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## Original Article

## Effect of ready-to-use foods for preventing child undernutrition in Niger: analysis of a prospective intervention study over 15 months of follow-up

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## Abstract

Strategies for preventing undernutrition comprise a range of interventions, including education, provision of complementary food and cash transfer. Here, we compared monthly distributions of two different lipid-based nutrient supplements (LNS), large-quantity LNS (LNS-LQ) and medium-quantity LNS (LNS-MQ) for 15 months on prevention of undernutrition among children 6 to 23 months. Both groups also received cash transfer for the first 5 months of the intervention. We conducted a prospective intervention study in Maradi, Niger, between August 2011 and October 2012. Six and 11 villages were randomly allocated to LNS-LQ/Cash and LNS-MQ/Cash, respectively. Children measuring 60–80 cm were enrolled in the respective groups and followed up monthly. Poisson regression was used to assess differences between interventions and adjust for baseline characteristics, intervention periods and child-feeding practices. The analysis included 2586 children (1081 in the LNS-LQ/Cash group and 1505 in the LNS-MQ/Cash group). This study suggests that provision of LNS-LQ (reference) or LNS-MQ had, overall, similar effect on incidence of severe acute malnutrition (RR = 0.97; 95% CI: 0.67–1.40;  $P = 0.88$ ), moderate acute malnutrition (RR = 1.20; 95% CI: 0.97–1.48;  $P = 0.08$ ), severe stunting (RR = 0.94; 95% CI: 0.70–1.26;  $P = 0.69$ ), moderate stunting (RR = 0.95; 95% CI: 0.76–1.19;  $P = 0.67$ ) and mortality (RR = 0.83; 95% CI: 0.41–1.65;  $P = 0.59$ ). Compared with LNS-LQ, LNS-MQ showed a greater protective effect on moderate acute malnutrition among children with good dietary adequacy: RR = 0.72; 95% CI: 0.56–0.94;  $P = 0.01$ . These results highlight the need to design context-specific programmes. Provision of LNS-LQ might be more appropriate when food insecurity is high, while when food security is better, distribution of LNS-MQ might be more appropriate.

**Keywords:** undernutrition, stunting, prevention, lipid-based nutrient supplement, cash transfer, Niger.

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## Introduction

Undernutrition among children under 5 years is a major global public health problem, with an estimated 8% global prevalence of wasting and 25.7% prevalence of stunting (Black *et al.* 2013). Child undernutrition has both short-term and long-term effects, including susceptibility to disease, severity of illness, cognitive development, school achievement, economic productivity, risk of non-communicable diseases later in life and maternal reproductive outcomes (Dewey & Begum 2011). Moreover, malnutrition contributes to almost half of all

child deaths, with more than 1 million deaths attributable to stunting and about 800 000 to wasting (Black *et al.* 2013). In 2012, the World Health Organization (WHO) adopted a resolution on maternal, infant and young children nutrition, including a global target to reduce by 40% the number of stunted under-five children by 2025 (de Onis *et al.* 2013).

Strategies for preventing undernutrition comprise a range of interventions, including education and improvement of diet, such as provision of complementary food, food fortification with micronutrients and cash transfers. Prevention of undernutrition is best targeted

at the first 1000 days of child's life (pregnancy, lactation and through the first 2 years of life). Ready-to-use foods (RUF) are commonly used for preventing undernutrition and treating acute malnutrition. They comprise a range of products, most of them consisting of a spread based on peanut butter but varying in composition and nutrient content. Ready-to-use therapeutic foods (RUTF) were developed for treatment of severe acute malnutrition (SAM) (World Health Organization, UNICEF, WFP, UN System Standing Committee on Nutrition, 2007), and ready-to-use supplementary foods, such as large-quantity lipid-based nutrient supplement (LNS-LQ), were developed for the treatment of moderate acute malnutrition (MAM) (World Health Organization, 2012). Medium-quantity lipid-based nutrient supplements (LNS-MQ) were conceived for prevention of undernutrition. Current guidance on the use of LNS for prevention of undernutrition is mostly based on contextual information, such as programme circumstances and availability of commodities, and highlights the needs for more evidence about impact of the different supplements on nutritional status in specific circumstances (De Pee & Bloem 2009; Style *et al.* 2013).

Several intervention studies aiming at preventing undernutrition showed contrasted effects on incidence of wasting and stunting as well as on mean change in weight for height, weight gain, height for age and height gain, with some experiments demonstrating positive results and others indicating no impact (Lopriore *et al.* 2004; Kuusipalo *et al.* 2006; Adu-Afarwua *et al.* 2007; Isanaka *et al.* 2009; Grellety *et al.* 2012; Huybregts *et al.*, 2012; Mangani *et al.* 2013; Iannotti *et al.*, 2014; Ackatia-Armah *et al.* 2015). Variations in outcomes might be due to differences across studies, such as targeting of children of various age groups and nutritional status; use of different types and quantities of

RUF, and of different study designs; and implementation in different contexts. Few studies compared the use of different types of RUF. Two studies comparing milk-based RUF and soy-based RUF showed no difference in outcomes between groups (Kuusipalo *et al.* 2006; Mangani *et al.* 2013). One study comparing the use of RUTF with LNS-MQ showed no difference on incidence of stunting and severe stunting (Isanaka *et al.* 2010). Incidence of wasting and severe wasting was lower in the group receiving LNS-MQ compared with the group receiving RUTF only in villages having previously received a nutritional intervention. Only three studies, all conducted in Niger, investigated the effect of RUF on mortality. Two studies comparing RUTF with no intervention (Isanaka *et al.* 2009) or RUTF with LNS-MQ (Isanaka *et al.* 2010) showed no difference in mortality although neither study was powered for this outcome, while a study comparing LNS-MQ with no supplement showed halving in mortality in the intervention group (Grellety *et al.* 2012).

