Effect of diversified meals only, or either enriched with Amaranthus tricolor and Moringa oleifera leaf powder or commercial micronutrient powder on prevention/treatment of anemia in Adivasi children, West Bengal, India

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Abstract

Background and objectives: Malnutrition associated with anemia remains a leading cause of morbidity and mortality among Adivasi children in India. The present trial aimed to test three possible ways of designing improved supplementary meals and to define their role in decreasing rates of anemia, thus increasing hemoglobin (Hb) concentrations as primary health objective: diversified meals only (intervention group 1 (IG 1)), with the addition of locally producible Amaranthus tricolor/Moringa oleifera leaf powders (ALP/MLP) in the ratio 2:1 (IG2) or with an adjusted amount of commercially produced micronutrient powder TopNutri (IG3).

Methods: Cluster-randomization of 21 villages resulted in the inclusion of n=293 children aged 6-39 months after baseline assessment. The trial duration was 18 months, beginning in February 2015 (baseline assessment), with application of study meals three times a week at community level. Anthropometric, Hb (HemoCue201+) and morbidity data were collected in a total of four assessment points. At baseline a socio-economic questionnaire was performed.

Results: Adjusted for age and Hb concentrations at baseline, time between assessment points, and gender; IG1 showed significant higher Hb concentrations as compared to the control group (CG) throughout the intervention period. The Hb of the remaining intervention groups IG2 or IG3, remained comparable to the CG at all assessment points. The effect on growth indices was less consistent, however most positive tendencies related to nutrition status (stunting, underweight, wasting) and morbidity reduction were attributable to IG3, indicating the beneficial role of a holistic nutrient composition in addressing undernutrition and infectious diseases.

Conclusion: This low-dose intervention trial proofed the feeding of diversified diets alone (IG1) to be sufficient to significantly increase Hb concentrations of study children. On the way of achieving diversified diets for Santal children the promotion of kitchen garden programs combined with interactive awareness trainings may be a key measure. Trial registration: the trial was retrospectively registered at the German Clinical Trials Register on the 1 st July 2019 (DRKS00017388). URL: https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00017388

Introduction

Globally, almost half of all under-five deaths are attributable to malnutrition as underlying contributing factor to mortality and disease burden [1], [2]. The prevalence of stunting (HAZ), underweight (WAZ), and wasting (WHZ) varies across low- and middle-income countries in severity and affects on world level 22% (2013-18) [3], 14% (2010-15) [4], and 7% (2013-18) [3] of children below five years of age, respectively. Globally the WHO reports 43% of children below five years to suffer from anemia in 2011 [5] or according to data of the World Bank 42% in 2016 [6]. In India the National Family Health Survey (NFHS-4 of 2015-16) revealed prevalences of 38.4%, 35.8%, and 21% for growth deficits (HAZ, WAZ, WHZ) respectively, with anemia affecting 58.6% of all under-five year old children [7]. In Birbhum district, West Bengal the anemia rate was similar (59.0%), but the prevalence for stunting, underweight, wasting ranged higher with 40.5%, 43.1%, 29.5%, respectively [8].

The Integrated Child Development Scheme (ICDS) program was launched in 1975 and is aimed at improving the nutritional and health status of children aged 0-6 years by supplementary nutrition, health checkups and education of mothers to improve their caring capacities [9]. Despite this holistic health program Kubde & Kokowar found no significant difference in the prevalence of anemia in ICDS (47.9%) versa non-ICDS (56.1%) areas in urban slums of Nagpur city [10]. Studies including ICDS Centers in Hooghly and Nada District of West Bengal provide evidence that despite the implementation of the ICDS scheme children are still suffering from acute and chronic forms of malnutrition indicating a major public health problem ([11], [12]). On the avenue to address malnutrition supplementary

feeding programs have to be optimized. Locally accessible, cost-effective and sustainable strategies have to be seeked to fight this burden. For anemia prevention and control three conventional approaches are in theory accessible: fortification or supplementation with iron or other micronutrients, and dietary modification/diversification including food-to-food fortification (increased availability and consumption of improved diversified diets composed of a variety of foods). Combined with disease control and education, the latter is a promising and sustainable approach on household (HH) level through adequate selection of foods, proper preparation methods, and adequate feeding [13]; [14], [15], [16]. The greater usage of traditional plant biodiversity is of increasing importance in the scope of food scarcity and the upcoming nutrition transition toward simplification of diets and energy-surplus [17]. The leaves of Moringa oleifera, indigenous to northwest India [18], and Amaranthus tricolor are possible local sources of a variety of nutrients −including iron, beta-carotene, B-vitamins or vitamin C (improve iron absorption and utilization in the blood building system [19], [20], [21], [22]) (**Supplementary Material 1**). The nutritional value of green-leafy vegetables and its role in food security is discussed to be under-exploited [23], thus their utilization and cultivation may be promoted when seeking for sustainable food-based approaches on the avenue to diminish rates of anemia and undernutrition.

As primary health outcome the conducted trial assessed the effect of diversified diets alone (IG1), as well as diversified meals with the enrichments of Amaranthus tricolor leaf powder/Moringa oleifera leaf powder (ALP/MLP) (IG2), or an adjusted amount of a commercial micronutrient powder TopNutri (IG3) on hemoglobin (Hb) concentrations in Santal children aged 6-39 months (**Table 1**, **Figure 2**). Secondary objectives were to investigate the impact of the nutritionally improved meals on growth indicators (HAZ, WAZ, WHZ) and reduction of morbidity prevalence (diarrhea, fever, respiratory infection) of the targeted young children.

By applying the same framework conditions for the intervention and control groups, the study is able to define single effects of measures applied, thereby demonstrating the effect of the nutrient-dense meals and the added value of provided leaf powder or micronutrient sprinkle. This longitudinal study approach allows the investigation of long-term physiological effects implied by natural supplementation dosages in the children. Thereby Hb-development, growth trends, morbidity as well as the influence of season can be taken into consideration more precisely.

Materials And Methods

Study design and intervention

In the current trial three nutritionally improved meals have been valuated by mean increases of hemoglobin concentrations. Beneficiaries either received diversified meals only (IG1), the same diversified meals enriched with Moringa/Amaranthus leaf powder (ratio ALP 2:1 MLP) (IG2), or the same diversified meals enriched with an adjusted amount of an industrial micronutrient powder (MNP) TopNutri (IG3) (**Figure 1**). The supplementary feeding took place on community level in a supervised feeding setting, three times per week and beneficiaries were aware of the components of the meals. Children of the control group (CG) received no nutrition intervention however equally benefitted of medical checkups at each study point. To maintain social peace in the villages the CG received additional awareness sessions on community level in order to understand the usefulness of government schemes and offered nutrition programs, thereby the connection between the villagers to the respective ICDS Centre, surrounding health centres and accredited social health activists or health worker was strengthened.

The trial was conducted over a total period of 18 months from the end of winter season in February 2015 to rainy season in August 2016 including baseline assessment (t0), and three follow-ups, each consecutively 6 months later (t6, t12, t18), with t18 constituting the endline assessment. Prior to the baseline assessment a treatment protocol was

designed by Shining Eyes e.V., which assures a defined treatment of all participants of the study in accordance with the overaching study objectives (i.e. iron/folic-acid supplementation was reserved for severely anemic (Hb<7g/dl) children, and in case of symptoms of other micronutrient deficiencies i.e. dry eyes –wavy strucutre of eyeball, Bitot´s spot (vitamin A); skin lesions, pigmentation, rough skin, perlèche (vitamin B-complex); the supplementation was performed in a defined way). The incidence of symptomatic micronutrient deficiencies during baseline assessment is outlined in a previous publication [24], chi-square analysis showed comparability (p>0.05) across the study groups (not presented). Enrolled children allocated to the four study arms were assessed in the same manner (i.e. medical checkup/required treatment, Hb determination by HemoCue Hb201+, morbidity status and anthropometric assessment as well as the collection of demographic data by means of a semi-structured questionnaire addressed to the main caretaker).

As opposed to ICDS feeding programs enhancements included in the current research study design were dietary diversification (variety of locally available foods for adequate nutrient and energy density in the meal [25]), enhanced monitoring of program implementation, and community-based preparation and consumption of supplemented meals.

Criteria for selecting children for intervention

Inclusion criteria applied after baseline assessment were: children aged 6-39 months, having an Hb ≥ 7.0g/dl, residing in the 21 Santal villages around Bolpur defined as study site, and parents having given their informed consent. Children with severe anemia (Hb<7.0g/dl) were referred to the St. Mary´s Child and Mother Health Care Centre for further treatment. If the condition of severe anemia occurred during the baseline, 2nd, or 3rd assessment children were excluded from statistical analysis. Still, excluded children continued to attend the nutrition program, and were eligible of all benefits – to ensure healthy development as well as social freedom in the village community. Severely wasted children were equally referred to the health care centre for clarification of health condition but remained in analysis as no targeted treatment for malnutrition was possible due to short admission periods as mothers perceived their children as active and healthy.

Study area, village selection, target population and drop-out rates

The cluster-randomized control trial was conducted in 21 villages (rural site) in the catchment area around Bolpur, Birbhum District in West Bengal, India with the majority of n=243 caretakers belonging to the Santals (94.4%) (Table 2). All villages belong to the sphere of action of the NGO Manab Jamin and all are beneficiaries of the government schemes [9]. Cluster-randomization allocated the villages to the four trial arms (three intervention groups (IG 1-3), and one control group (CG)). An alphabetic list comprising 19 village names (of the 21 villages, four were forming two hamlets) was generated. 19 pieces of paper were serially numbered at random. Then all pieces were shuffled well and one by one the pieces were drawn and the number noted down next to the village starting at the top of the list. Then the village name list was ordered according to the randomly obtained numbers and from top to bottom categorized into the four homogenous study groups of participants (thereby a trial arm was composed of 3 up to 7 villages). A total of 295 children aged 6-36 months was estimated to be available in the 19 villages before performing baseline assessment, resulting in an average of 15.5 individuals sampled per cluster to be randomized.

Children aged 6-36 months at baseline assessment were the study's primary target group (due to reasons of sample size extended to 39 months). For further information on population data and response rate at baseline please see

previous publication [24]. At baseline assessment a total of n=307 children were analyzed with the subsequent inclusion of n=293 children (6-39 months) in the feeding trial. Data analysis to validate the intervention effect on the primary indicator Hb concentration was based on n=254 children that were present at all four consecutive assessment points with n=64 (IG1), n=58 (IG2), n=67 (IG3) and n=65 children in the CG. Drop-out rates from baseline measurement to analysis account for n=53 (17.3%), or when considering only children meeting the inclusion criteria at baseline n=39 (13.3%) (**Figure 1**). In total n=20 children were excluded from intervention analysis due to being found severely anemic at the baseline or 2nd assessment and subsequently having received medical treatment (investigator-caused discontinuation). Three children were lost due to child death due to drowning (n=1), and infection (n=2). Overall n=30 children were at least once absent out of all four measuring points (lost-to-follow-up or refused).

Sample size calculation

In June and September 2014 a small pre-study has been conducted to document mean hemoglobin values in two Santal villages to estimate the study sample size. The measurement of n=40 children aged between 6 to 35 months resulted in a mean hemoglobin value of 8.74g/dl with a variance of 2.163 and standard variation of 1.471. The sample size calculation was performed according to Allen, 2011 [26], with the following values: μ= 0.05, b= 0.2, zμ= 1.6449, zb = 0.8416, d= 0.7. In the present long-term trial a difference of 8% (0.7g/dl) in hemoglobin mean value between baseline and endline measurement was assumed according to observed effects by Hirve et al., 2013 [27]: after supplementing elemental ferrous fumarate (average dosage of 5mg/d ≈ 1.7mg elemental iron [28]) through the ICDS to reduce anemia in Indian pre-school children over a total period of four months, thereby achieving a significant increase in mean Hb concentrations of 0.71g/dl in boys and 0.48g/dl in girls. The sample size calculation for two independent groups resulted in a minimum sample size of n=55 children, multiplied with the design effect a sample size of n=63 children resulted. For calculation of the design effect the intra-class correlation-coefficient (ICC) was set according to Adams et al., 2004 [29] at ICC=0.01, and the cluster size accounted for m=15.5. With an assumed drop-out rate of 10%, an estimated minimum sample size of n=70 children per study group is required.

Testing the overall fit of the performed regression models requires a minimum acceptable sample size of N=138 (Model A $_{\text{Hb Diff 3rd 1st assessment}}$) or N=146 (Model B $_{\text{Hb Diff 4th 1st assessment}}$), respectively following the proposed rule of thumb 50+8m (with m being the number of candidate predictor variables) [30], [31].

Figure 1: Flow chart on enrolment, follow-up and drop-out in the trial

Socioeconomic household survey, anthropometric and hemoglobin measurement and devices

Data on socio-demographic characteristics including maternal educational level, cash income, agricultural assets, or infant and young child feeding and caring practices were collected in form of a semi-structured questionnaire conducted by trained field workers. For further details please see previous publication to baseline assessment [24].

Moreover at baseline (t_0) and the subsequent assessment points (t_6, t_{12}, t_{18}) anthropometric outcome indicators and hemoglobin concentrations have been measured. Hb was determined by using a portable hemoglobinometer (HemoCue Hb 201+) for all children donating a finger prick of capillary blood at each assessment point. At each checkup children were dewormed (albendazol/mebendazol) in order to reduce the risk of iron deficiency anemia due to worm infestation. For details on the assessment, computing and interpretation of Hb and anthropometric outcome variables (MUAC, weight, height, length) please see previous publication to baseline assessment [24].

Morbidity incidence during the intervention period

At baseline, 2nd, 3rd assessment the current health status, i.e. fever, cold and cough, or diarrhea during the week prior or on the respective medical checkup day were queried/diagnosed by the doctoral research team (endline assessment did not include a medical checkup). The morbidity prevalence is expressed as percentage of children suffering from any sickness. Morbidity data obtained during medical checkups give insight in possible trends over the study period, thereby seasonal variations in sickness can be taken into account.

Further a 5-weeks-morbidity questionnaire was conducted in Nov to Dec 2015 by social workers on HH level on a weekly basis. The findings of the five-weeks morbidity survey were analyzed as average per week (children with a response rate of ≥3 social worker visits out of 5 were valid). Responses were given as number of days (sickness during last week). Results of the morbidity questionnaire were considered during regression analysis in order to assess possible effects of morbidity on Hb increases, and to compare days of sickness across the groups.

Nutrient content of Amaranthus tricolor and Moringa oleifera leaves

Supplementary Material 1 presents an overview on the nutrient content of Amaranthus tricolor and Moringa oleifera fresh as well as dried leaves. Average values of the leaf powder analysis are the basis for recipe calculation in this study. **Supplementary Material 2** illustrates the amino acid content of dried Moringa leaves according to the analysis of the LA Chemie University of Hohenheim. Moringa oleifera leaf consumption can make a distinct contribution to the intake of vitamin A, B, C, and E as well as the minerals calcium, iron, potassium, and magnesium. Moringa also contains valuable amounts of zinc, however whole-grains, legumes or seeds remain more outstanding plant-sources for enhancing zinc intake. Moreover Moringa leaves contain high amounts of protein composed of a good balance of all essential amino acids [32]. Amaranthus tricolor leaves were found during the current laboratory investigations to have an iron content five times higher than Moringa (**Supplementary Material 1**), thus the combination of both plants was decided in order to achieve an optimized nutrient composition in the intervention study. Moreover sensory attributes were decisive for the combined use of ALP and MLP, as ALP has a pleasant nutty taste, whereas MLP is characterized by a more leafy and slightly bitter taste.

Recipes applied in the intervention groups

Diets for children suffering from moderate malnutrition should aim at a fat energy percentage between 35 and 45 percent [33]. Recipes designed for this study (**Table 1**) are energy-rich with an adequate contribution of protein (Halwa 14E%, Khechuri 22E%) and fat (Halwa 42E%, Khechuri 44E%) to total energy for a sweet wheat-lentil-milk-fruit porridge

served with half an egg "Halwa", and a rice-lentil dish with vegetables and chicken "Khechuri", respectively. Lentils were roasted during food processing to decrease antinutrients and enhance protein digestibility [25], [34].

