimulation practices (translated and adapted for the local context from UNICEF's Family Care Indicators, including number of books, play objects, and play activities with any adult in the household in the previous 3 days).³⁷

Statistical analysis

Descriptive statistics for outcomes by intervention group are shown as mean (SD) for the control group to show the magnitude of variation in outcomes and mean (SE) for the treatment variant groups. Robust SEs are based on separate regressions in which each outcome variable is

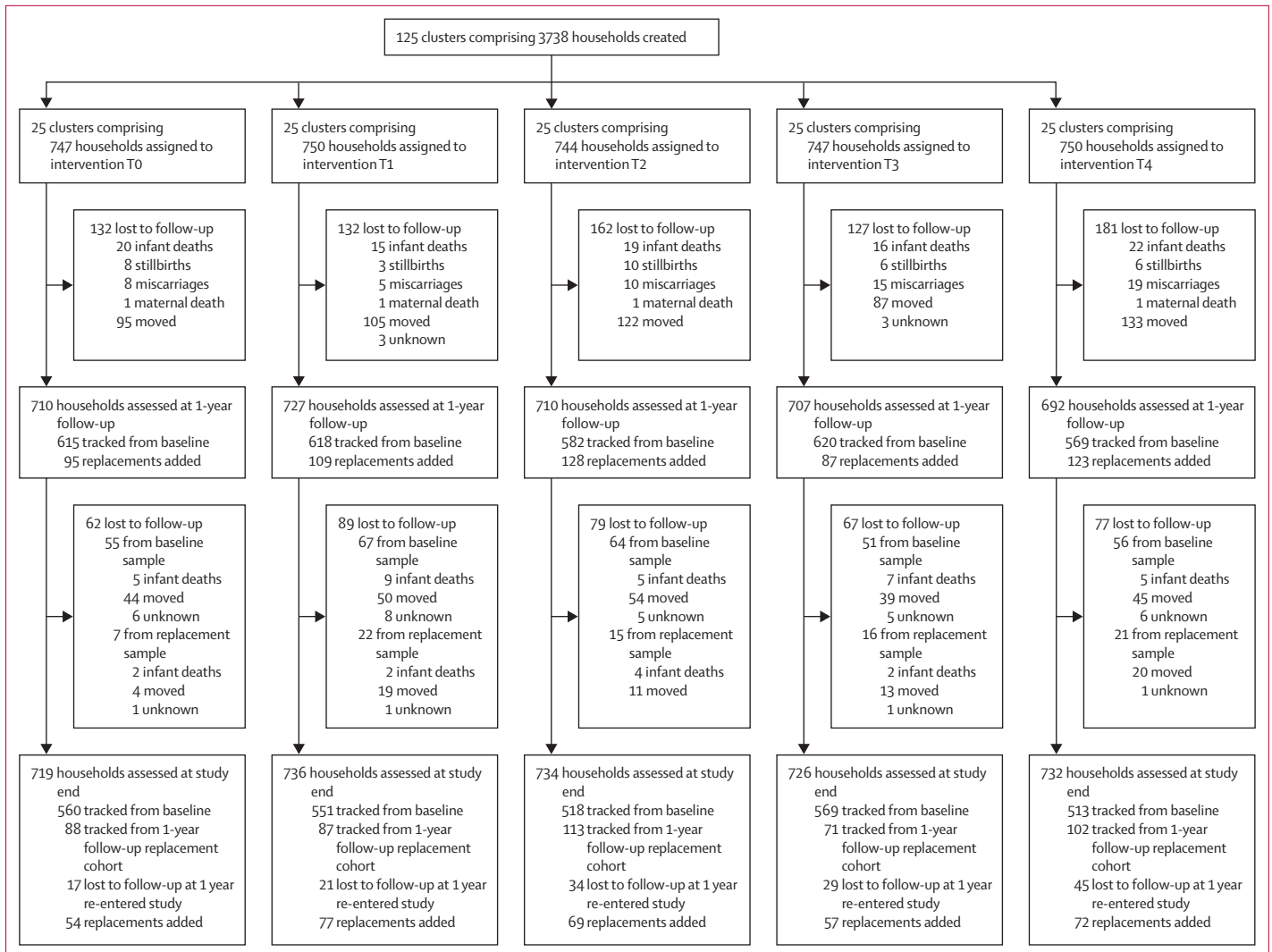


Figure 2: Trial profile

T0: current standard programme (control group). T1: intensive nutrition counselling. T2: intensive nutrition counselling plus LNS to children aged 6–18 months. T3: intensive nutrition counselling plus LNS to pregnant women, lactating mothers of children aged 0–5 months, and to children aged 6–18 months. T4: intensive nutrition counselling and home visiting for early stimulation of children aged 6–30 months. LNS=lipid-based nutritional supplementation.

regressed on a set of treatment indicators and dummy indicators for sampling strata, adjusted for clustering at the site level. Showing SEs for the baseline comparison is a common approach in the economics literature to assess the power for testing differences in group means across these groups.

Analyses were by intention to treat (ITT) to minimise selection bias from selective take-up of the programme and provide the lower bound on estimated impact. We relied on the random assignment of intervention group at the community level for identification of causal effects on primary outcomes, which were estimated through a series of pairwise comparisons of mean outcomes between intervention groups at study end.

We used ordinary least square linear regressions for the analyses. All regressions were adjusted for key covariates

(sex, birth order, maternal age, maternal education, and household wealth) that might have been associated with treatment assignment by chance alone and are known to be predictive of one or more primary outcomes.^{5,38} In all specifications, we controlled for strata effects (region and age) to account for the study design. We obtained robust SEs by adjusting for clustering at the community level.

Heterogeneous treatment effects were estimated by interacting treatment status with each of three prespecified variables of interest in separate regressions: child age (younger than vs equal to or older than the median age at study end), maternal education (primary or less vs secondary or higher), and child sex.

All data analyses were done with Stata/MP 15. This trial has been registered with the ISRCTN registry, number ISRCTN14393738.