Cash transfer programmes have also been shown to have some effect on children's nutritional outcomes. A review on the impact of conditional cash transfers in South-Central America concluded that cash transfer had a positive impact on nutritional status (Lagarde *et al.* 2009). Evaluations of cash transfer programmes in Africa seemed to indicate a positive effect on anthropometric status (Adato & Basset 2009; Wakoli *et al.* 2012; Fenn *et al.* 2015).

Effectiveness data on these interventions remains patchy. There is a particular need for evidence generation on the magnitude of effectiveness of different strategies for the prevention of stunting and wasting, and among different target groups and contexts. The present study was conducted to compare seven strategies using food supplements and/or cash distribution in the

### Key messages

- Provision of LNS-LQ or LNS-MQ had overall similar effect on incidence rate of acute malnutrition, stunting and mortality.
- LNS-LQ was more efficient than LNS-MQ in preventing acute malnutrition and stunting when child's diet was poor and the latter when child's diet was better.
- Prevention of acute malnutrition and stunting should be tailored to context and reach maximum impact at lower cost and delivered along with a comprehensive maternal and child health intervention.

short term (5 months) and long term (15 months). The results of the first 5 months of the trial have been published previously (Langendorf *et al.* 2014). Here, we compare the effect of provision of LNS-MQ and LNS-LQ, in addition to cash transfer during the first hunger gap, to 6- to 23-month-old children over 15 months on incidence of SAM, MAM, severe stunting, moderate stunting and mortality as well as in mean change in weight-for-length Z-score (WLZ), mid-upper arm circumference (MUAC) and length-for-age Z-score (LAZ).

## Materials and methods

### Study design

The study is a prospective intervention study comparing the effect of different food supplements and cash transfer on nutritional status and mortality in children 6–23 months in Niger between August 2011 and October 2012. There was no control group because prior studies showed effectiveness of nutritional supplementation in the same context (Isanaka *et al.* 2009; Grellety *et al.* 2012). Villages corresponding to inclusion criteria were split in seven groups of nearby villages for allocation of one of seven interventions, so that each villages group comprised approximately the number of children required to meet the sample size per intervention group. Full methodological details have been published previously (Langendorf *et al.* 2014).

### Study sample

The study was conducted in Madarounfa health district, Maradi region, Niger, with approximately 405 000 inhabitants. Food security and nutritional situation is chronically poor in the area. The district was declared at severe risk of food insecurity in January 2011 (Government of Niger 2011), while in June 2011, acute malnutrition and stunting among 6- to 23-month-old children were 21.4% and 59.5%, respectively (Institut National de la Statistique et Direction Nutrition du Ministère de la Santé du Niger, 2011). The main harvest period takes place between October and December, while the rainy season, also corresponding to the hunger gap period, occurs between July and September

(FewsNet 2013). Médecins Sans Frontières, in partnership with Forum Santé Niger (FORSANI), has been supporting health and nutrition activities in five health areas in the district since 2008.

Villages were included in the study if they were in the health areas supported by Médecins Sans Frontières–FORSANI, within 15 km of the nearest health centre, not in an urban area and no preventive nutrition intervention other than the study was anticipated. Children were eligible if their main residence was in one of the selected villages; they had a height  $> 60$  and  $\leq 80$  cm (as a proxy of 6 to 23 months of age in this highly stunted population as per common practice in large-scale nutritional programmes where age registration is poor); they had no known food allergy and no difficulties in swallowing. All children eligible at the beginning of the study were enrolled. In addition, new children were enrolled monthly when they reached 60 cm. All children were followed-up monthly until the end of the study or until they reached 80.1 cm.

Group assignment was random for four intervention groups using a computer-generated random sequence. However, two groups receiving distributions for 5 months were forced to be geographically close to each other and distant from those receiving 15 months distributions. The assignment of the LNS-MQ/Cash group was forced to the group of villages located in the same health area as villages receiving this nutritional supplement through a planned distribution programme so as not to interfere with existing programming. Blinding of parents and investigators were not possible because of the obvious differences in the interventions.

The sample size of 500 children per group was required to detect a 20% difference in average WLZ over 5 months of follow-up between LNS-LQ and LNS-MQ as reference. A *post hoc* calculation confirmed the study was sufficiently powered to detect this same difference for wasting between the LNS-MQ/Cash and LNS-LQ/Cash groups over 15 months.

### Interventions

Nutritional supplement and cash were distributed monthly between August 2011 and October 2012 to caretaker accompanied with enrolled child as per booklet and beneficiary card at a central distribution point

located within 3 km of villages. Nutritional education sessions, consisting of common messages plus specific information tailored to each intervention, were conducted at each distribution. The groups LNS-LQ/Cash and LNS-MQ/Cash received Supplementary Plumpy® (Nutraset, Malaunay, France) and Plumpy'Doz® (Nutraset, Malaunay, France), respectively, for 15 months as well as cash for the first 5 months of intervention. Daily ration of LNS-LQ was 92 g (500 kcal), and LNS-MQ daily ration was 46 g (247 kcal) (Appendix 1 in the Supporting Information). Moreover, LNS-MQ ration contained more potassium, magnesium and phosphorus in quantity per 100 kcal than LNS-LQ. Cash distribution was 25 000 francs de la Communauté Financière Africaine per month (€38 euros or around 80% of the minimum wage) as recommended by the government of Niger and similar to that distributed by other organizations.