Table 1: Ingredients of the study recipes Halwa (served twice a week plus half an egg per capita). Ingredients of Khechuri (served once a week).

Ingredients Halwa	Amount (g)
Milk powder, whole	10
Wheat, flour, white (Ata, sada, packet)	10
Lentil, raw (Mosur dal)	5
Banana, ripe, raw	60
Dates, dried	16
Pumpkin, raw (Mistikumra)	55
Poppy seeds (posto dana)	5
Jaggery, solid (Gur, Akh)	8
Oil, sunflower, added Vit A, D, E	10
Water (absorbed after cooking process)	94
Water (entered in Nutrisurvey for subsequent use of the "boiled function")	120
Ingredients Khechuri	Amount (g)
Rice	15
Green gram (Mung dal)	10
Soya chunks	5
Chicken (without bones)	30
Spinach, raw (Palong shak/ Kulmi)	30
Pumpkin, raw (Mistikumra)	30
Garlic, raw	2.5
Onion, raw	7.5
Ginger root, raw	5
Turmeric	0.5
Cumin seeds (Jira)	0.5
Iodized salt	0.9
Oil, Sunflower, added A,D,E	12
Water (aborbed after cooking process)	84
Water (entered in Nutrisurvey for subsequent use of the "boiled function")	112

The vitamin C density (Halwa: 24.5mg/1000kcal, Khechuri: 39.2mg/1000kcal) exceeds the minimum required density of ascorbic acid (20mg/1000kcal) to maintain the desired iron absorption rate of 5-8% as stipulated by the Indian Council of Medical Research [33].

Application of the enrichments leaf powder or industrial micronutrient sprinkle

In IG2 the dosage of dried leaf powder was set at 3g per 100g cooked food, which equals an additional provision of 1.9mg iron per 100g food consumed. The dosage of the industrial micronutrient powder (IG3) was adjusted to the iron content provided by the local plant sources (IG2) to make the groups comparable and allow the subsequent investigation of possible differences concerning bioavailability. Consequently per 100g cooked food an additional 1.84g TopNutri (=1.9mg iron) were provided. Children were entitled to eat as much they like, but the first portion distributed was set at 100g for children aged 6-<12 months, 150g for children aged 12-<24 months, 200g for children 24-<36months and 250g for children >36 months. Attendance was recorded throughout the study period, portion sizes consumed were documented by comparing food served versa left-overs. Two to three previously instructed village helpers performed the cooking at the community feeding centers during late afternoon. After completion of the cooking process a measured amount of the leaf powder or the micronutrient sprinkle was mixed into the ready cooked food before distributing it to the study children. The plants Moringa oleifera and Amaranthus tricolor were cultivated, and harvested followed by washing, shade-drying and further processing of leaves to powder on-sight by professional horticulturists, assuring high-quality of leaf powder due to self-optimized production sequence. The industrial micronutrient powder TopNutri was obtained by the company "Compact for Life". To summarize: a 200g portion (257.2kcal) of diversified meals alone (Halwa 2:1 Khechuri) provides on average 2.2mg iron. Thus, further enrichment with either 0.3mg iron (2g MLP) and 3.5mg iron (4g ALP), or 3.8mg iron (3.68g TopNutri); results in a total iron provision of 6mg iron per supplementary meal (200g portion) in IG2/IG3. The iron content per 100kcal accounts for 0.86mg (IG1), and 2.33mg (IG2/IG3).

Percent of fulfillment of Indian dietary reference intake values by study recipes

Figure 2 demonstrates the percentage of fulfillment of the dietary reference intake (DRI) values for Indian children [33] (CHO, vitamin E, D have been obtained from IOM [35]) by the three intervention groups. The graphs yields have been calculated in NutriSurvey by using the Food Composition Database for Bangladesh [36] (except B12 content for whole milk powder or egg have been obtained from USDA nutrient database [37]). Presented is the estimated daily intake of nutrients by a moderate breastmilk intake of 532.3ml ([38]; [39]), by complementary foods including the AWC meal ([40]), and further the nutrient intake provided by a 200g exemplified supplementary meal enriched by ALP and MLP.

Figure 2: Percent of fulfillment of Indian RDA by assumed moderate frequency of breastfeeding, by complementary feeding (CF) over the day, as well as Halwa:Khechuri (2:1) supplemented with either Amaranthus:Moringa (2:1) leaf powder mixture or an adjusted amount of TopNutri.

Note: Potassium or vitamin B12 intakes are not presented in **Figure 2**, as no estimations were provided on CF by available food weighed protocol analysis [40]. Concerning the supplementary meal nutrient contents are as follows: 175g Halwa+25g chicken egg provide 552mg potassium (18% of DRI), 0.7µg B12 (78% of DRI); 200g Khechuri provide 568mg potassium (19% of DRI), 0.1µg B12 (11% of DRI) [35]. B12 and potassium intakes by breastmilk account for 0.085µg[LL], or 316.7mg, respectively. For ALP no analysis for nutrient content were available concerning energy, CHO,

vitamin D, niacin, folate (compare **Supplementary Material 1**) thus reference intake values may be fulfilled at a higher percentage than presented in **Figure 2**.

Statistical analysis

The data were analyzed using SPSS statistics 22, 25 and 26. The general level of significance was set at $p<0.05$. The results are expressed in percentages or in means ± SD/median. Tests applied were the Kolmogorov-Smirnov Test, Q-Q-plots/histograms, the Pearson Chi-square/Fisher-test (Monte-Carlo-Simulation in case of 4x2 contigency tables if more than 20% have expected frequency <5) for proportions, for comparisons at multiple points of time within one group (intra-group comparison) univariate ANOVA with repeated measurements/Friedman, and for comparing multiple groups at one point of time (inter-group comparison) univariate ANOVA/Kruskal-Wallis test was applied. To determine which mean values varied over time Bonferroni-adjusted post-hoc test/Dunn-Bonferroni-test was performed, respectively, and in order to ascertain amongst which study groups a significant difference was found at one point of time the Duncan Post-Hoc test/Dunn-Bonferroni-test was performed. To identify significant predictors determining the highest percentile of Hb increases between $1^{st}/3^{rd}$, and $1^{st}/4^{th}$ assessment a multiple logistic binomial regression with Forward procedure was performed on a set of covariates ($p<0.25$ in preceding bivariate analysis). The pre-post intervention effect (i.e. which study groups differ significantly over time) was validated by performing a general linear model: with Hb concentrations or z-scores (HAZ, WAZ, WHZ) at 2nd, 3rd and 4th assessment respectively, being applied as dependent variable (post-test scores). Covariates considered for adjustment were: baseline Hb and age (significant confounders identified during linear Forward regression), time between assessment points, and gender (confounders additionally considered for reasons of integrity) (ANCOVA-post). Similarly the Hb changes or z-score changes occurred between baseline and 2nd, 3rd and 4th assessment, respectively were investigated (adjusted for pre-treatment Hb values and age, time between assessment points, gender) (ANCOVA-change), in order to picture adjusted mean Hb gain scores over time per study group [41]. Both methods are reported to be equivalent resulting in same treatment effects [42], [43]. Although during data management HAZ, WAZ is already age/gender normalized -based on known population data rather than our sample; it was further adjusted for both the gender and age of the child during data analysis to find effects independent of age and sex. This way of adjustment was already chosen by other researchers [44].

Authors suggest LSD to be used as hypothesis generator rather than simultaneous hypothesis generation and testing [45], [46]. In the current trial LSD post-hoc test was chosen to test for study effects as it is inherently applied during GLM by the software SPSS itself when producing paramter estimates against the CG. Moreover LSD bears the advantage of keeping false negatives (type II errors, which may increase cost as failing to detect real differences) small, but thereby increases the possibility of false positive findings (type I error, claiming differences that are not real). Every comparison of repeated pairwise testing should be interpreted independently as the LSD post-hoc is not controlling for the family-wise error-rate, and the differences assessed need confirmation in subsequent studies. Still the only use of a more conservative test Bonferroni post-hoc may result in a waste of statistical power [47]. Thus, authors of the study suggest the LSD post-hoc test to examine trends amongst the study groups, and to validate main trends by additional consideration of the Bonferroni post-hoc test (equally presented).

Results

Socio-demographic parameters

Socio-demographic characteristics of the households and the study children are presented in **Table 2**. Statistical significant differences between groups prior to the intervention were assessed for ethnicity, maternal age at the time of the interview, mean number of days mother and child sit together for eating (assessed for five consecutive weeks), and parity. The time investment in child caring activities was highest for mothers of IG1, and also sitting next to the child while eating was most practiced by IG1 -significantly more than in IG2 or CG.

Table 2: Socio-demographic information by study group

(n=number of children[c], or number of mothers/households[HH]. *Note:* 10 HH have two study children)		Total valid	IG1	IG2	IG3	CG	p-value
		n (%)	n (%)	n (%)	n (%)	n (%)	IG1, 2, 3, CG
Ethnicity (n=243) [HH]	*Konra*	14 (5.8)	0 (0)	11 (19.6)	3 (4.6)	0 (0)	0.000***
	Santal	229 (94.2)	61 (100.0)	45 (80.4)	62 (95.4)	61 (100.0)	
Marital status (n=234) [HH]	*married*	229 (97.9)	55 (96.5)	53 (98.1)	63 (100.0)	58 (96.7)	0.516
	single, formerly married or living deserted from husband	5 (2.1)	2 (3.5)	1 (1.9)	0 (0)	2 (3.3)	
Child´s age (n=254) [c]	*6 to 23 months*	132 (52.0)	31 (48.4)	32 (55.2)	34 (50.7)	35 (53.8)	0.884
	≥ 24 months	122 (48.0)	33 (51.6)	26 (44.8)	33 (49.3)	30 (46.2)	
Child´s sex (n=254) [c]	*female*	110 (43.3)	28 (43.8)	21 (36.2)	28 (41.8)	33 (50.8)	0.437
	male	144 (56.7)	36 (56.3)	37 (63.8)	39 (58.2)	32 (49.2)	
Maternal educational level (n=242) [HH]	*no formal education (never attended school)*	110 (45.5%)	29 (48.3)	26 (46.4)	25 (38.5)	30 (49.2)	0.605
	any formal education	132 (54.5%)	31 (51.7)	30 (53.6)	40 (61.5)	31 (50.8)	
HH head (n=241) [HH]	*husband only, parents in law, elder*	223 (92.5)	55 (91.7)	53 (94.6)	59 (92.2)	56 (91.8)	0.914
	wife alone or together with husband	18 (7.5)	5 (8.3)	3 (5.4)	5 (7.8)	5 (8.2)	
HH type (n=243) [HH]	*nuclear family*	121 (49.8)	27 (44.3)	26 (46.4)	40 (61.5)	28 (45.9)	0.175
	extended family	122 (50.2)	34 (55.7)	30 (53.6)	25 (38.5)	33 (54.1)	
Type of dwelling (n=243) [HH]	*kacha (mud house)*	198 (81.5)	52 (85.2)	47 (83.9)	51 (78.5)	48 (78.7)	0.682
	semi-pukka (combination mud with metal or stones)	45 (18.5)	9 (14.8)	9 (16.1)	14 (21.5)	13 (21.3)	
Household cash income (n=226) [HH]	*0 to 4999 INR*	149 (65.9)	35 (60.3)	31 (62.0)	46 (76.7)	37 (63.8)	0.226
	more than	77 (34.1)	23 (39.7)	19 (38.0)	14 (23.3)	21 (36.2)	

	5000 INR					
Does the HH cultivate any land (n=243) HH	no	132 (54.3)	30 (49.2)	34 (60.7)	39 (60.0)	29 (47.5)	0.315
	yes (own land, leased land)	111 (45.7)	31 (50.8)	22 (39.3)	26 (40.0)	32 (52.5)	
Does the HH cultivate any vegetables (n=238) HH	no	213 (89.5)	55 (91.7)	45 (84.9)	57 (89.1)	56 (91.8)	0.605
	yes, normally or sometimes	25 (10.5)	5 (8.3)	8 (15.1)	7 (10.9)	5 (8.2)	

Mean±SD, Median, Min/Max, n

Age mother at the birth of her oldest child (years) NN*** HH	Mean±SD, Median, Min/Max	19.8±2.5, 19, 14/29, n=236	19.5±2.4, 19, 14/27, n=59	19.3±2.1, 19, 14/25, n=56	19.7±2.6, 19, 15/29, n=63	20.5±2.7, 20, 17/29, n=58	0.147
Age of mother at time of the interview (years) NN*** HH		24.5±3.9, 24, 18/40, n=237	24.9±4.0, 23, 19/37, n=59	23.2±3.1, 23, 18/35, n=56	25.1±4.1, 25, 19/40, n=63	24.8±4.2, 25, 19/35, n=59	0.033* (IG2 vs. IG3)
BMI mother (kg/m2) NN** HH		18.6±1.8, 18.5, 14.8/27.4, n=234	18.6±1.7, 18.3, 16.0/24.6, n=58	18.7±2.3, 18.6, 14.8/27.4, n=54	18.4±1.7, 17.9, 14.8/26.5, n=64	18.9±1.6, 18.6, 15.2/22.5, n=58	0.278
Hb mother (g/dl) NN** HH		10.4±1.3, 10.6, 6.9/14.1, n=234	10.4±1.3, 10.3, 6.9/12.6, n=58	10.6±1.3, 10.6, 7.3/14.1, n=54	10.4±1.3, 10.7, 6.9/12.9, n=64	10.4±1.4, 10.5, 7.1/12.8, n=58	0.907
Average number of FG consumed by study child at baseline NN*** c		3.7±1.3, 4, 0/6, n=223	4.1±0.9, 4, 2/6, n=58	3.6±1.4, 4, 0/5, n=55	3.5±1.3, 4, 0/6, n=57	3.8±1.4, 4, 0/6, n=53	0.088
Time use for child caring activities (caring, eating, learning together) (h/day) NN*** c		2.9±1.9, 2.5, 0.5/9.5, n=202	3.1±2.1, 3, 0.5/8.0, n=53	2.8±1.7, 2.5, 0.5/7, n=48	2.9±1.9, 2.5, 0.5/9.5, n=57	2.6±2.0, 2, 0.5/8, n=44	0.566
Average number of days mother and child sit together/week when eating at home (5-week		2.19±1.03, 2, 1/7, n=243	2.44±0.73, 3, 1/3, n=61	1.90±0.76, 2, 1/3, n=56	2.20±1.10, 2, 1/7, n=64	2.19±1.32, 2, 1/7, n=62	0.002** (IG1 vs. IG2, IG1 vs. CG)

questionnaire) NN*** [c]						
Parity NN*** HH	1.8±0.8, 2, 2, 1/5, n=237	2.0±0.9, 2, 1/5, n=59	1.6±0.7, 1, 1/3, n=54	2.0±0.8, 2, 1/5, n=64	1.8±0.9, 2, 1/4, n=60	0.039* (IG2 vs. IG3 marginal signif. (p=0.053)).

Note: Levels of significance *p<0.05; **p<0.01; ***p<0.001, and in case of multiple comparisons p-values are already adjusted for Bonferroni-correction. NN not normally distributed tested by Kolmogorov-Smirnov Test, the hypothesis regarding the distributional form is rejected with *,**,***. Definition of food groups (FG): starchy foods (grains, roots, tubers), legumes and nuts, dairy products, flesh foods (meat, fish, poultry, organ meats), eggs, vitamin A rich fruits and vegetables, other fruits and vegetables.

Mean changes in Hemoglobin concentrations occurred over time

Figure 3 depicts the mean Hb concentrations (as measured) at the different assessment points. IG1 had the highest Hb concentration at baseline assessment, followed by the CG, IG2, and IG3, respectively. These differences were non-significant (p=0.055) according to ANOVA with subsequent Duncan Post-hoc test, thus ANOVA assessed comparability of the study groups at baseline (Table 3).

Figure 3: Mean Hb concentrations at baseline, 2nd, 3rd, endline assessment (n=254), per study group.

The mean Hb increase was highest for IG1 and IG3 until the 3rd assessment. IG2 was characterized by a slower increase but almost caught up at the end of the first year of trial. The control group equally shows an increase over time, yet lower as compared to the intervention groups. Between the 3rd and 4th assessment all study groups experience a slight decrease in Hb concentrations. When comparing the baseline versa the endline assessment, then the highest increases in Hb were found for IG2/IG3, followed by IG1, and CG, respectively. Figure 4 depicts the mean changes in Hb concentrations over time.