	T0 mean values (SD)	Regression coefficients on treatment indicators (SE)			
		T1	T2	T3	T4
Household characteristics at baseline					
Household size	5.65 (2.50)	5.70 (0.21)	5.88 (0.21)	5.61 (0.14)	5.77 (0.14)
Asset index					
Quintile 1 (poorest)	0.21 (0.41)	0.19 (0.05)	0.18 (0.05)	0.26 (0.05)	0.16 (0.04)
Quintile 2	0.19 (0.39)	0.18 (0.03)	0.21 (0.03)	0.21 (0.02)	0.22 (0.03)
Quintile 3	0.20 (0.40)	0.18 (0.03)	0.20 (0.03)	0.22 (0.02)	0.20 (0.03)
Quintile 4	0.21 (0.40)	0.20 (0.03)	0.23 (0.03)	0.19 (0.02)	0.18 (0.02)
Quintile 5 (most affluent)	0.20 (0.40)	0.25 (0.05)	0.19 (0.05)	0.11 (0.03)	0.24 (0.06)
Household access to safe drinking water	0.33 (0.47)	0.23 (0.06)	0.25 (0.06)	0.25 (0.07)	0.33 (0.07)
Mother education					
Did not attend school	0.23 (0.42)	0.29 (0.05)	0.28 (0.04)	0.25 (0.04)	0.26 (0.04)
Primary or less	0.51 (0.50)	0.49 (0.03)	0.53 (0.04)	0.56 (0.03)	0.51 (0.03)
Secondary or higher	0.26 (0.44)	0.23 (0.03)	0.19 (0.03)	0.20 (0.02)	0.24 (0.04)
Maternal height (cm)	152.63 (5.75)	151.82 (0.45)	151.92 (0.50)	152.54 (0.49)	152.35 (0.47)
Mother or caregiver age (years)	26.26 (7.67)	26.83 (0.34)	26.13 (0.29)	25.49 (0.38)	25.68 (0.31)
Child characteristics at baseline					
Child birth order	2.63 (1.27)	2.66 (0.07)	2.67 (0.05)	2.61 (0.07)	2.68 (0.07)
Length-for-age Z score	-1.53 (1.24)	-1.64 (0.08)	-1.61 (0.10)	-1.67 (0.07)	-1.61 (0.09)
Weight-for-age Z score	-1.01 (1.18)	-1.12 (0.08)	-1.07 (0.08)	-1.19 (0.08)	-0.98 (0.09)
Weight-for-length Z score	0.07 (1.20)	0.02 (0.10)	0.09 (0.09)	-0.08 (0.10)	0.18 (0.08)
ASQ-I child development Z score	-0.09 (0.99)	0.04 (0.09)	0.13 (0.07)	-0.12 (0.11)	0.04 (0.09)
Intermediate outcomes					
Maternal knowledge index score	-0.18 (1.11)	-0.07 (0.20)	-0.05 (0.18)	0.13 (0.16)	0.15 (0.28)
Material diet diversity score index	2.90 (1.26)	2.98 (0.11)	3.00 (0.10)	2.86 (0.14)	2.75 (0.13)
Learning opportunities: number of activities with any adult	2.01 (1.51)	2.33 (0.16)	2.41 (0.21)	2.04 (0.20)	2.32 (0.21)
Total books, general plus children's books	3.60 (4.96)	3.36 (0.36)	3.57 (0.39)	3.33 (0.36)	3.73 (0.41)
Play objects and materials	1.61 (1.39)	1.67 (0.06)	1.72 (0.08)	1.63 (0.08)	1.72 (0.10)
Family Care Indicators score	-0.10 (0.81)	0.05 (0.09)	0.11 (0.11)	-0.11 (0.10)	0.05 (0.11)
Child dietary diversity score	1.00 (1.15)	1.02 (0.06)	1.19 (0.06)	0.92 (0.06)	0.92 (0.09)

Coefficients are from separate regressions in which a dependent variable is regressed on the full set of treatment indicators and strata dummies. Robust SEs are clustered at the community level. Household asset index is obtained from a principal component analysis of asset ownership and dwelling characteristics. Child length-for-age, weight-for-age, and length-for-age Z scores were calculated using the growth standards issued by WHO. ASQ-I is the age-normalised score in 1-month age increments for all five subdomains of development. The maternal knowledge index score is given by a principal component analysis of correct knowledge of the causes of diarrhoea, not walking, malnutrition, and developmental delays. The maternal diet diversity score is given by the number of food groups consumed, obtained from a 24-h dietary recall module.³⁷ The Family Care Indicator score is obtained from a principal component analysis of the number books, the number of play objects and materials available at home, and the number of play activities done with any adults in the household in the previous 3 days.³⁷ The child dietary diversity score is a continuous score for the number of food groups consumed by the child from a 24-h dietary recall. ASQ-I=Agas and Stages Questionnaire: Inventory.

Table 1: Balance table of key characteristics at baseline

Role of the funding source

The funders were not involved in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

3738 households were enrolled in the study at baseline and 3647 households were interviewed at study end (figure 2). The intervention groups seemed generally well balanced along baseline outcomes (length, weight, and cognitive development), maternal characteristics (education and height), and household variables (asset index

and access to safe water; table 1). However, there was some evidence of imbalance in the top wealth quintile for households, mother or caregiver age, and child food diversity (table 1). Children were 4–29 months of age (median 17 months, IQR 12–21) at the first follow-up and 16–42 months of age (30, 25–34) at the second follow-up.