### Data collection

One month prior to first distribution, teams conducted a door-to-door enumeration of the children in the selected villages and enrolled children fulfilling inclusion criteria, after study participation consent of child's representative. If the date of birth was unknown, age was estimated using a local events calendar. Included children were followed up monthly at each distribution, during which weight, length, oedema and MUAC were measured by experienced health workers using standardized methods and materials. A standardized questionnaire was administered to the child's caretaker at each follow-up visit and child-feeding practices recorded in accordance with international guidelines (World Health Organization, 2010) and compliance to food supplementation. If a child was severely malnourished, she or he was referred to the nearest treatment centre. Children who did not attend distribution were visited at home within 10 days, in order to collect the reason for absence and, if the child was at home, take anthropometric measurements.

### Ethical considerations

The National Ethical Committee of Niger, Ministry of Public Health and the Comité de Protection des

Personnes, Ile de France XI, France, approved the study protocol. The study was registered as NCT01828814 on clinicaltrials.gov. Chiefs of selected villages, heads of households and caretakers were explained about the study objectives and procedures and asked for their consent. The informed consent statement was read to the consenting adult in the local language before it was signed or fingerprinted. Confidentiality of data was preserved through a coding system. Names of children were not disseminated outside of study sites, and patient information was kept among health staff and study investigators.

### Data management and analysis

Data were recorded on standardized forms and entered twice into EPIDATA 2.1 (EpiData Association, Odense, Denmark). STATA 13.1 (StataCorp, College Station, TX, USA) was used for analysis. WLZ and LAZ were calculated using WHO ANTHRO 3.2.2 macro for STATA. SAM, MAM, severe stunting and moderate stunting were respectively defined as  $WLZ < -3$  Z-score WHO standards and/or  $MUAC < 11.5$  cm and/or bipedal oedema;  $-3 \leq WLZ < -2$  Z-score WHO standards and/or  $11.5 \leq MUAC < 12.5$  cm and no oedema;  $LAZ < -3$  Z-score WHO standards; and  $-3 \leq LAZ < -2$  Z-score WHO standards.

For each follow-up visit, indicators of breast-feeding and minimum acceptable diet were calculated according to international guidelines (World Health Organization, 2010) as follows:

**Breastfeeding:** A child was considered breastfed if the mother reported he or she was breastfed during the 24 h preceding the follow-up visit.

**Minimum acceptable diet:** A child was considered having an adequate diet if during the day preceding the follow-up visit, for breastfed children, a child had (1) consumed foods from four or more food groups and (2) consumed at least two meals for children 6–8 months and three meals for children 9–24 months, and, for non-breastfed children, a child had (1) received milk feeds, (2) consumed foods from four or more food groups, not including milk feeds, and (3) had consumed at least four meals.

Proportion of follow-up visits where the child was breastfed and had a minimum acceptable diet, respectively, were computed and divided into the following categories: criteria met at no follow-up visits, criteria met at less than 50% of follow-up visits and criteria met at 50% or more of follow-up visits.

Children initially enrolled in the study but not meeting inclusion criteria were excluded from the analysis. Aberrant values were removed. Incidence of mortality as well as first event of SAM, MAM, severe stunting and moderate stunting was calculated using survival analysis. We also examined incidence of multiple events of SAM and MAM, defined as repeated episodes separated by at least 2 months. Analysis of first event was performed among children who were not malnourished at the beginning of the study: children who had SAM or for whom SAM status was unknown at the first distribution they attended were excluded from the analysis for SAM; for MAM, children who had SAM or MAM at first distribution or for whom SAM or MAM status was unknown were excluded from the analysis. The same exclusion criteria applied for severe and moderate stunting, using the respective outcomes. Losses to follow-up were censored, and missed visits or visits where data were missing were excluded from person-time at risk.

Summary measures of child characteristics at entry, i.e. age, sex and nutritional status, were calculated for each intervention group. The influence of baseline characteristics for variables known to be related to the outcomes (Pelletier 1994; de Vitoria *et al.* 2010) was taken into account by adjusting *a priori* on these variables in regression analysis to obtain a more precise estimate of intervention effect. Time-to-event multivariable Poisson models were fitted including incidence rate of event as dependent variable and intervention as independent variable to calculate rate ratio and 95% confidence intervals (95% CI) for each outcome. The models also included sex, length as a proxy for age, WLZ, LAZ and MUAC at baseline as independent variables. Except for sex and intervention groups, all variables were entered in the model as continuous variables. To take into account potential correlation of data at village level, robust standard errors were calculated.

Potential confounding and interaction effect of the different intervention periods, i.e. first 5 months of study when both food supplement and cash were distributed, and 6–15 months of study, where only food supplements were distributed, on the relation between intervention and outcomes, were investigated. Potential confounding and modifying effect of breastfeeding and minimum acceptable diet were also examined as, together with the food supplement, they are related to nutrient intake, which influences nutritional status (Jones *et al.* 2014) and mortality (WHO CST 2000). Rate ratios between the Poisson models with and without the potential confounding factor were compared, and the factor was retained as a confounding factor if there was a change of >10% in the rate ratio. To assess effect modification, an interaction term between intervention and the potential modifying factor was entered in the Poisson models. Rate ratio and 95% CI for each stratum of the factor were calculated, and combined Wald test was used to assess evidence of interaction effect.