Figure 4: Mean changes in Hb concentrations occurred over time (n=254), per study group.

Inter- and intra-group comparisons

The statistical analysis of possible effects induced by the different intervention measures on Hb concentration and nutritional status of the children is illustrated in Table 3 (Hb, HAZ, WAZ, WHZ), and Supplementary Material 3 (age, weight, height/length, MUAC z-scores). The statistical analysis presented along the lines show inter-group comparisons at one point of time, and those at the bottom of the columns depict intra-group comparisons over the different check-up points.

Inter-group comparisons

For the primary indicator hemoglobin the mean values assessed at baseline were comparable across the groups (Table 3). At 2nd and 3rd assessment significant differences were found between IG1 to all other groups. When considering mean Hb changes occurred over time, no significant increase could be shown for the single intervention groups versa CG.

The age of children was comparable across all study groups at baseline and further assessment points (Supplementary Material 3).

Concerning weight, the initial baseline values were comparable across all study groups. The comparison of weight at respective assessments showed no significant differences across the groups (Supplementary Material 3). For height/length (Supplementary Material 3) and stunting z-score values (not comparable at baseline) (Table 3) no significant increases could be detected in relation to the control group, however IG2 was significantly inferior to IG3 concerning gain in HAZ-scores between baseline and endline assessment (p=0.024). There was a tendency of highest achieved gains in HAZ scores for IG3 at 3rd and endline assessment. Also mean underweight z-scores could not be significantly improved when compared to the control group. Concerning WHZ-scores increases were significant higher for IG2 versa IG3 (p=0.056, marginal significant), for CG versa IG3 (p=0.048), and for IG1 versa IG3 (p=0.004) between the 2nd and 4th assessment. Concerning MUAC z-score values similarly no significant differences occurred across study groups.

To sum up, effects observed in relation to the CG: At 2nd and 3rd assessment the hemoglobin concentration of IG1 was significantly higher as compared to CG (Table 3). Gain in weight, length or height, MUAC, HAZ, WAZ, WHZ scores showed no significant effects when compared to CG (Supplementary Material 3).

Intra-group comparisons

Mean Hb concentrations significantly increased between baseline and 3rd assessment for all intervention groups and the control group, respectively. The strength of effect size between 1st and 3rd assessment was the weakest for CG (r=0.392) and the strongest for IG1 (r=0.822), followed by IG3 (r=0.736), and IG2 (r=0.557). Between baseline and endline assessment all intervention groups experienced a significant increase, whereas the increase in CG was not significant. The strength of effect size between 1st and 4th assessment was strongest in IG3 (r=0.548), followed by IG2 (r=0.538), and IG1 (r=0.535). The increase of Hb concentrations between 2nd and 4th assessment was significant for IG2 (Table 3).

Increases over time in weight and height/length were significant across all assessment points for all groups (Supplementary Material 3). Stunting z-scores showed no significant gains (decline in HAZ prevalence) for any study group from baseline to endline, with IG1 and IG2 even ending up with lower HAZ scores at 3rd and endline assessment as compared to the baseline and 2nd assessment, respectively. Still IG3 showed the best development in mean scores amonst all study groups, with a significant improvement between the 3rd and endline assessment (Table 3).

Underweight scores significantly improved between baseline and 3rd assessment for IG3; whereas no group showed a significant increase between baseline and endline. Merely IG1 significantly improved their WAZ scores between the 2nd and 4th assessment. All groups except CG experienced significant faltering in mean scores (increase in underweight prevalence) between the 3rd and 4th assessment.

Wasting scores significantly improved between baseline and 3rd assessment for all intervention groups but not CG. Again between baseline and endline no group showed a significant increase. Between the 3rd to endline assessment all groups experienced faltering of scores, with the decrease being significant for IG1 and IG3. Between 2nd and endline assessment the CG and all intervention groups except IG3 significantly improved the WHZ scores.

MUAC z-scores significantly decreased in the CG between baseline and endline, and showed no change between baseline and 3rd assessment. IG1 showed a significant increase between 2nd and 3rd assessment followed by a significant decrease between 3rd and endline assessment. IG2 and IG3 experienced no significant changes in MUAC z-scores. There was a tendency of higher experienced increases in MUAC scores for all intervention groups as opposed to the CG at the 3rd and endline assessment, respectively.

To sum up intra-group effects considering key points of the trial: hemoglobin concentrations showed a significant increase between 1st and 3rd assessment for all intervention groups and CG, with the effect size being smallest for CG. Between baseline and endline all intervention groups but not CG showed significant increases (Table 3).

Weight as well as height/length increases were significant for all groups over the study period. Stunting scores showed no significant changes in any study group between baseline and 3rd/endline assessment. Still, IG3 showed significant improvement in HAZ scores between the 3rd and endline assessment. Similarly, underweight scores significantly increased between 1st and 3rd assessment for IG3. Wasting scores significantly rose between 1st and 3rd assessment for all intervention groups but not CG. MUAC scores significantly decreased between 1st and endline assessment for CG, whereas all intervention groups showed a tendency of increasing MUAC z-scores (Supplementary Material 3).

Table 3 **Effect of diversified meals only (IG1), or either enriched with ALP/MLP (IG2), or an adjusted amount of industrial micronutrient powder (IG3) on Hb concentrations and the nutritional status (HAZ, WAZ, WHZ) of study children.**

Hemoglobin (mg/dl)	IG1 n=64	IG2 n=58	IG3 n=67	CG n=65	p-value (IG 1, 2, 3, CG) ANOVA or Kruskal-Wallis test
Baseline	9.5±1.1	9.2±1.1	9.1±1.0	9.4±1.0	p=0.055
2nd	10.1±1.3	9.5±1.2	9.7±1.2	9.6±1.1	p=0.027* a,d,f
3rd	10.5±1.2	10.0±1.2	10.0±1.1	9.9±1.1	p=0.021* a,d,f
Endline NN*	10.2±1.2	10.0±1.1	9.9±1.0	9.9±1.1	p=0.202
Difference 3rd-1st	0.99±1.04	0.84±1.3	0.93±1.17	0.49±1.06	p=0.064
Difference 4th-2nd	0.11±1.11	0.52±0.96	0.23±1.10	0.28±1.07	p=0.209
Difference 4th-1st NN*	0.70±1.15	0.81±1.31	0.82±1.33	0.45±1.24	p=0.119
Friedman baseline to endline	p<0.001*** A, D, F (p<0.001) B (p=0.050 marginal)	p<0.001*** D, F (p<0.001), E (p=0.007), B (p=0.004)	p<0.001*** D, F (p<0.001), A (p=0.024), B (p=0.010)	p=0.007** F (p=0.009)	
	Effect size of Dunn-Bonferroni (pairwise comparison of 1st versa 4th/3rd assessment) D: (z=-4.279, r=0.535) F: (z=-6.573, r=0.822)	Effect size of Dunn-Bonferroni (pairwise comparison of 1st versa 4th/3rd assessment) D: (z=-4.099, r=0.538) F: (z=-4.243, r=0.557)	Effect size of Dunn-Bonferroni (pairwise comparison of 1st versa 4th/3rd assessment) D: (z=-4.483, r=0.548) F: (z=-6.022, r=0.736)	Effect size of Dunn-Bonferroni (pairwise comparison of 1st versa 3rd assessment) F: (z=-3.159, r=0.392)	

Height-for-age z-score (stunting)	IG1 n=64	IG2 n=57	IG3 n=67	CG n=64	p-value (IG 1, 2, 3, CG) ANOVA or Kruskal-Wallis test
Baseline	-1.82±0.99	-1.79±0.90	-2.05±1.25	-2.27±1.09	p=0.040* d, e
2nd	-1.80±0.88	-1.92±0.87	-1.93±1.12	-2.22±1.09	p=0.121
3rd	-1.87±0.88	-1.98±0.86	-1.99±1.12	-2.24±0.99	p=0.168
Endline	-1.84±0.84	-1.95±0.85	-1.86±1.02	-2.24±0.99	p=0.062
Difference $_{3rd-1st\ NN***}$	-0.054±0.572	-0.194±0.660	0.058±0.655	0.029±0.542	p=0.122
Difference $_{4th-2nd\ NN***}$	-0.039±0.446	-0.025±0.449	0.068±0.349	-0.023±0.43	p=0.400
Difference $_{4th-1st\ NN***}$	-0.027±0.676	-0.158±0.751	0.188±0.605	0.035±0.638	p=0.034* b: p=0.024 Bonferroni-corr.
ANOVA repeated measurements	p=0.630	p=0.076	p=0.032* C (p=0.003)	p=0.724	

Weight-for-age z-score (underweight)	IG1 n=64	IG2 n=58	IG3 n=67	CG n=64	p-value (IG 1, 2, 3, CG) ANOVA or Kruskal-Wallis test
Baseline	-1.91±0.85	-1.78±0.98	-1.92±1.03	-2.01±1.07	p=0.625
2nd	-2.05±0.74	-1.95±0.96	-1.99±0.94	-2.20±1.03	p=0.465
3rd	-1.75±0.76	-1.73±0.94	-1.68±0.97	-1.94±0.95	p=0.390
Endline	-1.91±0.76	-1.84±0.89	-1.96±0.89	-2.06±0.89	p=0.536
Difference $_{3rd-1st}$	0.162±0.532	0.045±0.513	0.239±0.548	0.072±0.548	p=0.162
Difference $_{4th-2nd}$	0.135±0.297	0.112±0.345	0.024±0.387	0.132±0.408	p=0.254
Difference $_{4th-1st\ NN*}$	-0.005±0.559	-0.065±0.548	-0.041±0.582	-0.052±0.611	p=0.831
ANOVA repeated measurements	p<0.001*** B, C (p<0.001), E (p=0.003)	p=0.003** A (p=0.037), B (p<0.001), C (p=0.007)	p<0.001*** B, C (p<0.001), F (p=0.004)	p=0.001** A (p=0.023), B (p<0.001)	

Weight-for-height/length z-score (wasting)	IG1 n=64	IG2 n=57	IG3 n=67	CG n=64	p-value (IG 1, 2, 3, CG) ANOVA or Kruskal-Wallis test
Baseline	-1.30±0.84	-1.10±0.98	-1.15±0.88	-1.08±1.09	**p=0.551**
2nd	-1.54±0.75	-1.29±0.95	-1.34±0.90	-1.41±0.93	**p=0.438**
3rd	-1.00±0.65	-0.88±0.92	-0.81±0.85	-0.98±0.89	**p=0.502**
Endline	-1.24±0.75	-1.03±0.90	-1.30±0.79	-1.12±0.87	**p=0.250**
Difference $_{3rd-1st}$	0.296±0.684	0.219±0.594	0.338±0.704	0.091±0.751	**p=0.188**
Difference $_{4th-2nd\ NN**}$	0.293±0.454	0.264±0.534	0.032±0.601	0.288±0.696	**p=0.003**** b: p=0.056 marginal signif., Bonferroni-corr. c: p=0.048 Bonferroni-corr. f: p=0.004 Bonferroni-corr.
Difference $_{4th-1st}$	0.056±0.697	0.075±0.606	-0.159±0.747	-0.048±0.822	**p=0.240**
ANOVA repeated measurements baseline to endline	**p<0.001***** A (p=0.037), B, C, E (p<0.001) F (p=0.006)	**p<0.001***** B (p<0.001), E (p=0.003), F (p=0.044)	**p<0.001***** B, C (p<0.001) F (p=0.001)	**p<0.001***** A (p=0.002) B (p<0.001) E (p=0.009)	

Values represent Mean ± SD

NS non significant

Levels of significance *p<0.05; **p<0.01; ***p<0.001

Significant difference between groups small letter/between measurement points capital letter: [a/A] I and II; [b/B] II and III; [c/C] III and IV; [d/D] I and IV; [e/E] II and IV; [f/F] I and III

NN not normally distributed tested by Kolmogorov-Smirnov Test, the hypothesis regarding the distributional form is rejected with *,**,***.

If the sample size comprises n> 30 or 40 individuals, the violation of normal distribution is less problematic, as the sampling distribution approaches normality regardless of the shape of the data [48]. The division of the mean by median resulted in a ratio within the range 0.95-1.05 for measured data on anthropometry or Hb, and the graphical distribution by histogram ascertained no serious deviation from normality for none of the variables investigated. Still according to the Kolmogorov-Smirnov Test the decision for parametric or non-parametric tests was performed. However for visual presentation of Hb, and HAZ, WAZ, WHZ scores the means were preferred over the median.

Calculation of effect size (r) using z-value of Dunn-Bonferroni obtained during Friedman-test:

Interpretation of the strength of effect size according to Cohen (1992) [49]:

$0.1 \leq r < 0.3$ (weak), $0.3 \leq r < 0.5$ (medium), $r > 0.5$ (strong).

Prevalence of moderate/severe anemia and stunting, underweight, wasting at the different assessment points

Note: as Hb<7g/dl was an exclusion criteria during the nutrition program phase, merely at endline assessment a total of three children suffering from severe anemia (Hb<7g/dl) were remaining in analysis, one child per IG1, IG3, CG, respectively. At baseline the four study groups were not comparable concerning the prevalence of moderate anemia (7g/dl≤Hb<10g/dl) (p=0.007**). The initial prevalence of moderate anemia was highest for IG2, IG3 (81.0%, 80.6%), followed by 63.1% (CG), and 59.4% in (IG1). Again at 3rd assessment, the comparison of the four study groups showed a significant difference (p=0.021*), with IG3 having the highest prevalence of moderate anemia (49.3%), followed by IG2 (46.6%), CG (44.6%), IG1 (25.0%). The prevalence of moderate anemia was similar across the groups concerning the remaining assessments (2nd, 4th) (Figure 5).

Figure 5: Prevalence of moderate/severe anemia at different assessment points by study group

To sum up, considering all subjects suffering from moderate anemia at baseline assessment, and improving their Hb level to mild/or no anemia at 3rd or endline assessment, respectively then no significant differences across the four study groups could be detected. In other words, the proportion of children improving their Hb level from moderate anemia to mild/no anemia between the 1st and 3rd/4th assessment, respectively, was similar across all groups, indicating no significant effect of the intervention on the reduction of the prevalence of moderate anemia. Still, the prevalence of moderate/severe anemia between the 1st and 3rd, 1st and 4th assessment decreased least in the CG (18.5%, 10.8%), whilst the highest decrease was observed for IG2 (34.4%, 36.2%), respectively. IG1 (34.4%, 26.6%) and IG3 (31.3%, 26.9%) similarly showed invariable higher decreases in the rates of moderate/severe anemia as compared to the CG, indicating a positive tendency on the reduction of anemia by the intervention measures.

The Chi-square test (not presented) showed significant differences in regard to the initial stunting prevalence at baseline assessment across the four different study groups (p=0.033). All remaining comparisons concerning the prevalence of stunting (<2SD), wasting or underweight showed similarity across the four study groups at the different assessment points, indicating no significant effect of the intervention measure on growth indices across the different study groups (Supplementary Material 4).

Regression analysis

Table 2 presents differences in socio-demographic characteristics across study groups. It has to be considered that meaningful differences in baseline characteristics are often not detected, because studies are not powered for this purpose (type II error). This implies that a non-significant difference still can be a strong prognostic factor causing meaningful confounding and vice versa. Boer et al. [50] conclude that potential confounders should not be selected based on statistical analysis of differences at baseline. Thus, in subsequent regression models, all prognostic factors were taken into account in terms of bivariate analysis to identify meaningful confounders (p<0.25) in relation to the dependent variable.

Regression analysis to define predictors of the highest percentile of hemoglobin increases occurred at endline assessments (1st versa 3rd, 4th assessment, respectively)

A forward regression analysis with a step-wise approach was performed to identify independent predictors on the Hb response occurred during the 1st and 3rd (Model A, **Table 4**), as well as the 1st and 4th assessment (Model B, **Table 5**), respectively. The cutoffs to define the dependent variable were set to select the highest percentile of Hb increases observed across the different assessment points. First each covariate was examined for the presence of statistical association with the dependent variable ($Hb_{diff} \geq 1.8g/dl$ at $3^{rd}/1^{st}$, and $Hb_{diff} \geq 1.7g/dl$ $4^{th}/1^{st}$ assessment) by logistic binary regression (generation of crude p-values), respectively. Hereby covariates with a p-value of <0.25 in the bivariate analysis were considered during the process of multiple logistic regression in two models, in order to assess the independent predictors on the 20% highest Hb response of valid cases (merely maternal educational level and HH cash income were included even though not matching a p<0.25).