Of the 3738 households enrolled at baseline, 217 (5.8%) were lost to follow-up for the following reasons: stillbirth in 33 (0.9%) cases, miscarriages in 57 (1.5%) cases, maternal death in four (0.1%) cases, and child death before first follow-up in 92 (2.5%) cases and before final assessment in 31 (0.8%) cases. 841 children moved outside the programme site catchment area and 40 had unknown status before final assessment. 871 children

	T0 mean values (SD)		T1		T2		T3		T4	
	Difference from control (95% CI)	p value	Difference from control (95% CI)	p value	Difference from control (95% CI)	p value	Difference from control (95% CI)	p value	Difference from control (95% CI)	p value
Anthropometric outcomes										
Length-for-age Z score	-2.350 (1.064)	0.50	0.044 (-0.132 to 0.220)	0.62	0.097 (-0.049 to 0.244)	0.19	-0.026 (-0.192 to 0.139)	0.75		
Stunted	0.635 (0.482)	0.22	-0.009 (-0.023 to 0.096)	0.70	-0.040 (-0.101 to 0.020)	0.19	0.005 (-0.052 to 0.062)	0.87		
Severely stunted	0.259 (0.439)	0.45	-0.022 (-0.078 to 0.035)	0.88	-0.005 (-0.067 to 0.058)	0.88	-0.037 (-0.098 to 0.023)	0.45		
Weight-for-age Z score	-1.537 (0.927)	0.52	-0.049 (-0.196 to 0.097)	0.61	-0.035 (-0.191 to 0.120)	0.65	0.022 (-0.095 to 0.139)	0.23		
Weight-for-length Z score	-0.322 (0.905)	0.61	-0.037 (-0.178 to 0.105)	0.61	-0.100 (-0.247 to 0.048)	0.18	-0.065 (-0.183 to 0.053)	0.28		
Child development outcomes (age standardised)										
Gross motor	-0.110 (1.017)	0.63	0.080 (-0.244 to 0.405)	0.12	0.269 (-0.244 to 0.405)	0.12	0.032 (-0.288 to 0.352)	0.84	0.199 (-0.134 to 0.533)	0.24
Fine motor	-0.089 (1.023)	0.47	0.104 (-0.182 to 0.391)	0.47	0.235 (-0.077 to 0.547)	0.14	0.045 (-0.261 to 0.351)	0.77	0.163 (-0.153 to 0.479)	0.31
Problem solving	-0.098 (1.051)	0.27	0.174 (-0.137 to 0.485)	0.27	0.158 (-0.181 to 0.498)	0.36	0.074 (-0.274 to 0.422)	0.67	0.157 (-0.177 to 0.490)	0.35
Socioemotional development	-0.043 (0.990)	0.27	0.151 (-0.120 to 0.423)	0.27	0.107 (-0.197 to 0.411)	0.48	-0.083 (-0.378 to 0.213)	0.58	0.086 (-0.197 to 0.369)	0.55
Communication skills	-0.042 (0.990)	0.46	0.098 (-0.167 to 0.364)	0.46	0.136 (-0.126 to 0.398)	0.31	-0.089 (-0.336 to 0.158)	0.48	0.122 (-0.132 to 0.375)	0.34
Total ASQ-I score	-0.093 (1.005)	0.35	0.151 (-0.167 to 0.470)	0.35	0.220 (-0.131 to 0.572)	0.22	-0.011 (-0.353 to 0.332)	0.95	0.178 (-0.164 to 0.520)	0.31

95% CIs are based on robust SEs, clustered at the village or site level. All models are adjusted for child gender, child age, region, mother's education, mother's age, household wealth, and child's birth order. Child length-for-age, weight-for-age, and length-for-age Z scores were calculated using the growth standards issued by WHO. Binary indicators for stunted and severely stunted children were calculated at -2 SD and -3 SD below the median length-for-age Z score, respectively, of healthy same-age and same-sex children. ASQ-I subscales and total scores were age-adjusted Z scores, in 1-month age increments. ASQ-I=Agnes and Stages Questionnaire: Inventory version.