Mean change in WLZ, MUAC and LAZ between first and last distribution were calculated, and the effect of intervention was estimated by linear regression with adjustment on baseline characteristics and calculation of robust standard error to take potential clustering at village level into account.

Consumption of supplement by the intended beneficiary was assessed by two different indicators at each distribution. Firstly, we calculated for each child the proportion of follow-up visits attended where the food supplement was reported being consumed only within the nuclear family as opposed to also shared with extended family and/or with people outside the extended family, or also stored, exchanged or sold. Secondly, we calculated the proportion of follow-up visits where the child was the only recipient of the supplement within the nuclear family, i.e. the mother reported that only the targeted child consumed the supplement within the previous month. The median of these proportions were calculated for each group and compared with the Mann–Whitney test.

For all statistical tests,  $P$ -value < 0.05 was considered as evidence of difference.



## Results

From the 412 villages of Madarounfa, 48 corresponded to inclusion criteria and did not present access problems (Fig. 1). All villages agreed to participate. Six and 11 villages were randomized to LNS-LQ/Cash and LNS-MQ/Cash, respectively. In the selected villages, all households contacted agreed to participate, and over the 15 months period, a total of 1164 and 1594 children were enrolled in the respective groups. Total loss to follow-up and children not meeting admission criteria represented less than 10% in each group.

Missing data for SAM, MAM, severe stunting and moderate stunting occurred for less than 5% of children in each group, corresponding to less than 1% of participants over all follow-up visits.

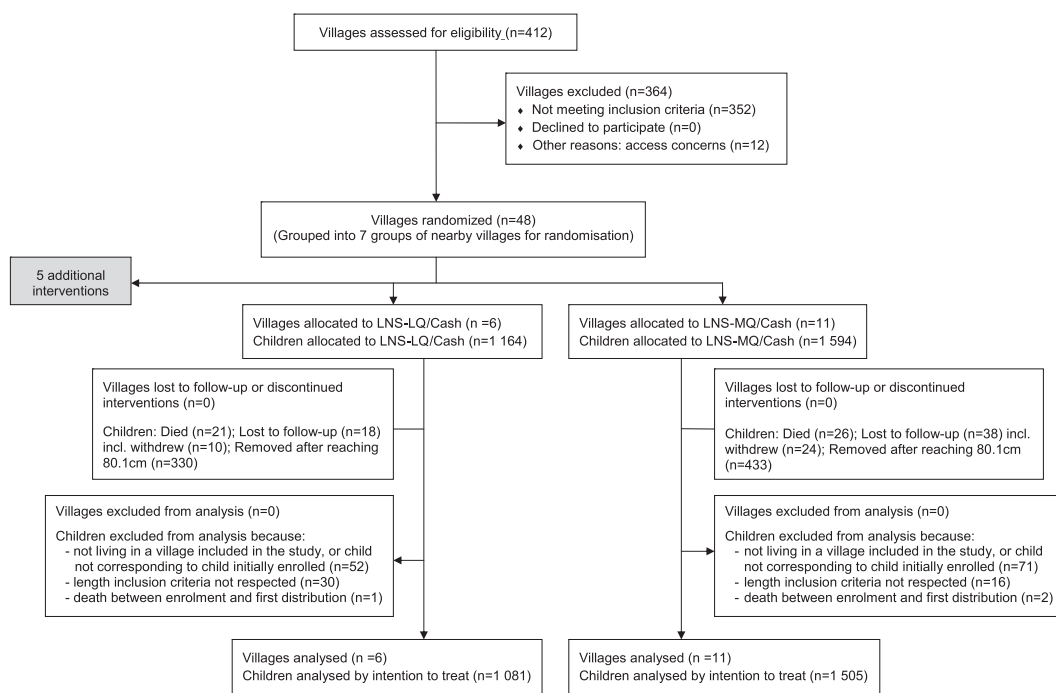
Around half of the children in each group were recruited at the beginning of the study and the other half during the course of the study. Around 50% of the children attended more than 10 follow-up visits, including 20% of children attending all 15 follow-up visits. Patterns were similar in the two groups.

Median age of children at enrolment during the study period was approximately 8 months, while median length was close to 65 cm. Prevalence of SAM, MAM and stunting showed poor nutritional status in the two groups (Table 1).

Overall, there was no evidence of difference in incidence rate between LNS-LQ/Cash and LNS-MQ/Cash groups for any outcome (Table 2).

Proportions of children experiencing more than one episode of SAM and MAM were 11.3%, and 13.6%, respectively. Monthly incidence rate of multiple events of SAM and MAM was lowest after harvest (December 2011–April 2012) and rose during the hunger gap period (Fig. 2). The same pattern was observed in the two intervention groups.

The exploration of potential confounding and interaction effect of intervention period and breastfeeding showed no evidence of effect in the relation between SAM, MAM, moderate stunting, severe stunting and death, and intervention. On the contrary, there was heterogeneity across strata of diet adequacy for all nutritional outcomes, with rate ratio of first and multiple events



**Fig. 1.** Intervention assignment and study flow of participants. LNS-LQ, medium-quantity lipid-based nutrient supplement; LNS-MQ, medium-quantity lipid-based nutrient supplement.