The following 11 covariates were enclosed in the initial model (for the dependent variable $Hb_{diff1st/3rd \geq 1.8g/dl}$): children´s age, sex, average number of days affected by respiratory disease assessed by 5-weeks morbidity questionnaire, maternal educational level, HH cash income, intervention group, ethnicity (categorical variables), as well as WHZ at baseline, Hb concentrations at baseline, count of food groups consumed the day before the interview at baseline assessment, delivery number/birth order of study child (continuous variables).

The following 12 covariates were enclosed in the initial model (for the dependent variable $Hb_{diff1st/4th \geq 1.7g/dl}$): children´s age, sex, maternal educational level, HH cash income, intervention group, any land cultivation, ethnicity (categorical variables), as well as age of the main caretaker, Hb concentrations at baseline, delivery number/birth order of study child, average number of days affected by any morbidity (fever, cold/cough, diarrhea) assessed during the 5-weeks morbidity questionnaire, average number of days mother and child sit together while eating (continuous variables).

All continuous covariates were assessed for interactions with their logit (log odds), and all relationships were found to be linear (Box-Tidwell Test), further the initial model was assessed for the presence of multi-collinearity [51], and fitness to the data was proofed by the Hosmer-Lemeshow´s goodness-of-fit test.

Variables with a p-value below 0.05 assessed during forward regression were declared to be significantly associated with the dependent variable Hb increase$\geq$1.8/1.7g/dl at 3rd, and 4th assessment, respectively.

Predictors of the highest percentile of Hb increases occurred between baseline and 3rd assessment were: low baseline Hb concentrations, and a diversified diet at baseline, as well as to be amongst the first-borns in a family. Considering the highest percentile of Hb increases occurred between baseline and endline assessment: then again low baseline Hb concentrations, were a distinct predictor for high increases in Hb, but also the availability of a higher HH cash income was associated with higher increases in Hb over time. The affiliation to any of the study groups was not shown to be significantly associated with the highest Hb increases occurred during the intervention period.

Table 4: Ratio of odds of Hb response accounting for Hb$_{Diff}$$\geq$1.8g/dl (3rd vs. 1st assessment), (n=44/195, 22.6% prevalence), 11 covariates included in the intitial model, 83.1% of cases were correctly predicted.

Model A: Forward Wald	Beta	S.E.	Odds ratio Exp(B)	95% C.I.	p-value
Hemoglobin concentraions at baseline (g/dl)	-1.334	0.257	0.264	0.159, 0.436	0.000
Count of food groups consumed during previous 24h at baseline	0.616	0.183	1.851	1.293, 2.650	0.001
Delivery number/birth order of study child	-0.560	0.278	0.571	0.331, 0.985	0.044

Levels of significance *p<0.05; **p<0.01; ***p<0.001.

Table 5: Ratio of odds of Hb response accounting for Hb$_{Diff}$$\geq$1.7g/dl (4th vs. 1st assessment), (n=46/218, 21.1% prevalence), 12 covariates included in the initial model, 83.5% of cases were correctly predicted.

Model B: Forward Wald	Beta	S.E.	Odds ratio Exp(B)	95% C.I.	p-value
Hemoglobin concentrations at baseline (g/dl)	-2.013	0.315	0.134	0.072, 0.248	0.000
Cash income (two groups)	0.916	0.435	2.498	1.066, 5.857	0.035

Levels of significance *p<0.05; **p<0.01; ***p<0.001. *Note:* exclusion of serial No 65 (IG1) in model B (as standardized residual |z|>3SD in the preliminary model [52], and Box-Tidwell test turned significant). Without exclusion of outliers,

merely baseline hemoglobin concentrations were assessed as significant predictor for the highest percentile of Hb increases between 1st and 4th assessment.

In Supplementary Material 5 the mean hemoglobin changes occurred between the respective assessment points are presented by baseline anemia status. To conclude, children with no/mild anemia at baseline (n=50) experienced significant lower mean increases in Hb than children suffering from moderate anemia at baseline.

General linear model to ascertain the intervention effect on Hb adjusted for significant confounders

Additionally an univariate general linear model was performed, in order to ascertain the effect of the intervention on Hb concentrations at 2nd, 3rd and 4th assessment, respectively, adjusted for selected confounders. Similarly, the 1st assessment was investigated for comparability of groups adjusted for the same confounders (except baseline Hb concentrations, time period in months between respective assessment points).

First the correlation coefficient for a set of covariates, was assessed by Pearson or Spearman at each assessment. Then those covariates correlating with a p<0.25 were further considered in linear Forward regression models to ascertain significant confounders at each assessment point on the dependent variable Hb concentration. Hereby age and Hb concentrations at baseline were the two covariates significant to all models, thus were selected for designing GLM with the variable intervention group as fixed factor, and the respective Hb concentration at each assessment as dependent variable. Additional covariates considered as relevant for adjustment were gender, as well as time in months between assessment points. The intervention effect on investigated dependent variables (Hb concentrations) was validated by significant differences for any of the intervention groups versa the control group (p<0.05), according to LSD. Altogether three GLM resulted: GLM A2, A3, A4 (comparison of Hb concentrations at 2nd, 3rd, 4th assessment, respectively across intervention groups toward CG) (Supplementary Material 6).

GLM A2, A3, A4 reveal significant higher mean Hb concentrations for IG1 as opposed to the CG, at 2nd (p=0.029), 3rd (p=0.006), and endline (p=0.040, after exclusion of standardized residual |z|>3SD [52]) assessment, adjusted for age and Hb at baseline, time in months between assessment points, gender. When including all valid cases at 4th assessment, no significant differences between any study groups were detected.

Unadjusted and adjusted means of Hb concentrations are presented in **Table 6** (outlier considerations are contained herein). At baseline assessment the unadjusted/adjusted Hb concentrations of IG3 significantly differed from IG1 (p=0.028/0.016), and from CG (p=0.037/0.004), respectively, assessed by LSD post-hoc test. When considering the pairwise comparison of intervention groups versa control group (unadjusted/adjusted), then IG1 had significantly higher Hb concentrations at 2nd (p=0.024/0.029), 3rd (p=0.006/0.006), and 4th assessment (p=0.046/0.040), as opposed to the CG.

Table 6: Inter-group comparison of mean Hb concentrations (g/dl) at respective assessment points by GLM. Mean Hb concentrations by study group.

Assessment points	Total (n=254)	IG1 (n=64)	IG2 (n=58)	IG3 (n=67)	CG (n=65)
Hb measurement		Mean, 95% C.I.	Mean, 95% C.I.	Mean, 95% C.I.	Mean, 95% C.I.
1st Assessment Hb (g/dl)	9.29 (9.16, 9.43)	9.47 (9.20, 9.75)[a]	9.19 (8.89, 9.49)[a,b]	9.06 (8.82, 9.31)[b]	9.45 (9.20, 9.70)[a]
adjusted	9.30 (9.18, 9.42)	9.42 (9.18, 9.67)[a]	9.25 (8.99, 9.50)[a,b]	9.01 (8.77, 9.24)[b]	9.51 (9.27, 9.75)[a]
2nd Assessment Hb (g/dl)	9.72 (9.57, 9.87)	10.10 (9.77, 10.43)[a]	9.48 (9.16, 9.80)[b]	9.65 (9.37, 9.94)[b]	9.62 (9.34, 9.89)[b]
adjusted	9.71 (9.60, 9.83)	9.96 (9.73, 10.20)[a]	9.57 (9.32, 9.81)[b]	9.73 (9.50, 9.96)[a,b]	9.59 (9.36, 9.83)[b]
3rd Assessment Hb (g/dl)	10.12 (9.97, 10.26)	10.50 (10.19, 10.80)[a]	10.03 (9.73, 10.34)[b]	9.99 (9.73, 10.26)[b]	9.94 (9.67, 10.21)[b]
adjusted	10.12 (10.00, 10.24)	10.39 (10.16, 10.63)[a]	10.08 (9.83, 10.34)[a,b]	10.06 (9.82, 10.30)[a,b]	9.93 (9.69, 10.16)[b]
4th Assessment Hb (g/dl)	10.03 (9.89, 10.16)	10.27 (10.00, 10.55)[a]	10.00 (9.71, 10.28)[a,b]	9.94 (9.71, 10.17)[a,b]	9.90 (9.62, 10.18)[b]
adjusted	10.03 (9.91, 10.15)	10.20 (9.95, 10.44)[a]	10.08 (9.83, 10.34)[a,b]	10.00 (9.76, 10.24)[a,b]	9.83 (9.59, 10.08)[b]

Note: all results are reported as means (95% confidence interval). Differing superscript letters indicate statistical significant differences (p<0.05) between study groups assessed by GLM, post-hoc tests according to least significant difference (LSD) (unadjusted, adjusted).

Adjusted for: age (months) at baseline and gender (male=1) (1st assessment), age (months) and hemoglobin concentrations (g/dl) at baseline, time between baseline and investigated assessment point (months), gender (male=1) (2nd, 3rd, 4th assessment), respectively.

Outlier considerations for the above presented unadjusted/adjusted means: **1st Assessment (n=253):** exclusion of Serial No 48 (IG1) as z-residual of |z|>3SD. Before as well as after outlier exclusion residuals normally distributed, and same study groups showed significant difference in pairwise comparison (unadjusted, adjusted model). **2nd and 3rd Assessment (n=254):** residuals normally distributed and no z-residual of |z|>3SD. Note: 3rd assessment: pairwise comparison in adjusted model revealed significant difference between IG1 vs. CG (p=0.006), and IG1 vs. IG3 (p=0.051, marginal significant). **4th Assessment (n=252):** exclusion of serial No 106 (IG1), 216 (IG3) as z-residual of |z|>3SD. Before as well as after outlier exclusion residuals normally distributed. Before outlier exclusion pairwise comparison found no significant differences between any study groups concerning unadjusted/adjusted mean Hb concentrations.

GLM, post-hoc test for adjusted model according to Bonferroni (adjustment for multiple comparisons): all pairwise comparisons non-significant (p>0.05), except 1st Assessment: IG3 vs. CG (p=0.024), 3rd Assessment: IG1 vs. CG (p=0.039).

In Table 7 the unadjusted/adjusted means of occurred changes in Hb over time are presented and in Supplementary Material 7 the respective GLM.

Table 7 Inter-group comparison of mean Hb changes (g/dl) occurred between indicated assessment points by GLM. Mean Hb changes by study group.

Mean Hb change occurred within indicated assessment period	Total (n=254)	IG1 (n=64)	IG2 (n=58)	IG3 (n=67)	CG (n=65)
		Mean, 95% C.I.	Mean, 95% C.I.	Mean, 95% C.I.	Mean, 95% C.I.
2nd_1st Hb change (g/dl)	0.412 (0.280, 0.544)	0.588 (0.354, 0.821)[a]	0.290 (-0.016, 0.595)[a,b]	0.588 (0.319, 0.857)[a]	0.168 (-0.086, 0.422)[b]
adjusted	0.409 (0.293, 0.525)	0.659 (0.425, 0.893)[a]	0.264 (0.019, 0.508)[b]	0.424 (0.194, 0.653)[a,b]	0.290 (0.057, 0.522)[b]
3rd_1st Hb change (g/dl)	0.811 (0.669, 0.954)	0.986 (0.727, 1.245)[a]	0.840 (0.497, 1.182)[a,b]	0.930 (0.644, 1.216)[a]	0.491 (0.228, 0.753)[b]
adjusted	0.812 (0.693, 0.930)	1.090 (0.852, 1.327)[a]	0.780 (0.529, 1.031)[a,b]	0.755 (0.519, 0.992)[a,b]	0.622 (0.385, 0.859)[b]
4th_1st Hb change (g/dl)	0.716 (0.564, 0.869)	0.733 (0.449, 1.017)[a,b]	0.807 (0.463, 1.150)[a,b]	0.885 (0.586, 1.183)[a]	0.448 (0.140, 0.755)[b]
adjusted	0.719 (0.598, 0.841)	0.887 (0.643, 1.132)[a]	0.772 (0.517, 1.027)[a,b]	0.692 (0.450, 0.934)[a,b]	0.525 (0.280, 0.770)[b]

Note: all results are reported as means (95% confidence interval). Differing superscript letters indicate statistical significant differences (p<0.05) between study groups assessed by GLM, post-hoc tests according to least significant difference (LSD) (unadjusted, adjusted).

Adjusted for: age at baseline (months), hemoglobin concentrations (g/dl) at baseline, time between respective assessment points (months), gender (male=1).

*Outlier considerations for the above presented unadjusted/adjusted means: **2nd 1st assessment period (n=254):** residuals normally distributed and no z-residual of |z|>3SD. **3rd 1st assessment period (n=254):** residuals normally*

*distributed and no z-residual of |z|>3SD. Note: 3rd1st assessment: pairwise comparison in adjusted model revealed significant difference between IG1 vs. CG (p=0.006), and IG1 vs. IG3 (p=0.051, marginal significant). **4th1st assessment period (n=252):** exclusion of serial No 106 (IG1), 216 (IG3) as z-residual of |z|>3SD. Before as well as after outlier exclusion residuals normally distributed. Before outlier exclusion pairwise comparison found no significant differences between any study groups concerning unadjusted/adjusted mean Hb changes.*

GLM, post-hoc test for adjusted model according to Bonferroni (adjustment for multiple comparisons): all pairwise comparisons non-significant (p>0.05), except 3rd1st assessment period: IG1 vs. CG (p=0.039).

In Figure 6 the adjusted mean changes in Hb over time are depicted.

ANCOVA with repeated measurements (n=251, with age as covariate) showed: the within-subjects effects -considering overall Hb concentrations from baseline, 2nd, 3rd, to endline assessment; to be significantly different within IG1 (p<0.001, =0.110, f=0.352), IG3 (p<0.001, =0.111, f=0.353), CG (p<0.024, =0.048, f=0.225), whereas for IG2 the intra-group comparison of Hb concentrations over time did not differ significantly (p=0.119, =0.119, f=0.193). The within-group pairwise comparison of baseline versa 3rd or endline (4th) assessment, respectively, was found invariably significant for all study groups with p<0.001, merely in case of 1st versa 4th for CG with p=0.005. The decline in mean Hb concentrations between 3rd and endline assessment was found non-significant for all study groups.

On the basis of estimates for age-adjusted means reflecting the total intervention period: 10.06 g/dl (IG1), 9.73 (IG2), 9.61 (IG3), 9.80 (CG) the pairwise between-group comparison proved IG1 to be superior toward IG2 (p=0.026), or IG3 (p=0.001), however with the IG1 versa CG comparison remaining non-significant (p=0.072). The in this section described analysis via ANCOVA with repeated measurements is based on the exclusion of standardized residuals of |z|>3SD (serial No: 048 (IG1), 106 (IG1), 216 (IG3)).

Figure 6 Adjusted mean changes in Hb concentrations occurred over time, per study group (covariates age and Hb at baseline, time between baseline and investigated assessment point, gender).

General linear model to ascertain the intervention effect on HAZ, WAZ, WHZ adjusted for baseline age and baseline z-scores for stunting, underweight, wasting, respectively

The GLM was performed for the z-scores at 2nd, 3rd, endline assessment controlled for age (months) and z-scores at baseline, time in months between baseline and investigated assessment point, as well as gender, respectively. The unadjusted/adjusted means are presented in Supplementary Material 8, Supplementary Material 9, Supplementary Material 10 (outlier considerations are contained herein).

For adjusted HAZ (including all valid cases) merely at endline (4th) assessment a significant effect has been assessed with IG3 achieving best mean scores amongst all study groups and being found significantly superior to IG2 (p=0.018).

With the exclusion of outliers -standardized residual |z|>3SD (serial No: 051 (IG1), 163 (IG2), 349 (CG)) this superiority remained (p=0.026).