Table 2: Primary outcomes: effects of the interventions on child growth and development

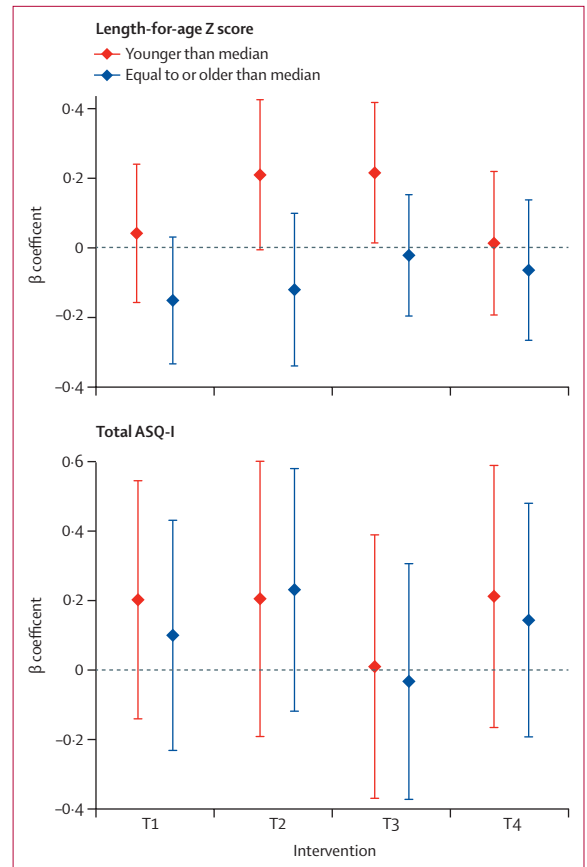


Figure 3: Heterogeneity impact on length-for-age Z score and total ASQ-I score by child median age and intervention group
Child age is dichotomised as younger than versus equal to or older than the median values at study end. Total ASQ-I is the age-normalised score for all five subdomains of the ASQ-I. ASQ-I=Agnes and Stages Questionnaire: Inventory version.

were replaced and 146 children who had moved after the baseline returned before final assessment and were re-interviewed. Ten (1.8%) child deaths were reported before endline from the 1-year follow-up replacement sample of 542 children. Balance across groups in the final sample at survey end, including replacements, was comparable to that obtained at baseline (appendix p 9). Replacement households and households lost to follow-up were comparable in terms of household socioeconomic status (appendix p 10). Replacement households had slightly higher maternal height but did not exhibit any difference across intervention groups (appendix p 10).

Survey data suggest that home visits occurred as expected: of all enrolled households, 70–75% (at 1-year follow-up) and 63–70% (at study end) of caregivers in intervention groups T1–T3 received home visits for nutritional counselling in the 3 months before the survey. 83% (at 1-year follow-up) and 77% (at study end) of caregivers in the nutrition and early stimulation group (T4) received any home visits in the month before

the survey. At 1-year follow-up, approximately 95% of the target children had received LNS in intervention groups T2–T3 and 80% of pregnant or lactating women had received LNS in T3. Intracluster correlation of age-adjusted ASQ-I scores was 0.15 at baseline and 0.38 at survey end in the T0 control group.

We observed no main effects of any of the intervention groups on any measure of anthropometry or any of the child development outcomes in the full sample (table 2). However, there were interactions by group with child age on length-for-age Z scores (significant for T2 and borderline for T3), stunting (T2), and weight-for-age Z score (T2 and T3; appendix p 11). We observed potentially greater effects of LNS on length-for-age Z scores (0.210 SD [95% CI –0.004 to 0.424] for T2 and 0.216 SD [0.043 to 0.389] for T3) and on the prevalence of stunting (–9.0% [95% CI –16.7 to –1.2] for T2 and –8.2% [–15.6 to –0.7] for T3) for the youngest children with age below the median of the sample at study end, which is equivalent to the children being fully exposed to LNS and the mothers being more likely to be fully exposed to LNS (figure 3; appendix p 11). Heterogeneity effects by maternal education and child sex were inconclusive (see appendix pp 12–16 for primary and intermediate outcomes).