**Table 1.** Characteristics of children at enrolment

	LNS-LQ/Cash N = 1081	LNS-MQ/Cash N = 1505	Total N = 2586
Male <i>n</i> (%)	618 (53.6)	724 (45.9)	1342 (51.9)
Age median (IQR)	7.6 (5.6; 15.6)	8.7 (5.9; 15.8)	7.8 (5.7; 15.2)
Length (cm) median (IQR)	64.3 (61.9; 71.7)	65.0 (61.2; 72.5)	64.6 (62; 72.3)
Mid-Upper-Arm-Circumference (cm) median (IQR)	13.4 (12.6; 14.0)	13.2 (12.5; 14.0)	13.2 (12.6; 14.0)
Weight-for-length* mean (SD)	−0.73 (1.17)	−0.82 (1.16)	−0.79 (1.16)
Length-for-age* median (IQR)	−2.01 (−2.86; −1.21)	−2.14 (−2.92; −1.43)	−2.10 (−2.89; −1.35)
Severe acute malnutrition <i>n</i> (%)	53 (4.7)	71 (4.6)	118 (4.6)
Moderate acute malnutrition <i>n</i> (%)	221 (19.4)	346 (22.4)	548 (21.5)
Severe stunting <i>n</i> (%)	254 (22.3)	360 (23.1)	578 (22.6)
Moderate stunting <i>n</i> (%)	327 (28.7)	529 (33.9)	796 (31.1)

LNS-LQ, large-quantity lipid-based nutrient supplement (500 kcal per day); LNS-MQ, medium-quantity lipid-based nutrient supplement (247 kcal per day); IQR, interquartile range; SD, standard deviation.\*Z-score of World Health Organization standards.

**Table 2.** Incidence rate and rate ratio for severe and moderate acute malnutrition, severe and moderate stunting and mortality

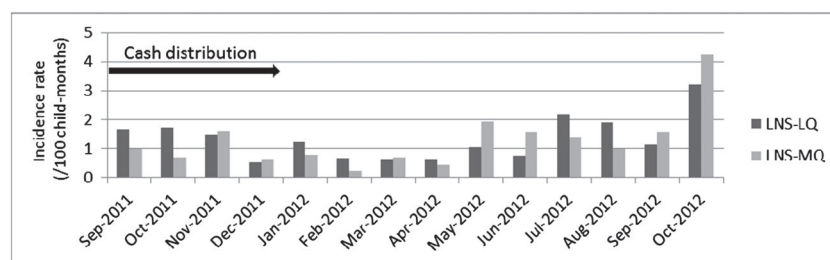
	Number of events	Child-months at risk	Incidence per 100 child- months (95% CI)	Crude rate ratio (95% CI)*	<i>P</i> -value	Adjusted rate ratio (95% CI) <sup>†</sup>	<i>P</i> -value
<b>First event</b>							
<b>Severe acute malnutrition</b>							
LNS-LQ/Cash	88	7905	1.11 (0.90–1.37)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	126	11 065	1.14 (0.96–1.36)	1.02 (0.60–1.73)	0.93	1.01 (0.66–1.54)	0.97
<b>Moderate acute malnutrition</b>							
LNS-LQ/Cash	217	5251	4.13 (3.62–4.72)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	348	6877	5.06 (4.56–5.62)	1.22 (0.87–1.73)	0.25	1.29 (0.94–1.77)	0.12
<b>Severe stunting</b>							
LNS-LQ/Cash	167	5740	2.91 (2.50–3.39)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	228	7892	2.89 (2.54–3.29)	0.99 (0.82–1.20)	0.94	0.82 (0.64–1.04)	0.11
<b>Moderate stunting</b>							
LNS-LQ/Cash	234	2955	7.92 (6.97–9.00)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	301	3427	8.78 (7.84–9.83)	1.11 (0.87–1.42)	0.41	0.94 (0.79–1.12)	0.48
<b>Mortality</b>							
LNS-LQ/Cash	20	8894	0.22 (0.15–0.35)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	24	12 458	0.19 (0.13–0.29)	0.86 (0.45–1.64)	0.64	0.83 (0.41–1.65)	0.59
<b>Multiple events<sup>‡</sup></b>							
<b>Severe acute malnutrition</b>							
LNS-LQ/Cash	117	8703	1.34 (1.12–1.61)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	157	12 182	1.29 (1.10–1.51)	0.96 (0.57–1.62)	0.87	0.97 (0.67–1.40)	0.88
<b>Moderate acute malnutrition</b>							
LNS-LQ/Cash	341	7549	4.52 (4.06–5.02)	1.00 (reference)		1.00 (reference)	
LNS-MQ/Cash	540	10 268	5.26 (4.83–5.72)	1.16 (0.89–1.52)	0.26	1.20 (0.97–1.48)	0.08

LNS-LQ: large-quantity lipid-based nutrient supplement; LNS-MQ: medium-quantity lipid-based nutrient supplement; CI, confidence interval.

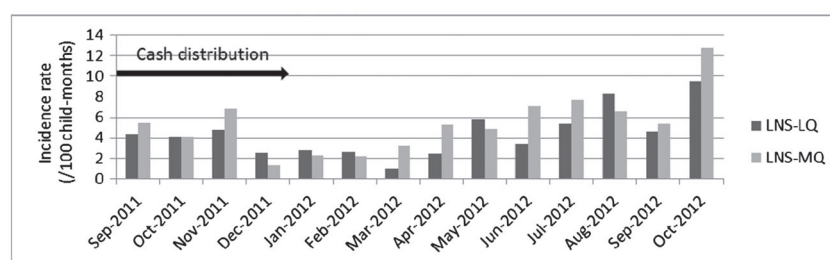
\*From time-to-event Poisson models with 95% confidence intervals calculated using robust standard errors to take into account potential clustering at village level.<sup>†</sup>From time-to-event Poisson models adjusted on *a priori* potential confounders, i.e. sex, length, weight for length, mid-upper arm circumference and length for age, and with 95% confidence intervals calculated using robust standard errors to take into account potential clustering at village level.<sup>‡</sup>Incidence rate of multiple events defined as repeated episodes separated by at least 2 months.