For adjusted WAZ at the 2nd assessment -only after exclusion of outliers (serial No: 202 (IG2), 349 (CG), 378 (CG), 424 (CG), 439 (CG)); significant higher z-scores were assessed for IG3 versa CG (p=0.049). At 3rd assessment IG3 was found superior toward CG (p=0.043), and IG2 was assessed to be significantly inferior toward IG3 (p=0.024); after the exclusion of outliers (serial No: 069 (IG1), 349 (CG), 439 (CG)) these differences in mean adjusted WAZ-scores increased in significance (IG3 vs. CG (p=0.005), IG2 vs. IG3 (p=0.014)); and additionally IG1 versa CG (p=0.044) turned significant.

For adjusted WHZ-scores at 3rd assessment IG3 was sigificantly better than CG (p=0.026), this superiority increased after excluding outliers (serial No: 439 (CG)) (p=0.010). At 4th assessment IG2 achieved significant better WHZ-scores than IG3 (p=0.024), this superiority increased after exclusion of outliers (serial No: 051 (IG1), 327 (IG3), 379 (CG)) (p=0.004).

To conclude, tendencies revealed by the LSD post-hoc test for the adjusted model showed: IG3 to be significant better in scores for WAZ at 2nd, 3rd assessement and for WHZ at 3rd assessment as opposed to the CG, and showed best development amongst all study groups in overall HAZ scores. IG3 showed superiority toward IG2 at 3rd assessment (WAZ) and at endline (HAZ). IG2 failed to show significant higher z-scores as opposed to the CG, however at endline assessment IG2 had the best scores for WHZ amongst all study groups and significantly higher than IG3 (which experienced unexpected decreases in WAZ/WHZ scores at endline). IG1 showed similar positive trends concerning WAZ scores as IG3, being equally superior to CG at 3rd checkup.

The Bonferroni post-hoc test for the adjusted model confirmed IG3 being superior to CG at 3rd assessment for WAZ (p=0.029), WHZ (p=0.059, marginal significant). Moreover at endline IG2 was found superior toward IG3 (p=0.027) in WHZ scores (IG3 experienced excessive faltering at endline), but remained comparable to CG (subtext Supplementary Material 8, Supplementary Material 9, Supplementary Material 10).

The adjusted mean z-score changes occurred, were highest for WHZ, followed by WAZ, with HAZ showing the slightest changes over time. It is observed that stunting scores show reziprocal curve processing to WAZ or WHZ (Figure 7, Figure 8, Figure 9). Moreover clear effects on season are palpable determining growth patterns.

Figure 7 Adjusted mean changes in HAZ scores occurred over time, per study group (covariates age and HAZ scores at baseline, time between baseline and investigated assessment point, gender).

Figure 8 Adjusted mean changes in WAZ scores occurred over time, per study group (covariates age and WAZ scores at baseline, time between baseline and investigated assessment point, gender).

Figure 9 Adjusted mean changes in WHZ scores occurred over time, per study group (covariates age and WHZ scores at baseline, time between baseline and investigated assessment point, gender).

Size of feeding center

The participants per feeding center ranged from 7 to 29 children. No significant correlation between number of participants and Hb increases between different assessment points could be detected. Also the increases in Hb over time between centers with less than 20 children versa centers with 20 or more children were found similar. Altogether this finding indicates the size of feeding center having no influence on program delivery. Size of feeding center, attendance or consumption rates were not considered during regression models as being variables not applicable to the CG.

Attendance and portion sizes consumed

The primary objective of this research was to determine the effect of diversified meals in the scope of community nutrition programs on the nutritional, hematological and health status of study children. The analysis followed an intention-to-treat approach investigating all participants according to their allocation status to the intervention, whether they received it or not. Thereby the non-compliance and treatment changes that are likely to occur in practice are considered, without the risk of attrition bias [53]. Still, the attendance was recorded to validate the program. Hereby, the respective four weeks before each follow-up assessment (2nd, 3rd, endline) were analyzed to picture the attendance rate and consumption rate of the three half-yearly intervention periods (IP) (compare **Figure 1**). Thereby, each analyzed attendance period consists of 12 supplementary feeding program days, as the program was conducted three times per week. Consequently a total of 36 feedings were analyzed to estimate the attendance and consumption rates over the total study period of 18 months. The attendance rate is expressed in percent of possible feeding days, and the consumption rate as percent of the age-dependent portion size served. Additionally the attendance rate (but not consumption rate) was analyzed for the total 78 weeks (18 months).

The overall attendance rate in the periods IP1-3 (36 feedings) for total IG was 81.5%, and the overall consumption rate 90.8% ranging from no consumption up to 141% of the reference portion. The attendance rate over the total intervention period of 78 weeks accounted for 80.3% for total IG. Throughout all IPs and for the overall study period IP1-3, IG2 had the lowest consumption rates amongst all study groups. Significant differences were detected for IG1 having higher consumption rates than IG2 at IP1 (102.3% versa 85.4%) and IP3 (85.7% versa 82.3%), respectively. For attendance rates no significant differences were detected across the study groups.

Boys and girls had similar attendance rates at the program (81.9% versa 80.9%), however the average consumption rate assessed was significantly higher for boys (94.2% versa 85.8%) (p=0.017).

Correlation of attendance and hemoglobin

The Spearman correlation between attendance rates over the three IPs with the Hb concentrations at the 2nd, 3rd, 4th assessment, respectively, as well as of the 78 weeks attendance rate with Hb at the 4th assessment showed no

significant association. Similarly, when testing for associations between changes occurred in Hb (during 1st/3rd and 1st/4th assessment, respectively) and attendance rates, adjusted for consumption rates, no significant association was found. However when testing for the effect of attendance rates during all three IPs at once (36 feeding days) on Hb concentrations at the 4th assessment, and controlling for consumption rates, then a negative association was detected (r= -0.155, p=0.034).

Correlation of portion size and hemoglobin

Correlations between portion size and Hb concentrations at the 2nd, 3rd, 4th assessment, respectively, showed no significant association, with or without adjustment for attendance rates. Similarly, when testing for the effect of consumption rates during all three IPs at once (36 feeding days) on Hb at the 4th assessment, and controlling for attendance rates, merely a marginal positive association was detected (r=0.143, p=0.050). However, when testing for the association of the occurred changes in Hb concentration (during 1st/3rd assessment, and 1st/4th assessment, respectively) and consumption rates, then a slight association was found for the changes occurred in Hb (1st/3rd assessment) and portion sizes consumed (r=0.154*, p=0.034), the significance increased after adjusting for attendance rates (r=0.169, p=0.020). None of the tested associations between the changes in Hb (1st/4th assessment) and consumption rates proofed to be significant.

Morbidity throughout the study period and assessed by morbidity questionnaire

The morbidity analysis concerning fever or diarrhea prevalence revealed no significant differences between the study groups at 1st, 2nd, 3rd assessment point, respectively. Merely the prevalence of respiratory infections (comparable across groups at baseline) was significantly different between the study groups at 2nd (p=0.006), and 3rd (p=0.002) assessment (Figure 6), respectively. Baseline data ([24]) revealed the morbidity prevalence (fever, respiratory infections, diarrhea) to be highly age-dependent, with children aged 12 to 23 months being most vulnerable to morbidity, with continuous decline thereafter. As the age distribution was comparable across study groups, the observed higher decreases in the prevalence of respiratory infections (from 69.7% to 33.3%) for IG3 may be related to the higher zinc intakes amongst beneficiaries of this intervention arm. Similarly, comparing all study groups IG3 showed the highest decreases in fever prevalence (from 27.3% to 6.1%) or diarrhea rates (19.7% to 7.6%) between the 1st to the 3rd assessment. By comparing 1st versa 3rd assessment, effects of season are considered. In general, no clear trends related to seasonality were visible, probably due to the confounding factor age. Yet, for respiratory infections and diarrhea prevalence some flattening or even positive slope of the line could be observed between the 2nd and 3rd assessment, indicating the winter season having increased the rates of infectious diseases in this study. The trend of fever rates however showed a continuous decrease for all study groups across all assessment points.

Figure 10 **Prevalence of morbidity across different assessment points by study group**

Discussion

Problem statement

The recommended iron densities of complementary foods (CF) for infants 12-23 months are 1.6 and 0.8mg/100kcal assuming low and average bioavailability, for 6-11 months these densities rank invariably higher (4.6-7.7mg/100kcal and 2.4-4mg/100kcal, respectively) [54]. The iron provided in IG1 accounted for an iron density of 0.86mg iron per 100kcal, and for IG2/IG3 2.33mg iron per 100kcal, respectively. Iron and zinc are considered to be the limiting nutrients in family nutrition in developing countries. Recommended intakes of iron and to a lesser extent of zinc are still unlikely to be provided by improved traditional CF in the first year of life, when portion size is limited and iron gap is biggest. During a child´s first year of life, growth and therewith blood creation is particular high in the child, so are iron needs [55]; [56]. The special iron needs of children under age two get palpable by the increased prevalence of anemia among children aged 6 to 23 months as elaborated by Kotecha based on the data of the Indian NFHS-3, and similarly confirmed by baseline data of the current trial [24]. Kotecha suggests low-birth weights infants, premature infants, and infants of mothers with anemia to require additional iron from two months of age on, otherwise iron stores remain insufficient and iron demands for rapid growth are not met [57]. Ruel et al. concluded that the densities for iron and zinc in traditional complementary recipes in resource-constraint environments remain highly inadequate for children younger than one year, even after inclusion of locally available fortified corn-soy blend (CSB) and optimal combination of locally available, acceptable and affordable foods. An overall challenge remains for targeted beneficiaries to meet appropriate infant feeding practices by adequate nutrient density, consistency and texture, as well as frequency of feeding [58].

In the current study mothers were informed that the feeding program has a supplementary purpose to enhance child´s nutrient intake, still at endline assessment of 189 mothers the majority (74.1%) reported that the meal offered at the nutrition program replaced a meal at home, with one mother stating that only due to the rare attendance of her child (due to disliking the ALP/MLP taste) the meal did not replace a meal at home, and merely 25.4% indicated that the meal supplemented the dietary routine of the child. The reason for meal replacement (n=137), was "the time of nutrition program was the same time when child would receive food at home anyway" (89.8%), thus "children had full stomach after program, could not eat extra food at home" (2.2%), or "because other family members can eat more at home, if one child eats outside" (8.0%). The hosting of the nutrition program in the late afternoon was intentionally chosen, in order that caretakers may be free after work to bring their child to the nutrition program. Still, observations showed children were frequently accompanied by older siblings or even came alone to the program. Altogether the practice of replacing a meal at home is likely to have diminished the possible effect of the low-dose feeding trial. Still, the locally produced supplementary meals were composed of affordable and available ingredients, thus constitute a sustainable complementary food option to be adapted by caregivers after closure of the feeding program. Accordingly, at endline assessment of 188 mothers, more than every fourth (28.2%) indicated that they have modified their cooking behavior at home -inspired by the nutrition program. Of these 53 mothers, 32.1% improved their hygienic behavior (proper cleaning of utensils, intensified washing of vegetables, using food cover, serving spoon), and 83.0% changed composition of their diet (add more vegetables/leafy vegetables, started to use or to add more Amaranthus/Moringa leaves, use more frequently egg or soybean). 157 mothers indicated reasons for not having changed anything or problems faced when trying to change something (no money (70.1%), husband did not like a change (40.1%), mother felt unable to change something (8.3%), time constraints (1.9%), and 55.5% of cases stated they felt no need to change anything e.g. as home food is perceived to be of very good quality). To conclude economic as well as social limitations stand out as main reasons; combined with lack of awareness of the need for modifications.

The Copenhagen Consensus 2008 concluded that nutrition-focused interventions (micronutrient supplementation, fortification as well as community-based nutrition promotion) generate highest economic returns [59], thus are of priority when advancing the well-being of people in developing countries.

The WHO recommends a daily dose of 10-12.5mg elemental iron amongst infants aged 6 to 23 months when the prevalence of anemia is 40% or higher [60]. The absolute absorption efficiency depends on intestinal factors (host-related factors), individual´s iron status or infection state (systemic factors), the dose and form of iron compounds and absorption modifiers consumed with the food vehicle (diet-related factors) [34].

Food synergies in diversified study meals

Food synergy is considered as a key to healthy diet with food components deemed „to act in concert on health" implying additive effects, this means the whole is more than the sum of its parts. Food consists of a biological complexity developed under evolutionary control, that cannot be imitated by single nutrients. The focus on isolated nutrients in nutrition research may be counterproductive and less-beneficial [61], thus this study investigates the effect of diversified meals only (IG1), and either enriched with whole-food leaf powder (IG2) or an adjusted amount of industrially synthesized isolated micronutrients (IG3). Between IG2 and IG3 no significant differences in Hb concentrations at different assessment points were observed (**Table 6**, Table 7).

The bioavailability of iron is increased by small amounts of animal-protein "meat factor", or by ascorbic acid [62]. The latter however may experience substantial losses during storage or preparation, in particular in the presence of oxygen, metals, humidity and/or high temperatures if the food is not appropriately packaged or the vitamin C not encapsulated [63].

Proteins from other food sources in particular eggs, milk and dairy products (especially casein) inhibit iron absorption. Serum ferritin was reported to be positively associated with flesh foods intake and negatively related to dairy product consumption [34]. Still, in the current trial iron absorption may be equally impaired by the egg or milk proteins across all study groups, as the only variation is the ALP/MLP (IG2) or adjusted amount of TopNutri (IG3).

Zinc and iron were found to show competitive interactions, similarly calcium may have an acute inhibitory effect on iron absorption [34]. The adverse effect is dependent on the calcium amount administered rather than the Ca:Fe molar ratio [64]. Negative effects have been shown with the addition of 165mg calcium from milk products [65]. The maximum inhibitory effect is suggested to be achieved at calcium doses of 300mg (77% inhibition) in a meal, but already starts at 40mg (39% inhibition) [64]. Still, reported negative effects of calcium on iron absorption are predominantly assessed in single-meal studies; whereas multiple-meal studies -embracing a huge amount of other inhibitors and promoters, suggest calcium to have merely a limited effect [65]. Moreover it remains uncertain if the observed adverse effects are due to the increased calcium or rather related to inhibitory milk proteins of dairy products commonly applied as primary source of calcium in single-meal studies [64]. The calcium content per 100g Halwa including half egg/Khechuri was highest for IG3 (148.1mg/117.4mg), followed by IG2 (119.8mg/88.8mg), with IG1 providing lowest calcium amounts (70.8mg/40.1mg). Thus, a potential inhibitory effect of calcium on iron absorption is conceivable with the decrease in absorption rate to be considered highest for IG3.

Measuring the molar ratio of phytate/minerals in the diet predicts bioavailability of minerals in the body. Phytate (PA):mineral molar ratios (PA:Fe, PA:Zn, PA:Ca, Ca*PA/Zn, Ca:P, Oxalate:Ca, Zn:Fe) were calculated based on the Indian Food Composition [66] and Annex 1 for the study recipes (results not shown). Hereby, for PA:Fe the critical ratio of 1:1 - as suggested by Hurrel for plain cereal or legume-based meals [67], has been exceeded by all study groups. For an exemplified serving size of 100g, the highest PA:Fe ratio was assessed for diversified study meals only (IG1, PA:Fe ratio: 3.97, 2.96), followed by diversified meals plus ALP/MLP (IG2, PA:Fe ratio: 1.41, 1.35), with diversified meals plus an adjusted amount of TopNutri (IG3, PA:Fe ratio: 1.37, 1.31) having the lowest ratio for Halwa including half egg/Khechuri, respectively. Moreover for IG3 the Ca*PA/Zn ratio highly exceeded the critical value of 0.5, -as suggested by Ferguson [68], with 8.98 and 9.47 for Halwa including half egg and Khechuri, respectively. The latter indicates that calcium may influence zinc absorption for IG3.

Foods considered as being high in PA are defined to contain >400mg PA/100g food [69]. Yet, the dose-dependent inhibitory effect of phytate on iron absorption is reported to start at low concentrations of 10mg/meal [70]. The PA contents of all study meals were <65mg/100g serving size of Halwa/Khechuri. According to Hurrel [67], [71] for composite meals, containing ascorbic acid from vegetables or meat as enhancers, a PA:Fe ratio of 6:1 may be acceptable. Thus, the PA content in the current study meals may not be a major inhibitory factor.