We observed significant programme effects of interventions T1, T2, and T3 on animal source food consumption (meat, fish, and egg intake) and of interventions T3 and T4 on dairy intake in the previous 24 h (table 3). The increase in animal source food consumption was mirrored by a non-significant reduction in consumption of vitamin A-rich foods, with no net effect on dietary diversity score or on morbidity (table 3). None of the intervention groups were effective in changing caregivers' behaviour around hygiene practices, maternal diet diversity, or engagement in early child stimulation (eg, the Family Care Indicator score) compared with the T0 community-based programme (table 3).

Discussion

In this cluster-randomised controlled trial in Madagascar, we found that none of the LNS interventions we studied had any effect on any measure of anthropometry or child development in the primary analysis. However, children who were young enough to be fully exposed to LNS from 6 months to 18 months of age experienced an increase of 0.210–0.216 SD in length-for-age Z scores and an 8.2–9.0 percentage-point reduction in stunting. These effect sizes are similar to findings from other trials, including three trials in Kenya, Bangladesh, and Zimbabwe.⁹ We found no significant benefits in growth of children who did not receive the full 12 months of supplementation from age 6 months of age, or from additional supplementation of mothers during pregnancy or lactation.

Our study did not support the idea that home visiting to promote intensive stimulation of young children

	T1		T2		T3		T4		
	T0 mean values (SD)	Difference from control (95% CI)	p value	Difference from control (95% CI)	p value	Difference from control (95% CI)	p value	Difference from control (95% CI)	
Child level									
Dairy intake in the previous 24 h	0.013 (0.111)	0.018 (–0.002 to 0.038)	0.088	0.036 (–0.002 to 0.073)	0.062	0.023 (0.004 to 0.041)	0.015	0.035 (0.006 to 0.063)	0.017
Meat, fish, and egg intake in the previous 24 h	0.231 (0.422)	0.092 (0.031 to 0.152)	0.0031	0.096 (0.039 to 0.153)	0.0012	0.090 (0.023 to 0.157)	0.0087	0.061 (–0.006 to 0.128)	0.073
Vitamin A-rich foods in the previous 24 h	0.496 (0.500)	–0.135 (–0.275 to 0.005)	0.058	–0.140 (–0.282 to 0.002)	0.053	–0.102 (–0.235 to 0.030)	0.13	–0.126 (–0.263 to 0.011)	0.071
Dietary diversity score in the previous 24 h	2.748 (0.953)	0.025 (–0.149 to 0.199)	0.78	0.054 (–0.116 to 0.223)	0.53	0.079 (–0.064 to 0.221)	0.28	–0.046 (–0.206 to 0.114)	0.57
At least four food groups in the previous 24 h	0.199 (0.400)	0.054 (–0.004 to 0.112)	0.068	0.021 (–0.039 to 0.081)	0.49	0.044 (–0.005 to 0.092)	0.08	0.010 (–0.053 to 0.072)	0.76
7-day morbidity	0.641 (1.171)	0.048 (–0.139 to 0.236)	0.61	–0.029 (–0.200 to 0.142)	0.74	–0.154 (–0.316 to 0.008)	0.062	–0.055 (–0.238 to 0.128)	0.55
Mother level									
Hygiene practices score	0.073 (1.173)	–0.238 (–0.602 to 0.126)	0.20	–0.143 (–0.508 to 0.221)	0.44	0.109 (–0.276 to 0.494)	0.58	–0.050 (–0.424 to 0.324)	0.79
Maternal knowledge index score	0.052 (1.320)	–0.266 (–0.539 to 0.006)	0.055	–0.141 (–0.425 to 0.142)	0.33	0.254 (–0.060 to 0.567)	0.11	–0.046 (–0.377 to 0.285)	0.78
Maternal diet diversity score	2.952 (1.366)	0.125 (–0.116 to 0.367)	0.31	0.076 (–0.169 to 0.320)	0.54	0.032 (–0.207 to 0.271)	0.79	–0.102 (–0.376 to 0.173)	0.47
Food security score	2.184 (1.458)	0.187 (–0.189 to 0.561)	0.32	0.009 (–0.351 to 0.369)	0.96	0.195 (–0.209 to 0.599)	0.34	0.020 (–0.359 to 0.400)	0.92
Family Care Indicator score	0.303 (1.029)	0.004 (–0.152 to 0.160)	0.96	0.026 (–0.133 to 0.190)	0.76	0.147 (–0.052 to 0.345)	0.15	0.152 (–0.030 to 0.334)	0.10