### A Monthly incidence<sup>a</sup> of severe acute malnutrition



### B Monthly incidence<sup>a</sup> of moderate acute malnutrition



<sup>a</sup> Incidence of multiple events defined as repeated episodes separated by at least two months

**Fig. 2.** Monthly incidence of malnutrition per intervention. LNS-LQ, large-quantity lipid-based nutrient supplement; LNS-MQ, medium-quantity lipid-based nutrient supplement.

decreasing as diet adequacy improved (Table 3). However, there was strong statistical evidence of difference only for first and multiple events of MAM, while there was borderline evidence for multiple events of SAM.

Mean change in WLZ between first and last distribution attended (whenever of the time of enrolment) was  $-0.22$  (95% CI:  $-0.30$ ;  $-0.15$ ) in the LNS-MQ/Cash group and  $-0.12$  (95% CI:  $-0.20$ ;  $-0.05$ ) in the LNS-LQ/Cash group. After adjustment for baseline characteristics, there was evidence of difference in mean change of WLZ between LNS-MQ/Cash and LNS-LQ/Cash (reference):  $-0.20$  (95% CI:  $-0.29$ ;  $-0.11$ );  $P < 0.01$ . On the contrary, there was no evidence of difference in mean change of MUAC [ $-0.05$  (95% CI:  $-0.22$ ;  $-0.12$ );  $P = 0.74$ ] or LAZ [ $-0.02$  (95% CI:  $-1.22$ ;  $1.62$ );  $P = 0.77$ ]. Mean change in MUAC and LAZ between first and last distribution in LNS-MQ/Cash and LNS-LQ/Cash groups were  $0.06$  (95% CI:  $-0.73$ ;  $0.20$ ) and  $0.09$  (95% CI:  $-0.43$ ;  $0.13$ ), and  $-0.46$  (95% CI:  $-0.62$ ;  $-0.29$ ) and  $-0.40$  (95% CI:  $-0.44$ ;  $-0.35$ ), respectively.

Overall, in more than 90% of the follow-up visits, the food supplement was reported to be consumed just

within the nuclear family. The targeted child was the only recipient of the supplement within the nuclear family in around 70% of the follow-up visits (Appendix 2 in the Supporting Information). No difference was observed between LNS-LQ/Cash and LNS-MQ/Cash groups.

## Discussion

To our knowledge, our study is the first to compare the effect of LNS-LQ and LNS-MQ for preventing under-nutrition and mortality. The results showed no evidence of difference in effect of LNS-MQ and LNS-LQ on incidence rate of SAM, severe stunting and mortality, when distributed over 15 months with cash transfer for the first 5 months. This is comparable with the results of the first 5 months of the study (Langendorf *et al.* 2014). On the other hand, there was some evidence that LNS-MQ had better preventive effect on MAM than LNS-LQ, with a 30–40% lower incidence, when child's diet was adequate at more than half of the follow-up visits attended. However, when the diet was poor, LNS-LQ showed better preventive effect on

**Table 3.** Incidence rates and rate ratio for severe and moderate acute malnutrition, severe and moderate stunting and mortality per stratum of diet adequacy