The benefits and limitations of food-based approaches for combating iron-deficiency and malnutrition by dietary diversification are discussed in detail by reports of the FAO [15], [72]. Evaluations of the efficacy of multi-sectoral approaches for dietary diversification is challenging and remains inconclusive, due to the complexity of holistic food-based strategies, the variety of nutritional components contained in food, large number of confounders and difficulties for study design in regard to short-term and long-term effects. Food-based approaches for dietary diversification focus on food and livelihood-based models (e.g. home gardening and crop-diversification, the increased availability and consumption of animal-sourced foods, education and training, access to sanitary facilities, social services and health care), thereby strive for prevention and sustainability.

In the current trial altogether diversified meals alone (IG1) were found to have most effectively increased the Hb concentrations as opposed to the CG at 2nd, 3rd, and endline assessment. Leaf-powder enriched meals (IG2), or meals with an adjusted amount of MNP showed no superior effect toward the CG. The superiority of IG1 vs. CG in regard to Hb concentrations was also affirmed by the conservative Bonferroni-post-hoc test at 3rd assessment (subtext **Table 6**, Table 7). Concerning growth indices the effect of IG1 appears less conclusive. At 3rd assessment IG1 showed superiority toward CG concerning WAZ scores. Moreover IG1 showed highest mean time investment in caring activities, and at home mothers were sitting next to their child during eating on significant more days during a five-week assessment as compared to the other study groups (**Table 2**). This increased caring may promote increased food ingestion in the child, thus may positively contribute to anemia reduction or growth development in this study.

Leaf powder and bioavailability studies

Moringa oleifera is especially promoted due to its satisfying iron content. Gallaher et al [73] investigated the iron bioavailability of dried Moringa leaf powder (MLP) (0.5% dry weight basis diet) in rats, and came to the conclusion that

the high phytic acid content of the leaves implies not only a low bioavailability of iron from the Moringa supplement itself but also inhibits the absorption of iron provided from the general diet. Rats receiving commercial animal feed and MLP at 10%, experienced significant lower increases in Hb and weight as compared to another experimental group being fed MLP at 5% [74].

Equally, researches of the University of Pretoria [75], [76] concluded that the in vitro iron and zinc bioaccessibility of adding MLP in the weight amount of 5% to a standardized pearl millet porridge (dry weight basis) was superior to the adding of 15% of Moringa with regard to the fulfillment of physiological reference intake levels. As compared to other dried food-to-food fortifications e.g. hibiscus leaves, baobab fruit pulp, mango-carrot premix; MLP resulted in the lowest increases of iron and zinc accessibility attributable to the high calcium, phenolic, phytic and organic acid content. MLP increased (due to its high iron content) but also decreased bioaccessibilies, altogether a negative impact on the bioaccessibility of the porridge itself has to be considered due to the high levels of iron and zinc inhibitors. All studies used a realistic single-meal food matrix, which suggests that there is no amplified impact on iron absorption as it may be in studies utilizing isolated plant products. Still, it has to be noted that studies on single-meals versa whole diets tend to exaggerate the effect of nutrient interactions involving iron absorption [34]. In the current trial the applied overall leaf powder dose of ALP/MLP was rather low accounting for 3% in total (wet weight basis of overall served study meal), and in regard to MLP 1%. Without cooking water and not considering the served egg, fortification levels rank at maximum double. Still, a theoretical low dosage of <1%-5% MLP could exceed the critical amount according to investigations by Gallaher et al [73], however still may be an enrichment according to considerations of Merwe et al. [75] as outlined above. Tessera et al. [77] reported the bioavailability of iron to be highest for 5% MLP blending while zinc and calcium were found to be well available in blending up to 20% MLP with wheat flour on the basis of molar ratios of minerals and antinutrients.

According to analysis by the LA Chemie University of Hohenheim the phytate contents in dried ALP/MLP were <0.05%, thus not exactly detectable. According to the Indian Food Composition Table [66] fresh Amaranthus leaves contain less phytic acid than fresh Moringa leaves e.g. (4.89mg/100g vs. 128mg/100g). Other analysis published revealed phytic acid contents accounting for 234mg in 100g of Amaranthus leaf powder [78]; or ranging from 0.265mg [18] to 2100mg [79] in 100g of dried Moringa leaves (**Supplementary Material 1**).

In the current trial the mean adjusted Hb concentrations assessed in IG2 showed no significant differences toward the CG across all assessment points (**Table 6**, Table 7). Moreover IG2 was slightly worse than the CG and significantly inferior to IG1 concerning Hb concentrations at 2nd assessment (**Table 6**) or in regard to the Hb changes occurred between baseline and 2nd assessment (Table 7), possibly attributable to antinutrients (phytic acid, polyphenols, oxalate) or nutrient-to-nutrient interactions. Still, at the 3rd and endline assessment IG2 remained comparable to all intervention groups.

Similarly, in regard to adjusted means of growth indices (HAZ, WAZ, WHZ); IG2 failed to show significant differences as opposed to the CG. Concerning adjusted HAZ scores IG2 was significantly inferior to IG3 at endline, and showed most poor changes in scores over time amongst all study groups (Figure 7). For adjusted WAZ-scores IG2 was found significantly inferior to IG3 at 3rd assessment. In regard to adjusted WHZ scores at endline the highest scores were found for IG2 (lowest WHZ prevalence), moreover IG2 showed significant better WHZ scores than IG3 at endline, also confirmed by the conservative Bonferroni-post-hoc test (subtext, Supplementary Material 10). It has to be noted that IG3 experienced excessive faltering in WHZ scores at endline, but showed the best performance at 3rd assessment

(Figure 9). The positive effect on reduction of wasting prevalence may be attributable to the holistic amino acid composition present in ALP/MLP (IG2) (**Supplementary Material 2**), and TopNutri (IG3) equally containing high quality protein (amino acid score of 100 [80]).

IG2 showed lowest consumption rates throughout the trial as compared to the other intervention groups, significantly inferior to IG1 during IP1 and IP3. Similarly mothers were significantly less sitting next to their child during eating at home, in IG2 versa IG1 (**Table 2**). Altogether the lower consumption rates during the program and less attentive eating athmosphere at home, may have negatively affected the reduction in anemia rates or growth development.

Acceptability of MLP and left-over rate of distributed portions

The feasibility and acceptability of using dried Moringa leaves as nutrition supplement was rated to be high by several studies. In India, a pilot study on children aged 1-5 years over one month found the adding of 5-7g leaf powder /100g food as well accepted. A maximum left-over of 30% of distributed portion size was reported, equally observed in the control group consuming regular recipes [81]. Similarly Boateng et al. 2017 reported the daily MLP-supplementation of 5g MLP sprinkled over usual foods or incorporated in a 35g cereal-legume blend (15% fortification, dry weight) to be well-accepted in Ghanian infants aged 8-12 months, with a daily left-over rate of 13.8% or 28.5%, respectively during a 14-day period [82]. Boateng et al. [83] reviewed common MLP fortification levels applied in complementary food blends ranging from 1 to 25 %, with the authors´ recommendation of acceptable MLP fortification levels being 1 to 15 % (the minimum amount of MLP to significantly improve nutritional value was estimated with 10%). In the current trial the general acceptability of ALP/MLP application was perceived as good among children (as no child was recorded to reject the food -probably due to the young age). Few caretakers however seemed more critical towards the greenish color and uncommon "leafy" taste. Moreover the belief/fear that Moringa may decrease the blood pressure in a harmful way guides the skepticism amongst Adivasis (as being named in the baseline survey by 10 out of 43 caretakers as reason for not consuming Moringa at home). The lowest rate of consumption was assessed for IG2, possibly an indirect consequence of caretaker´s influence on the feeding process or directly on child´s appetite due to discomfort in taste. Few pregnant women (also entitled to participate in the nutrition program) mentioned to suffer from nausea when smelling the ALP/MLP-enriched meal.

Nutrition intervention studies including the feeding of green leafy vegetables (GLV) amongst others different Amaranthus species

Studies on the consumption of GLV are diverse in their results. Nawiri et al. [84] provided 80g fresh/re-hydrated sun-dried cowpea and Amaranthus tricolor leaves to Kenian pre-school children over a period of 13 weeks (IG1/IG2, n=56/20, baseline Hb 11.5/11.6g/dl), versa fresh/re-hydrated sun-dried white cabbage (CG1/CG2, n=51/25, baseline Hb 12.4/12.3g/dl). A non-significant but positive intra-group pre-post increase for Hb concentrations in the IG (0.7/0.6g/dl) was reported, with CG showing no increases (-0.1/-0.1g/dl), (descriptive study analysis). Similarly Egbi et al. [85] (inferential study) supplemented Ghanian children aged 4 to 9 years (IG, n=53, baseline Hb 11.8g/dl; CG, n=51, baseline Hb 11.7g/dl) with beans/tomato stews and groundnut soup (CG) enriched with dried composite GLV powder including Amaranthus cruentes (IG) five times a week over a period of three months, and found a significant higher increase in Hb (0.43g/dl versa -0.35g/dl) as well as higher decrease in anemia prevalence (Hb<11.5g/dl) from 41.5% to 33.3% in IG versa 37.3% to 57.5% in CG, respectively.

Two other inferential studies however could not show a positive effect of GLV on Hb: Hoeven et al. [86] found no significant differences in Hb increases between IG (n=86, Hb baseline 12.8g/dl, Hb increase 0.3g/dl) and CG (n=81, Hb baseline 12.7g/dl, Hb increase 0.4g/dl) in school-children aged 6-12 years receiving a starchy school meal including either 300g cooked leafy vegetables with Amaranthus cruentes accounting for 80-100% of GLV, versa only small amounts of cabbage or a teaspoon legumes or meat/soya mince over a period of 62 school days. The authors conclude that the regular consumption of GLV showed no effect on micronutrient status (Hb, serum ferritin, serum zinc and serum retinol) in South African children with mild deficiencies. Pee et al. [87] investigated potential differences in the provision of dietary sources rich in carotene/retinol. Hereby either meals predominantly based on GLV including three Amaranthus types (IG1, n=45, baseline Hb 11.1g/dl) versa meals based on carotene-rich fruits (IG2, n=49, baseline Hb 11.1g/dl), retinol-rich foods (IG3, n=48, baseline Hb 11.1g/dl) or foods low in carotene or retinol (CG, n=46, baseline Hb 11.2g/dl) were fed to anemic school-children with two meals a day over a period of nine weeks in Indonesia. The subjects fed on GLV experienced the smallest increase in Hb (0.1g/dl) amongst all four study groups, which was significant lower as compared to IG2 (0.5g/dl) and IG3 (0.5g/dl) possibly attributable to the low bioavailability of non-haem iron.

The effectiveness of leaf concentrates in improving the human nutritional status has been reviewed by Davys et al. [72] relating to studies in the more distant past. Positive effects on height and weight development, Hb concentration, vitamin A status, and diminished morbidity were observed as opposed to control groups, however the statistical relevance has not been discussed in detail.

Nutrition intervention studies including the feeding of Moringa oleifera

Indigenous nutrient-rich plant sources like Moringa oleifera are increasingly discussed as potential sustainable solution to combat malnutrition in children [88], [89], [90], [91], [92], [93], [94], [95], [96], [97], [98], [99], [100], [101], [102]. Descriptive studies (intra-group comparisons) comment positively on MLP application as preventive or treatment approach however bear distinct limitations: Isingoma et al [99] reported the application of a fermented millet porridge with 7% MLP (IG, n=26, baseline Hb 9.6g/dl) to be comparable to F-100 (CG, n=25, baseline Hb 9.8g/dl) in the rehabilitation of SAM children aged 7 to 36 months, Uganda. By reaching discharge criteria after 5 to 7 days children achieved significant increases in Hb of 0.6g/dl (IG) versa 0.2g/dl (CG), respectively. The wasting z-scores similarly improved by a comparable rate of 1.4 versa 0.9 within the study groups. Srikanth et al [100] successfully treated Indian children suffering from protein energy malnutrition grade (PEM) I or II (aged < 5 years), with the application of 30g MLP added to child´s daily diet (n=30) over a study duration of two months. There was a trend of higher weight gains for children of the IG as compared to the CG (n=30), however no report on compliance (mothers were in charge to administer the MLP to their children), nor a description of daily diet in the CG. Asante et al [102] reported an Hb increase of 0.9g/dl (baseline Hb 9.3 g/dl) after application of 15g MLP (IG, n=25) over a study period of four weeks, however neither baseline Hb concentrations nor increases observed in the CG (F-100, n=10) were presented. During the rehabilitation of Ghanian children (aged 6 to 36 months and suffering from PEM), there was a clear trend of higher weight increases for IG, with the authors of the study concluding MLP to have the potential to significantly contribute to the management of malnutrition. Nnam et al [101] conducted a study in Nigeria on children aged 6 to 12 months (unclear inclusion/exclusion criteria, baseline Hb 10.7g/dl in IG/CG, respectively) over a period of four weeks. Children in the IG (n=20) received a fermented maize porridge with MLP (3.67mg iron/day), with the CG (n=20) receiving the same porridge without MLP. Merely for the IG significant increases in Hb (2.3g/dl) as well as serum ferritin (26.2µg/l) could be observed, with zero increase in CG, respectively.

Two inferential studies (inter-group comparisons) commented positively on the effects of MLP application on Hb: Andrew [88] fed a with 25g MLP enriched maize porridge (IG, n=64, baseline Hb 7.4g/dl) to SAM children aged 6 to 24 months attending nutrition rehabilitation in Tanzania over a period of three months. A significant higher Hb increase was observed for IG (4.1g/dl) as opposed to CG (0.2g/dl) (n=76, baseline Hb 7.1g/dl). Similarly gains in weight, MUAC (cm), WAZ and WHZ were significantly higher in IG versa CG. Moreover a reduction on diarrhea prevalence from 13% at baseline to 1.4% at endline assessment was reported for IG.

Saturnin et al. [94] provided 10g MLP/d (IG, n=44, baseline Hb 10.3g/dl) to moderately acute malnourished (MAM) children which was applied to usual diet of the 6 to 30 months old children in Benin. A significant higher increase in Hb of 1.6g/dl was assessed for IG as compared to CG (-0.6g/dl) (n=40, baseline Hb 10.4g/dl) after six months.

A range of other inferential studies showed no significant increases in Hb in IG versa CG: in a study in Burkina Faso conducted by Zongo et al [98] the addition of 10g MLP/d to standard care diet (IG, n=52, baseline Hb 9.7g/dl) was efficient to increase weight gains but not Hb concentrations (-0.1g/dl (IG) versa -1.0g/dl (CG)) when compared to CG (n=58, baseline Hb 10.5g/dl). Hereby the admission period for SAM children aged 6 to 59 months accounted for an average of 36 days (IG) and 57 days (CG) due to significant higher weight gains in IG (8.9g/kg/d) versa CG (5.7 g/kg/d), respectively. Another trial by Zongo et al [97] conducted in Burkina Faso on pre-school children aged 12 to 59 months was ineffective in changing the nutritional status (HAZ, WHZ) by applying 30g MLP over the day for 12 weeks (IG n=60, CG n=59). A study on the Philippines conducted by Serafico et al. [96] found no significant effects of snack foods enriched with 3g MLP on Hb, weight or height after 120 days in 8 to 10 year old underweight school children (mean baseline Hb of 12.5g/dl for IG n=61/CG n=60, respectively). Similarly, in a trial by Menasria et al [95] (assigning its subjects during analysis in the categories "actual intervention received" and "non-compliers", thus not following the intention-to-treat approach), the application of 16g MLP over six months showed no significant effects on Hb, Ferritin, HAZ or WHZ in Cambodian children aged 6 to 23 months as opposed to the CG (baseline Hb 10.1g/dl, n=39 (IG) versa 9.9g/dl, n=79 (CG)). Hb increases accounted for 0.5g/dl (IG) and 0.4g/dl (CG). Equally a study by Glover-Amengor et al [93] found no significant increase in Hb in Ghanian school children aged 5 to 12 years by applying 2.4g up to 5.1g MLP (depending on body weight) along with study meals three times a week over nine weeks as compared to CG (baseline Hb 10.6g/dl for IG n=69/CG n=76, respectively). Another trial conducted in Ghana by Boateng et al [92] failed to show significant effects of a daily dose of 5g MLP – either as part of cereal-legume blend (IG1, n=80) or as a supplement sprinkled on infant´s usual home-based diet (IG2, n=74), on Hb concentrations or growth indicators of children aged 8 to 12 months after a total trial period of 16 weeks (baseline Hb n.a.) as compared to CG (n=83) receiving the cereal-legume blend without enrichments. Also Perlas et al [90] could not proof any significant increases in Hb, serum ferritin, weight or height as compared to the CG, after providing snacks enriched with 3g MLP on a daily basis over 120 days to Filipino school children (WAZ<-2SD) aged eight to ten years (baseline Hb 12.5g/dl for IG n=61/CG n=60, respectively). Lonati et al [91] concluded the application of 3 to 5g MLP (IG, n=88) to have no significant effects on the prevalence of anemia (Hb<11.5g/dl) in Cameroon school children aged 5 to 8 years as compared to placebo meal without MLP (CG, n=95). Merely the increase in height/HAZ was reported as significantly higher for IG than CG after 18 weeks.