95% CIs are based on robust SEs, clustered at the village or site level. All models are adjusted for child gender, child age, child's birth order, region, mother's education, mother's age, and household wealth. Binary indicators for child intake of dairy, meat, fish, egg and vitamin A-rich foods were obtained from a 24-h dietary recall. The dietary diversity score is a continuous score for the number of food groups consumed by the child from the same 24-h dietary recall and a binary indicator for having consumed at least four different food groups was calculated. A continuous indicator of child morbidity is calculated as the cumulative number of occurrences of child fever, cough, or diarrhoea in the previous 7 days. The hygiene practices score is a principal component score of indicators of hygiene practices before and during food preparation or conservation. The maternal knowledge index score is given by a principal component analysis of correct knowledge of the causes of diarrhoea, not walking, malnutrition, and developmental delays. The maternal diet diversity score is given by the number of food groups consumed, obtained from a 24-h dietary recall module.³⁸ The food security score is constructed from a series of questions that measure the frequency with which household members have insufficient access to food. The Family Care Indicator score is obtained from a principal component analysis of the number books, the number of play objects and materials available at home, and the number of play activities done with any adults in the household in the previous 3 days.³⁹

Table 3: Effects of the interventions on intermediate programme measures

at scale is an effective approach to promoting child development in this population living in extreme poverty. Work is ongoing to improve our understanding of the lack of impact of the T4 stimulation arm, including possible fade out of programme benefits from the first year of follow-up to study end. For example, the caregiver targeted for home visits might not have been the person spending the most time with the child in their second year of life—a programmatic issue identified in other contexts.³⁹ Caregiving responsibilities might have changed when children became mobile or when a younger sibling was born.

We found significant programme effects of more intensive nutrition counselling on increasing meat, fish, dairy, and egg intake in the previous 24 h, suggesting that the addition of individualised messages over and above the group messaging during growth monitoring sessions might be able to shift the take-up of key nutritional messages. There was no overall effect on dietary diversity score, however, which was probably due to a reduction in consumption of vitamin-A-rich fruits and vegetables that offset the increased intake of animal source foods. Adopting these key behaviours is clearly not sufficient alone to address growth faltering and severe nutritional deficiencies in settings with high food insecurity and poverty. In settings such as these, the provision of LNS might be necessary to fill key nutrient gaps.

A major strength of our study was that we integrated evidence-based intervention strategies into an existing, community-based programme, which is implemented by the government and operating at scale, covering around 7000 communities across Madagascar. There are undeniable benefits to building on the large-scale infrastructure of service delivery of the existing programme, including a strong sense of ownership by government administrators, local community health workers, and community members. Another strength of the study is that it adds to the literature on the feasibility and effectiveness of large-scale programmes to integrate health and nutrition with the promotion of child development. Existing studies testing effects of integrated programmes consist primarily of small efficacy trials, and have shown little evidence of synergistic interaction between nutrition and stimulation on child development.⁴⁰

A key weakness in our study is that although the study was powered for each intervention group for the whole sample, we might have been underpowered to detect small effects for certain subgroups. Although stratification by age at baseline was meant to account for the differences in potential exposure to the different intervention groups, the average estimated effect might be diluted due to the variable duration of exposure of the different age groups. Another limitation is that we do not have data allowing us to determine whether sharing of LNS occurred, although the quantities of LNS were designed to be small to medium quantity so they were less likely to be shared with

household members other than the targeted child or pregnant or lactating women. Additionally, the intra-cluster correlation for the ASQ-I was larger than expected, limiting our ability to detect significant differences in child development between groups. Another weakness is that loss to follow-up at 1-year follow-up and study end, mostly caused by temporary migration due to weather shocks and economic constraints, might have limited exposure, especially in the T4 group.