Category of adequate diet*	LNS-LQ/Cash group			LNS-MQ/Cash group			Rate ratio (95% CI) <sup>†</sup>	P-value
	Number of events	Child-months at risk	Incidence rate (95% CI)	Number of events	Child-months at risk	Incidence rate (95% CI)		
<b>First event</b>								
Severe acute malnutrition								
Never	14	1877	0.74 (0.44–1.26)	22	1672	1.32 (0.87–2.00)	1.99 (0.76–5.25)	0.16
<50% of follow-up visits	57	4714	1.21 (0.93–1.57)	91	7543	1.21 (0.98–1.48)	0.91 (0.62–1.31)	0.60
≥50% of follow-up visits	17	1315	1.29 (0.80–2.08)	13	1851	0.70 (0.41–1.21)	0.67 (0.30–1.50)	0.33
Moderate acute malnutrition								
Never	58	1391	4.17 (3.22–5.39)	73	1191	6.13 (4.88–7.71)	<b>1.76 (0.90–3.42)</b>	<b>0.10</b>
<50% of follow-up visits	123	3009	4.09 (3.42–4.88)	249	4462	5.58 (4.93–6.32)	<b>1.35 (0.97–1.87)</b>	<b>0.07</b>
≥50% of follow-up visits	36	851	4.23 (3.05–5.86)	26	1225	2.12 (1.45–3.12)	<b>0.56 (0.34–0.92)</b>	<b>0.02</b>
Severe stunting								
Never	42	1258	3.34 (2.47–4.52)	49	1234	3.97 (3.00–5.25)	1.12 (0.70–1.80)	0.64
<50% of follow-up visits	101	3370	3.00 (2.47–3.64)	153	5189	2.95 (2.52–3.45)	0.76 (0.61–0.94)	0.02
≥50% of follow-up visits	24	1113	2.16 (1.45–3.22)	26	1469	1.77 (1.21–2.60)	0.74 (0.39–1.39)	0.35
Moderate stunting								
Never	55	6036	9.11 (7.00–11.87)	52	5595	9.29 (7.08–12.20)	0.98 (0.67–1.45)	0.83
<50% of follow-up visits	132	1708	7.73 (6.52–9.17)	213	2136	9.97 (8.72–11.40)	1.02 (0.84–1.24)	0.85
≥50% of follow-up visits	47	6439	7.30 (5.48–9.71)	36	7315	4.92 (3.55–6.82)	0.63 (0.38–1.05)	0.08
<b>Multiple events<sup>§</sup></b>								
Severe acute malnutrition								
Never	15	1956	0.77 (0.46–1.27)	27	1748	1.54 (1.06–2.25)	2.20 (0.92–5.27)	0.08
<50% of follow-up visits	79	5178	1.53 (1.22–1.90)	113	8427	1.34 (1.12–1.51)	0.81 (0.55–1.17)	0.26
≥50% of follow-up visits	23	1570	1.47 (0.97–2.20)	17	2007	0.85 (0.53–1.36)	0.79 (0.39–1.59)	0.51
Moderate acute malnutrition								
Never	73	1762	4.14 (3.29–5.21)	82	1495	5.48 (4.42–6.81)	<b>1.51 (0.92–2.47)</b>	<b>0.10</b>
<50% of follow-up visits	202	4438	4.60 (4.01–5.27)	407	7013	5.80 (5.27–6.40)	<b>1.23 (0.99–1.53)</b>	<b>0.07</b>
≥50% of follow-up visits	64	1348	4.75 (3.72–6.07)	51	1760	2.90 (2.20–3.81)	<b>0.72 (0.56–0.94)</b>	<b>0.01</b>

LNS-LQ, large-quantity lipid-based nutrient supplement; LNS-MQ, medium-quantity lipid-based nutrient supplement; CI, confidence intervals. \*Percentage of follow-up visits where the child was reported to have an adequate diet the day before considering frequency of meals/snack and diversity. †From time-to-event Poisson models adjusted on *a priori* potential confounders, i.e. sex, length, weight for length, mid-upper arm circumference and length for age, and with 95% confidence intervals calculated using robust standard errors to take into account potential clustering at village level. ‡P-value of combined Wald test assessing evidence of interaction between intervention and adequate diet. §Incidence rate of multiple events defined as repeated episodes separated by at least 2 months. Difference statistically significant ( $p < 0.05$ ).

MAM than LNS-MQ. LNS-MQ also seemed to show a better preventive effect on SAM, moderate stunting and severe stunting than LNS-LQ, with 33%, 37% and 26% lower incidence, respectively, when child's diet was adequate at more than half of the follow-up visits attended. However, there was no evidence of difference in rate ratio, which could be due to the low number of events. It would be important to explore further this phenomenon in a study specifically designed to examine differences in dietary adequacy.

These results are in line with a study comparing RUTF (having a composition in micronutrient similar to LNS-LQ, except for potassium, which is twice as high in RUTF compared with LNS-LQ) and LNS-MQ, which showed that incidence rate of wasting and severe wasting was lower in the group receiving LNS-MQ compared with the group receiving RUTF only in villages having previously received a nutritional intervention (Isanaka *et al.*, 2010). Children in these villages might have had a more adequate diet and/or a better micronutrient status due to the previous nutritional intervention through the supplementation itself or through behaviour modifications.

These findings are biologically plausible and could be explained by several factors. Firstly, LNS-LQ ration provided twice more kilocalories than LNS-MQ ration (500 kcal per day vs. 250 kcal per day, respectively) and might be more beneficial to the children with a poor diet. Secondly, children with a more adequate diet might have a better micronutrient status and could use micronutrients more efficiently (Golden 1995), especially those of the LNS-MQ, which contained more type II micronutrients necessary for growth in quantity per 100 kcal, in that they do not need to rebuild their nutrient stocks before using them for growth, contrarily to children with poor diet. Finally, LNS-MQ is more nutrient dense than LNS-LQ and can be complemented by a larger quantity of home diet. If home diet is nearly adequate, the combination of LNS-MQ and home diet will provide the highest intake of essential nutrients. Children with a better diet might also live in more appropriate environmental sanitary conditions, and be less exposed to environmental enteric dysfunction, which could explain better micronutrient status and utilization of micronutrients. It has been hypothesized that environmental enteric dysfunction, which is associated

with poor sanitation environment, could be involved in growth faltering by 'repartitioning of exogenous and endogenous nutrients away from growth for: increased synthesis of antibodies, acute-phase proteins, cytokines, and increased glucose oxidation to fuel high metabolic rate' (Humphrey 2009).

Deterioration in mean WLZ was lower in the LNS-LQ/Cash group compared with the LNS-MQ/Cash group, which could be explained by the higher energy content of the LNS-LQ ration. On the other hand, there was no difference in change in MUAC. As MUAC is a good indicator of muscle mass in children (Jensen *et al.*, 2015), the absence of difference in MUAC might be a result of the same increase in muscle mass induced by LNS-LQ and LNS-MQ while LNS-LQ also led to a higher increase in fat mass, especially due to an accumulation of central fat.