Yet, there is no general agreement on an outstanding nutritional benefit of local plant sources in terms of preventing or treating malnutrition. Due to the inconsistency in the quality of human intervention studies it is difficult to come to a conclusive judgment.

Studies including supplementation of TopNutri and other micronutrient supplements

The bioavailability of nutrients from supplements/fortificants when taken along with a meal is affected by the same factors as those present in food, with the net effect depending on the ratio of promoters and inhibitors [34]. Among reviewed complementary food supplements by Pee et al. TopNutri provides the most complex mix of micronutrients along with high quality protein. TopNutri contains iron as ferric sodium ethylenediaminetetraacetate (NaFeEDTA) [103], which shows for food vehicles high in phytate a relative bioavailability of >100% (two to three times better absorbed) as compared to ferrous sulfate, with concurrent improvement of the iron, zinc and possibly copper absorption from foods [63], [104], [105]. Iron absorption from NaFeEDTA containing food products −unlike zinc, is reported not to be influenced by higher calcium levels [106]. The authors of the study assume the indicated 7.7mg iron/7.5g recommended dose TopNutri per day [80] to relate to the compound NaFeEDTA (no information available by the company), thus in the current trial the applied dose of 3.68g TopNutri/200g portion may provide 3.8mg NaFeEDTA ($\approx$0.5mg elemental iron [107]) The company GC Rieber Compact reviews TopNutri to have positive effects on stunting and underweight rates, to increase discharge rates of formerly severely malnourished children as compared to milk-based treatment, as well as to decrease anemia rates [108] from 63.8% to 17.6% in children aged 6 to 35 months with an increase in Hb of 1.3g/dl after four months of daily supplementation in a trial in Myanmar [109]. A small increase in iron status (reduction of soluble transferrin receptor), but no increase in Hb concentrations and similarly no decreased rates of anemia could be observed in a trial applying 2.5mg NaFeEDTA ($\approx$0.33mg elemental iron [107]) to women and children aged 6 to 59 months in a Kenyan refugee camp over a period of 13 months [110]. Similiarly, a South African trial on school children aimed to investigate the efficacy of a low-iron MNP containing 2.5mg NaFeEDTA, applied 5d/week for 23 weeks to a high-phytate maize porridge in the intervention group. Compared with the control, the MNP was effectively increasing serum ferritin, body iron stores, WHZ, and decreased transferrin receptor, also the prevalenc of iron deficiency fell significantly. However Hb concentrations and rates of anemia were not changed during the intervention [111]. Apart from the latter low-dose trials the effectiveness of MNP in increasing Hb is well investigated. Ying Yang Bao (2.5mg iron-EDTA, 5mg ferrous fumarate; $\approx$2mg elemental iron [28], [107])− a MNP similar to TopNutri, has been shown in a non-controlled trial to increase Hb of Chinese children aged 6 to 23 months by 0.9g/dl over a total period of 18 months [112]. A Cochrane database systematic review [113] including eight controlled trials (Ghana, Cambodia, India, Kyrgyz Republic, Haiti, Pakistan, Kenya) lasting two to twelve months, concluded home fortification with MNP (containing 12.5mg of iron as ferrous fumarate $\approx$ 4.2mg elemental iron [28], 5mg zinc, and 300µg of vitamin A) to be effective in improving haematological indices, and stated MNP to be possibly comparable to daily iron supplementation (as drops or syrups). All included trials applied at least 12.5mg ferrous fumarate on a daily basis. The review also relates to studies providing intermittend or flexible MNP allocation with a lower overall daily dose (e.g. 30mg ferrous fumarate per week [114]) which have been found to be as effective on haematological response. Hereby, Hyder et al. supplemented anemic Bangladeshi children aged 12 to 24 months with either 12.5mg iron daily versa 30mg weekly ($\approx$1.4mg/d elemental iron [28]) over 8 weeks, and reported no significant differences among the groups in the Hb increases occurred (16.1g/l versa 12.3g/l), respectively [114]. Reviewed studies significantly reduced anaemia on average by 31%, and iron deficiency by 51% as compared to no intervention or placebo in children aged 6 to 23 months. Thereby the decrease in anemia rates was equally effective in populations with different anemia prevalence, in all children aged 6 to 23 months, and independent of duration of intervention. In regard to Hb concentrations, six trials had a 5.87g/l higher mean Hb concentration at follow-up, as compared to studies with no treatment or placebo however with no obvious differences among subgroups. Two trials, that assessed effects on growth (HAZ, WAZ, WHZ), could not detect significant effects after six to twelve months of intervention, respectively. Effects on morbidity could not sufficiently be assessed, however in one trial there was a tendency of children supplemented with MNP to be more susceptible to diarrhea or recurrent respiratory infections during the first month of intervention, whilst another trial found upper respiratory infections to be similar in MNP group (7.6%) versa placebo group (6.5%) [113]. Similarly a

review including 13 studies on pre-school and school-age children found MNP to significantly reduce anemia and iron deficiency but concluded that effects on morbidity and mortality remain scarce, with no significant effects on diarrhea prevalence [115]. Hirve et al. stated sprinkles containing 12.5mg ferrous fumarate (≈4.2mg elemental iron [28]) to be similarly efficacious as compared to higher iron doses in sprinkles or drops in improving Hb in moderately anemic Indian children aged 6 to 18 months over a period of 8 weeks (mean Hb increase 1.5g/dl) [116]. The integration of MNP sprinkles in ICDS programs similarly has been found to effectively increase Hb concentrations and decrease rates of anemia from 50% to 33% in boys and from 47.4% to 34.2% in girls [27].

Findings in this trial are in conformity with studies reporting an increase in hemoglobin by MNP supplementation, however this increase was found for IG3 to be non-significant as compared to the control group.

Altogether, IG3 was not found to significantly increase Hb concentrations when compared to the CG (**Table 6**, Table 7). Still, IG3 remained comparable to IG1 and all other study groups throughout the intervention period. However in order to explain the lower increases in Hb or in other words the absence of the expected added value of IG3 toward IG1; probably unfavorable ratios of nutrients in the enriched supplementary meals may have had a negative impact on overall bioavailability. The risk of antagonistic interactions is deemed to be low in fortified diets, as micronutrients become chelated to dietary ligands during food digestion, implying an absorption by different pathways. Competitive interactions appear rather critical if amounts of micronutrient supplements are high and consumed without food [34]. Still, e.g. the calcium content may have possibly implied detrimental effects on iron absorption from total study meal in IG3 as outlined above. Interestingly, confirmed by the Bonferroni post-hoc test IG3 showed significant/marginal significant effects on WAZ and WHZ scores at 3rd assessment when compared to the CG. Moreover IG3 showed the best trends on reducing stunting prevalence (Supplementary Material 4), or concerning mean gains in HAZ-scores (Table 3, Figure 7). Moreover the LSD post-hoc test found IG3 superior to IG2 concerning better stunting z-scores at endline assessment (p=0.026) (Supplementary Material 8). This observation supports research that stresses the importance of an adequate supply of both, Type I and Type II nutrients for growth promotion, hereby TopNutri may provide the most holistic mix of isolated micronutrients [117]. Also for prevention or treatment of diarrhea or respiratory infections the higher zinc or vitamin A content provided may be conducive, still studies on the general application of industrial MNP remain controversial as recent studies even suggest an increased risk of diarrhea [118], [119] -probably attributable to iron promoting the growth of gastro-intestinal pathogens. The gut microbiome is increasingly discussed as crucial actor in the pathogenesis of intestinal imflammatory diseases negatively affecting iron availability [120]. Iron deficiency anemia was associated with microbiota dysbalance, and is discussed to impair the programming of infant´s physiologic systems with long-term host effects on metabolism and alteration of immunological response [121]. Moreover alterations in the mircobiome are reported to be implicated in childhood malnutrition in a mutually enhancing relationship [122]. The practical effects of interventions e.g. the current diversified study meals, on the gut microbiome need further investigation.

Predictors for the response size of hemoglobin increases

In this low-iron dose trial Hb concentrations at baseline were associated with age (baseline data previously published [24]), and over the intervention period children with lower Hb baseline values showed a better Hb response to the supplementary meals as compared to children with higher Hb baseline levels (**Table 4**, **Table 5**). Similarly, a study on

pre-school children in Zanzibar reported Hb at baseline to be strongly positively associated with age, and found Hb increases to be inversely related to baseline Hb concentrations after a low-dose iron treatment (10mg ferrous sulfate ≈ 2mg elemental iron [28]) for one year [123]. A trial on Bangladeshi children 6 to 12 months found a weekly supplementation of 20mg elemental iron ineffective to increase Hb concentrations in predominantly mildly anemic children, implying the conclusion that mild anemia may have other causes than iron deficiency [124], or requires higher iron doses. The current low-dose trial seems to be much more effective for treating moderate anemia than mild anemia. The decreases observed for children with baseline Hb≥11.0g/dl (Supplementary Material 5) have to be interpreted in consideration of the small number of children in this subsample, still the prevention of anemia seems to require more holistic approaches.

In this trial, equally an increased food group consumption at baseline was associated with higher increases in Hb during the trial (**Table 4**, **Table 5**), indicating that caretakers who practice a more diversified diet at baseline may be more likely to maintain this behavior throughout the trial or even to adopt new ideas of healthy diets possibly inspired by study meals.

Aside low Hb concentrations, and an increased dietary diversity at baseline, also to be among the first-borns in a family was associated with higher increases in Hb over intervention time. This increase may be not attributable to baseline Hb in this trial, as no clear association between baseline Hb and birth order was detectable. In contrast, birth order ≥2 was associated with poor growth and anemia in children aged 10 to 18 months, living in urban slums of Mumbai [125].

Moreover a cash income >5000 INR was associated with higher Hb increases over time, suggesting that a higher cash flow improves the nutritional outcomes for children early in life. This is in line with published evidence that household wealth status is associated with dietary diversity and nutritional status of Bangladeshi children [126], as well as with hemoglobin concentration of Bangladeshi women due to increased iron intake from animal sources [127].

Weight gain

No significant differences in weight gains across the study groups were found. At the endline assessment (after 548 days) the mean weight increase for total IG (2.7kg) (not presented) matched the observed weight gain for the CG (2.7kg) (Supplementary Material 3), being equal to a mean growth velocity of 0.52g/kg/d and 0.55g/kg/d, respectively. During nutrition rehabilitation a daily weight gain is suggested with 5g/kg/d to validate the treatment in children suffering from moderate acute malnutrition [128]. Jilcott et al. conducted a five weeks feeding trial with locally produced ready-to-use food (RUF) on moderately malnourished Ugandan children aged 6-59 months and reported a mean growth velocity of 2.5g/kg/d. The peanut-soybean porridge enriched with 13.5g MLP, provided 682kcal/d, if consumed as intended, however caretakers practiced dilution [129]. Moderately malnourished Malawian children aged 42 to 60 months gained on average 2.7g/kg/d, when being fed a maize/soy flour supplementation (500kcal/d) over 12 weeks [130]. Andrew achieved with a daily supplementation of a maize porridge either enriched with 25g MLP (IG) or served plain (CG) over three months, a weight gain of 2.96 g/kg/d versa 0.55g/kg/d in SAM children aged 6 to 24 months, respectively [88]. Purwestri et al. reported weight gains of mildly wasted Indonesian children (aged 6-59 months) in a ready-to-use food (RUF) rehabilitation program for 6 weeks with 3.1g/kg/bw (daily distribution of RUF-Nias biscuits with supervision of consumption for one-third of the daily portion) and 2.0g/kg/bw (weekly distribution of full ration of RUF-Nias biscuits and weekly compliance check) [131]. Scherbaum et al. found weight gains of

1.01g/kg/bw (peanut/milk-based spread), 1.76g/kg/bw (cereal/nut/legume-based biscuits (CNL-B)), 2.31g/kg/bw (CNL-B and intensive nutrition eduction) among moderately to mildy wasted Indonesian children in a daily feeding program for an average of treatment days of 25, 33, 30 days, respectively [132].

Therewith, the observed weight gain in our study is rather low, however is in line with other trials not achieving the proposed daily weight gain of 5g/kg/bw. Moreover the lower feeding frequency and long trial duration in the current study have to be taken into account.

Higher weight gains during the first year of life have been reported to have negative effects on iron status indices [133], [134] or to be not conducive to significant changes in Hb showing even negative correlation [98]. In contrast, findings of the current study suggest a positive association of weight gains and Hb changes (controlled for age and baseline Hb concentrations) at endline assessment (r=0.146, p=0.020).

Relationship between linear growth and wasting, as well as interrelations of nutritional status, morbidity, and seasonal change

At baseline assessment of this study, increasing age in the child was reflected in decreasing HAZ- and WAZ-scores (increasing prevalence), but increasing mean WHZ-scores [24]. This positive association of age with stunting, or negative association with wasting is also reflected in the worldwide timing of growth faltering [135].

Data by Helen Keller International on children 0-59 months showed acute malnutrition to highly vary by season in Bangladesh, with the highest peak occurring in August when rice storage is getting scarce [136]. Similarly Brown et al. reported greatest nutritional deficits during monsoon season persisting until subsequent harvest. Hereby the anthropometric indicator used to define malnutrition and detect seasonal change was important to be distinguished; i.e. in the discussed study on Bangladeshi children the highest prevalence of stunting occurred several months after the periods of greatest malnutrition identified by other indicators. Food availability and rate of infectious diseases are discussed as major determinants of children´s growth in less developed countries [137]. The multi-factorial etiology of the relationship between the acute and chronic form of undernutrition (wasting and stunting) is poorly understood. Repeated episodes of wasting are discussed to imply stunting, as periods of lowest weight acquisition are followed by periods of lowest linear growth. Linear growth is reported to merely occur when the body has a minimum of energy reserves, in other words when the weight-for-height is high. Wasting reflects a condition of depleted fat and muscle mass. Leptin –produced by fat tissue, stimulates bone density, catch-up growth and the immune system. Aside a lack of micronutrients –that are required for skeletal growth rather than growth of lean tissue [138], the reason how wasting leads to stunting may be partly explained by low fat stores, however the relation remains inconclusive [139], [140], [141]. Wasting was found predictive for stunting in a study on Gambian children, confirming stunting to be an adaptation process to undernutrition [142]. Birth weight and household wealth index are reported to be negatively related to both stunting and wasting. Other common predictors for stunting were low maternal height, low maternal BMI, low frequency of antenatal care visits, higher birth order, low maternal educational level, children of mothers without decision making power regarding food, lack of minimum meal frequency, no feeding of eggs, dairy products, fruits and/or vegetables, or the delayed introduction of complementary foods, increasing age of child, and households without access to improved sanitation [139], [143], [144], [145], [146]. Acute respiratory infection was predictive for underweight, whereas diarrhea was a major driver for stunting among Indian children below five years [147]. Hence,

multi-sectoral approaches have to be taken to avert underlying causes of stunting (child feeding, women´s nutrition, household sanitation), but also the distal and inter-generational drivers (adolescent marriage, women´s poor decision making power, low educational level, social exclusion and household poverty). South-Asia bears the highest global burden of child stunting (40%) [148]. Scaling-up the year-round food security by enhanced homestead food production programs already showed impact with reductions in stunting of 18% in Bangladesh [149]. Dewey reviews options for improved women´s and children´s diets and their positive impact on child growth. Still the linear growth response to improved nutrition remains heterogenous, highlighting the multi-factoral mechanisms of prenatal and post-natal growth restriction [150], also explaining why nutrition interventions alone are not necessarily implying a positive impact on growth.