In addition to these issues, there are many reasons that the MAHAY programme might have failed to achieve sizeable gains for child growth and development. First, as in other countries, communities in rural Madagascar are often geographically dispersed with low population density and high food insecurity, resulting in logistical challenges to the community health workers reaching families and spending sufficient time for intensive counselling during home visits.⁴¹

Second, there might have been little responsiveness of mothers due to either low take-up (eg, from insufficient time, willingness to engage with the community health workers, or interest in topics covered) or inability to act on suggestions made by the community health workers (eg, from insufficient money to purchase food or toys or insufficient time or materials to prepare special complementary foods or to make toys); this issue has been raised as a problem in other contexts within sub-Saharan Africa.⁴² Toys and books might be crucial to sustain mothers' interest in engaging in stimulation activities with children on a daily basis and review the skills learned from session to session. However, in the MAHAY study, the materials were not available to keep or to borrow due to the costs of providing and maintaining such materials.

A final reason that the MAHAY programme might have failed to achieve consistent benefits for growth or development could be the low frequency of supervisory visits to the community health workers, due to prohibitive cost and logistical constraints of reaching the villages. Nevertheless, the effects that we observed with the LNS interventions on growth in young children in the T2 and T3 intervention groups are similar to those seen in other studies, many of which were efficacy trials with a greater implementation intensity, and are therefore likely to be broadly generalisable to other programmatic contexts in low-income and middle-income country settings.

In conclusion, our results support the potential for LNS to be used effectively to increase linear growth and decrease stunting as a preventive component of a nutrition package in a low-income setting, but only if the supplementation starts at 6 months of age. We do show that intensive counselling can be effective in changing feeding behaviours, but also that these dietary shifts were not sufficient to address nutritional deficiencies over and above group messaging in a context of high poverty and food insecurity. Finally, there are important challenges to

improving early child development in a very low-income context, including difficulty for community health workers to make home visits in a geographically dispersed and challenging terrain, limits to caregivers' adoption of new early stimulation behaviours because of lack of time or resources, and the programme's lack of resources to provide toys and books for children to engage with between visits. In the future, we plan to evaluate programme design variations on the stimulation component in Madagascar to fill in the knowledge gap on the role of key design features of integrating child stimulation with health and nutrition programmes.

Contributors

EG, AMW, and LCHF drafted the manuscript with input from all coauthors. LR, AMW, and LCHF developed the child development assessment protocols and piloted and refined the instruments. CPS developed the nutrition interventions and the protocols for biochemical assays. EG, AMW, CPS, and LR oversaw piloting and study implementation, contributed to refinements in interventions and measurements, and responded to threats to validity. EG and AMW developed the analytical approach, conducted the statistical analysis and constructed the tables and figures with input from coauthors. All authors have read, contributed to, and approved the final version of the manuscript.

Declaration of interests

We declare no competing interests.

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Data sharing

The data collected for the study are documented and shared in accordance with the World Bank Open Data and Open Knowledge Initiative. The microdata are fully documented in compliance with international good practices and with the Data Documentation Initiative. The data and documentation (questionnaires, data dictionaries, interviewer manuals) are stored and documented in the World Bank Microdata Catalogue. De-identified survey data (individual participant, household, community worker and community data) collected for the study will be made publicly available on the World Bank Microdata Catalogue in September, 2019 with a signed data access agreement.

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