Our results are in agreement with current recommendations counselling the use of LNS-LQ for treatment of MAM and for prevention of undernutrition in highly food-insecure areas or periods, and the use of LNS-MQ for the children at risk for faltering linear growth during highly food-insecure periods (De Pee & Bloem 2009). However, our study shows that micronutrient status and diet adequacy at the individual level might also be taken into account to maximize the effect of interventions, although this would add implementation complexity in large-scale feeding programmes in nutritional emergencies.

The study has some limitations. Allocation of interventions was performed by group of nearby villages in order to take into account pragmatic considerations and reduce the likelihood of contamination between groups through the sharing of supplemental foods or cash. This might have introduced selection bias because living conditions might be different across the groups of villages. To account for this, baseline characteristics of children were adjusted for in the analysis. On the other hand, absence of refusal of participation from villages and individuals contributed in the study strength. Attrition was also good with less than 2% of withdrawal and less than 5% of missing visits and missing data in the groups.

Different teams performed monthly assessments in the two groups. Measurement bias could have occurred if teams in one group made systematic measurement errors. To mitigate this risk, standardized measurement

procedures were used, and adherence to those procedures was regularly checked by senior staff. In addition, quality control of anthropometric data was conducted by an independent team every 2 months on a random sample of 10% of children to identify needs for refresher trainings and improve performance.

There was no evidence of confounding of intervention period, breastfeeding and diet, but there might be residual confounding if factor categories were too wide. The study was randomized so that the risk difference in confounding factors is minimal, although imperfection of followed randomization process could have led to some imbalance. Confounding factors, such as food security, socio-economic status and access to safe water and sanitation, could have influenced the association between intervention and outcomes. However, the study was conducted in a relatively small area with standardized criteria for village selection in order to minimize such differences.

We investigated use of supplements by mothers' recall. Mothers might have been tempted to underestimate supplement diversion from the child (i.e. consumption by others), but it is unlikely that this was differential between the groups. We did not find any difference in the use of the supplements between groups, which is in favour of little influence of sharing on our results. However, it was not possible to measure the actual quantity of supplement consumed.

It could be possible that our findings are linked with a differential use of cash between the two groups or a differential influence of the same use of cash in the two groups. However, we did not find evidence of any difference in intervention effects between the intervention periods with or without cash on top of food supplementation. The analysis of the first 5 months of the study showed that the strategy associating LNS-LQ or LNS-MQ supplementation and cash transfer was more effective in preventing acute malnutrition and mortality than cash transfer alone or supplementation alone (Langendorf *et al.* 2014). The superiority of this combined strategy might be explained by several factors. Firstly, cash was largely used to buy additional food for the family (Langendorf *et al.* 2014). Secondly, cash might also have been spent to improve family and child welfare, such as food, health care and access to safe water, which can reduce the risk of undernutrition and

mortality. A noticeable increase in expenditure for health care, safe water and clothing was reported by a study investigating the use of cash transfer in Tessaoua district, Maradi region (Save the Children 2009). This might have had long-term effect throughout the 15 months of the study if the children benefiting from the additional expenditure because of cash were in a better position to affront the next hunger gap and to stay healthy.

The results of the study can reasonably be generalized to the study population considering there was no refusal to enrol and there were few dropouts. Generalizability to other populations requires caution considering that the study site is characterized by a very poor nutritional situation and the findings might apply only to the same type of settings. Moreover, other factors having an effect on nutritional status, such as infectious diseases, might be different in the study site compared with other settings. In addition, children in the study population had consistent access to free and comprehensive health care and treatment of SAM, which might have maximized the effect of interventions. The same type of study should be repeated in different settings to evaluate the replicability of the results.

Prevention of undernutrition is complex, and impact of interventions depends not only on the type of interventions but also on various contextual factors. Interaction between these two components needs to be better understood so that programmes are tailored to context and reach maximum impact at lower cost. Overall average cost of a monthly ration per child, i.e. purchase price inflated by 50% to take into account operational cost, was estimated at €5.28 (US \$7.28) for LNS-MQ and €10.91 (US\$15.05) for LNS-LQ (Langendorf *et al.* 2014). Although this study was not designed to look at cost-effectiveness, programming and supplementation costs will play a role in decision-making.

The results of this paper highlight the need to design context-specific programmes that may vary depending on the population, the objective of the intervention and the context. Our findings support the approach of complementing the home diet with nutrient-dense complementary food supplements that provide a limited amount of total energy required, e.g. LNS-MQ, depending on the nature and magnitude of the dietary

gap. Provision of LNS-LQ might be more appropriate in contexts with high food insecurity, while when food security is better, distribution of LNS-MQ might be more appropriate. Long-term child food supplementation may be particularly necessary in certain consistently vulnerable populations and those in crises. Where such interventions would be necessary, it is important to recognize that supplementation strategies alone would likely be insufficient to reduce long-term burden without a suite of complementary and comprehensive child health interventions, as well as maternal nutrition and health care to prevent undernutrition early in the life cycle.

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## Conflicts of interest

Authors declare no conflict of interest. None of the authors received specific salary support from the funders for this project and publication.

## Contributions

CL, TR, SP, SD and RFG conceived and designed the experiments. AM, LWM and MLM performed the experiments. CP and TR analysed the data. CP wrote the first draft of the manuscript. CP, CL, SP, SD and RFG contributed to the writing of the manuscript. CP, CL, TR, SP, SD, AM, LWM, MLM and RFG ICMJE read and met criteria for authorship. CP, CL, TR, SP, SD, AM, LWM, MLM and RFG agree with manuscript results and conclusions. AM enrolled the patients.

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## Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site.