Moreover rapid and simultaneous decrease in stunting and wasting rates may be challenging to achieve as any decline in stunting and underweight prevalence is commonly accompanied by a temporary increase or stagnancy in wasting [151].

Consistent with the above outlined considerations, in this study (Figure 7, Figure 8, Figure 9) underweight and wasting scores were found highest during baseline (t0), and 3rd assessment (t12) in Feb2015/16 (laggards measured in months Mar, Apr); and lowest scores were assessed at 2nd (t6), and endline assessment (t18) in Aug 2015/16 (laggards measured in months Sep, Oct), when rice storages are getting scarce close to the next harvest. Moreover during rainy season lasting from June to September, children may be more prone to infectious diseases [152], which is associated with additional nutrient requirements for the immune response. Infant feeding practices in South Asia have been shown to be highly inadequate during illness which contributes to a further deterioration of the nutritional status [153].

The prevalence of sickness at baseline was rated as high in this study as opposed to data of the NFHS-4 [24], with a perceived increase during winter season over the intervention period (Figure 10). Prevalences of sickness were invariably lower at 3rd assessment versa baseline, indicating a combined positive impact of intervention and increasing age over time on morbidity reduction in particular for IG3.

Correlation of attendance and hemoglobin

Although merely very weak correlations were detected between attendance rates throughout the study period and hemoglobin concentrations at endline assessment, the association of the effect of the attendance on the hemoglobin status of children was negative, suggesting an issue of reverse causality. Children deemed as more vulnerable by the caretakers were probably taken more often to the supplementary feeding program. The vulnerability may have been characterized by common signs of iron deficiency anemia like fatigue, pallor, or lassitude. This assumption is supported when allocating children according to their anemia status at baseline in two groups (no/mild versa moderate anemia) and considering mean rates of attendance during the 78 weeks. Children suffering from moderate anemia had a higher rate of program attendance than children with no/mild anemia (82.1% versa 75.2%), however this finding was not significant. Similarly children suffering from severe anemia were more likely to attend a feeding program in Burkina Faso, than children without severe anemia [154], altogether indicating that being more vulnerable is associated with higher attendance, and not vice versa. Reverse causality has also been suggested in other studies on breastfeeding and nutritional status, hereby mothers tended to breastfeed longer if their child was small and/or seemed to be ill [155], [156]. Besides frequent child´s illness may have implied increased program attendance. The

morbidity questionnaire revealed the number of days of cold/cough being associated with the attendance rates until 3rd (r=0.289**, p<0.001) and 4th assessment (r=0.292**, p<0.001).

Correlation of baseline hemoglobin concentrations or portion size with hemoglobin

The overall consumption rate over the three IPs showed a very weak positive correlation with the Hb at the 4th assessment after adjusting for attendance rates. Moreover a very weak association was detected between the Hb changes occurred during 1st to 3rd assessment and portion sizes consumed, adjusted for attendance. Both findings indicate the intervention having a positive effect on Hb. The Hb response (during $1^{st}/3^{rd}$ and $1^{st}/4^{th}$ assessment) proofed to be negatively associated (r= -0.459**, r= -0.539, p<0.001) with baseline Hb, respectively. Similarly, oral medicinal iron supplementation and lower baseline Hb concentrations were predictors of a greater Hb response in a systematic review of 55 controlled trials with iron supplementation interventions in children [157], or the number of micronutrient sachets consumed per week was associated with increases in Hb in a home-based fortification program of complementary foods [112].

Limitations

A general limitation to the study is the unknown exact amount of nutrient losses occurred on the way from market/storage, during cooking and finally to the plate, still a careful chain of action was adhered to. Lack of Hb response in individuals may be a consequence of multiple micronutrient deficiencies, and not limited to iron supply [158]. Variant types of anemia with different etiologies like thalassemia, sickle-cell anemia, could be a major confounding factor for the current study, which were not assessed in this research. In particular in countries where the pevalence of anemia exceeds 40%, the previously assumed anemia proportion of 50% amenable to iron deficiency [159] (42% of anemia in children and 50% of anemia in women [5]) might rank much lower e.g. suggested with 14% for pre-school children, and 16% for non-pregnant women in reproductive age [159]. A holistic clinical assessment (e.g. ferritin, transferrin saturation) would do better than Hb estimation alone, still HemoCue201+ remains the suitable method to the field to diagnose anemia. Moreover the re-examination of a race specific cut-off for mild anemia is discussed due to potential genetic determinants related to the heritability of Hb, partly explaining an unchanging high burden of anemia among Indian women [160]. Several studies assessed the distribution of Hb to be lower in black people [16]. Similarly anemia during infancy is suggested as common, thus lower cutoffs may be more representative to diagnose anemia in children aged 8 months [161].

Conclusion and recommendations

After adjusting for age, baseline Hb concentrations, time between assessment points, and gender; study findings suggest the application of diversified traditional diets (IG1) to be superior toward the enrichments of 3g leaf powder/100g meal in the ratio ALP 2:1 MLP (IG2) or a for the iron content of IG2 adjusted amount of industrial MNP (1.84g TopNutri/100g meal) (IG3), in significantly increasing Hb concentrations as compared to the CG analyzed by GLM LSD post-hoc test at 2nd, 3rd, and endline assessment (confirmed by Bonferroni post-hoc at 3rd assessment) (**Table 6**, Table 7). Still, at 3rd and endline assessment all intervention groups showed a tendency of higher increases in Hb as opposed to the CG, with IG2 and IG3 being comparable to IG1 but also to the CG indicating a positive impact of

all interventions on Hb concentrations (Figure 6). The diminished effect on Hb observed in IG2 and IG3 may be attributable to undesired nutrient interactions decreasing the bioavailability of the additionally enriched diets.

Adjusted for age, baseline z-scores, time between assessment points and gender; significant effects related to growth indices are less consistent (Supplementary Material 8, Supplementary Material 9, Supplementary Material 10). IG3 seemed to be most succeeding in improving growth indices (WAZ, WHZ) as opposed to the CG (confirmed by the conservative Bonferroni post-hoc test at 3rd checkup). Moreover IG3 showed as only intervention group tendencies of slight improvements in HAZ scores after one year of intervention (however without statistical relevance); as well as most efficiently reduced morbidity prevalence (in particular respiratory infection, but also fever and diarrhea rates).

Observed mean changes in Hb (Figure 4) have to be interpreted in relation to the low iron dose applied in this trial. Thus, the rather low increases in Hb over a long period of time are still deemed to be beneficial by the authors of this study, in particular when striving for sustainable solutions to combat anemia. The serving of a minimum of three diversified meals per week may be likely to be adopted by most caretakers on household level after nutrition counseling and interactive cooking trainings. Thus, diversified meals are a local possibility to decrease rates of anemia. Moreover to modify caregiver´s feeding practices and strengthen their resources for healthy meal preparation e.g. by maintaining kitchen garden programs which may be more cost-efficient as compared to hosting a long-term community feeding trial requiring extensive monitoring and being less appealing to caretaker´s own responsibility to make behavioral modifications. Still, for treatment of anemia therapeutic iron doses are recommended in the first line, as a rapid improvement in Hb concentrations is of priority for proper physical and mental development of the child, but still bears own limitations as outlined by the Indian National Iron Plus Initiative [162]. Moreover the enrichment with an adjusted amount of the MNP TopNutri (IG3) showed beneficial effects concerning growth indices, thus MNP may have to be considered as additional treatment approach for undernutrition. The absent effect on Hb and the inconsistency of IG3-effects on growth across different study assessment points has to be interpreted in relation to the applied dose (which was lower than recommended by GC Rieber Compact). Moreover some effects on e.g. HAZ scores which reflect the status of chronic undernutrition; need long-term interventions for improvement, thus the absence of significant effects on HAZ during the first year of study is not decisive. At endline for IG3 the beneficial impact of a holistic nutrient composition on improving stunting scores seems to slightly emerge, however without statistical relevance as opposed to the CG.

The Hb response was inversely related to baseline anemia status (Table 4, Table 5, Supplementary Material 5), suggesting low-dose trials to be most effective for treating moderate forms of anemia, with beneficial effects on mildly anemic children. For interpretation of the preventive effects of this trial on anemia the sample size was limited.

In order to alleviate micronutrient deficiencies a holistic food-based strategy – as suggested by Thompson and Amoroso [15], will embrace agricultural incentives to promote increased availability and consumption of diets composed of a variety of foods, nutrition education, implications for public health and disease control, as well as further enrichments through supplementation.

To conclude diversified supplementary meals of this trial (IG1) (dietary diversification) proofed to be a successful food-based approach to increase Hb concentrations in particular in moderately anemic Adivasi children. The enrichment of diversified diets with MNP (IG3) showed best effects on growth indices and reduction of morbidity prevalence amongst

all study groups. Yet, more research is needed to particularly investigate holistic approaches for sustainable treatment and prevention of anemia and undernutrition with locally available resources.

Declarations

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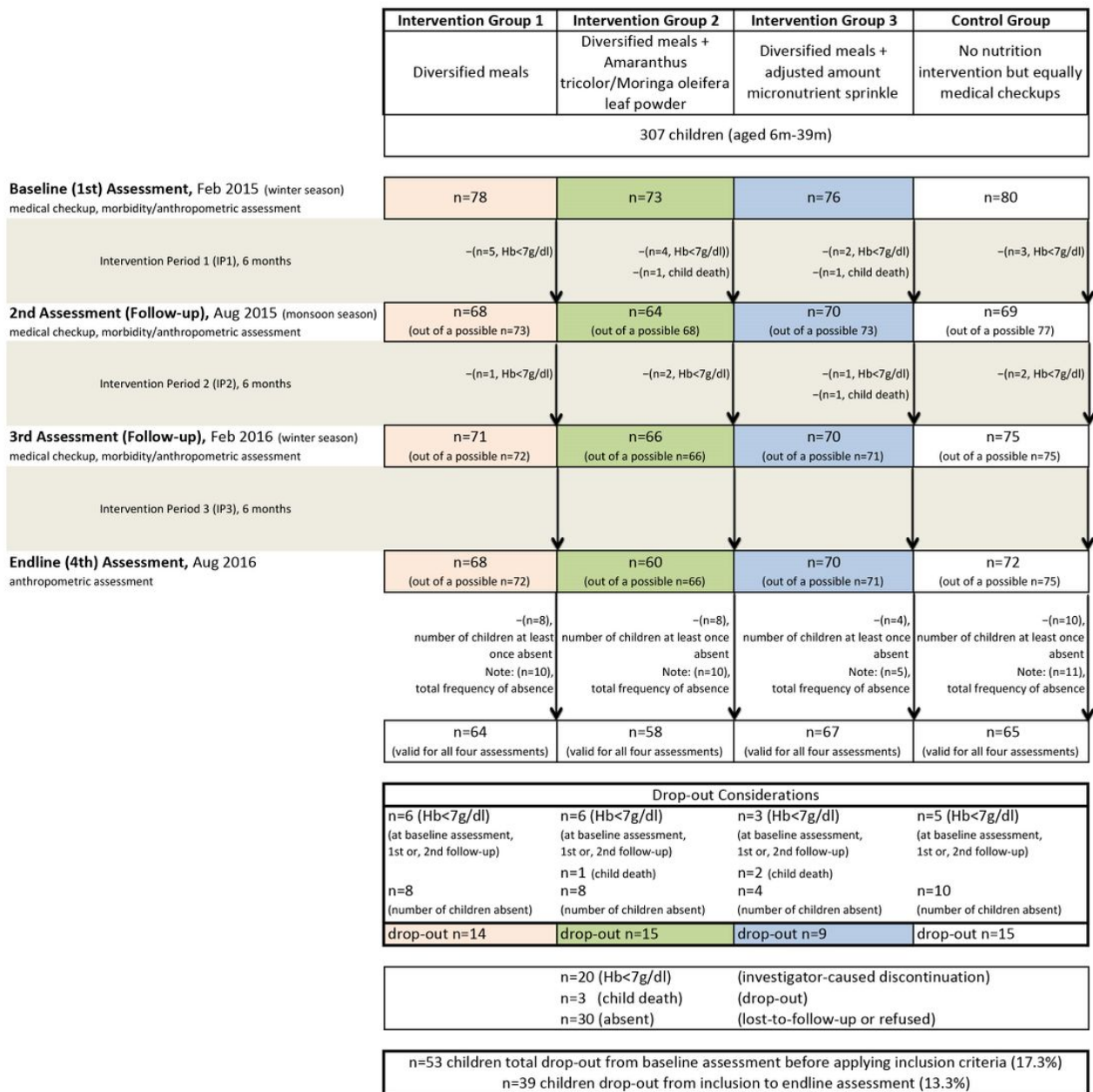
Figures

	Intervention Group 1	Intervention Group 2	Intervention Group 3	Control Group
	Diversified meals	Diversified meals + Amaranthus tricolor/Moringa oleifera leaf powder	Diversified meals + adjusted amount micronutrient sprinkle	No nutrition intervention but equally medical checkups
	307 children (aged 6m-39m)			

Baseline (1st) Assessment, Feb 2015 (winter season)
medical checkup, morbidity/anthropometric assessment

n=78	n=73	n=76	n=80

Intervention Period 1 (IP1), 6 months

–(n=5, Hb<7g/dl)	–(n=4, Hb<7g/dl))	–(n=2, Hb<7g/dl)	–(n=3, Hb<7g/dl)
	–(n=1, child death)	–(n=1, child death)	

2nd Assessment (Follow-up), Aug 2015 (monsoon season)
medical checkup, morbidity/anthropometric assessment

n=68	n=64	n=70	n=69
(out of a possible n=73)	(out of a possible 68)	(out of a possible 73)	(out of a possible 77)

Intervention Period 2 (IP2), 6 months

–(n=1, Hb<7g/dl)	–(n=2, Hb<7g/dl)	–(n=1, Hb<7g/dl)	–(n=2, Hb<7g/dl)
		–(n=1, child death)	

3rd Assessment (Follow-up), Feb 2016 (winter season)
medical checkup, morbidity/anthropometric assessment

n=71	n=66	n=70	n=75
(out of a possible n=72)	(out of a possible n=66)	(out of a possible n=71)	(out of a possible n=75)

Intervention Period 3 (IP3), 6 months

Endline (4th) Assessment, Aug 2016
anthropometric assessment

n=68	n=60	n=70	n=72
(out of a possible n=72)	(out of a possible n=66)	(out of a possible n=71)	(out of a possible n=75)

–(n=8), number of children at least once absent	–(n=8), number of children at least once absent	–(n=4), number of children at least once absent	–(n=10), number of children at least once absent
Note: (n=10), total frequency of absence	Note: (n=10), total frequency of absence	Note: (n=5), total frequency of absence	Note: (n=11), total frequency of absence

n=64	n=58	n=67	n=65
(valid for all four assessments)	(valid for all four assessments)	(valid for all four assessments)	(valid for all four assessments)

Drop-out Considerations

n=6 (Hb<7g/dl)	n=6 (Hb<7g/dl)	n=3 (Hb<7g/dl)	n=5 (Hb<7g/dl)
(at baseline assessment, 1st or, 2nd follow-up)	(at baseline assessment, 1st or, 2nd follow-up)	(at baseline assessment, 1st or, 2nd follow-up)	(at baseline assessment, 1st or, 2nd follow-up)
	n=1 (child death)	n=2 (child death)	
n=8	n=8	n=4	n=10
(number of children absent)	(number of children absent)	(number of children absent)	(number of children absent)
drop-out n=14	drop-out n=15	drop-out n=9	drop-out n=15

n=20 (Hb<7g/dl)	(investigator-caused discontinuation)
n=3 (child death)	(drop-out)
n=30 (absent)	(lost-to-follow-up or refused)

n=53 children total drop-out from baseline assessment before applying inclusion criteria (17.3%)
n=39 children drop-out from inclusion to endline assessment (13.3%)

Figure 1

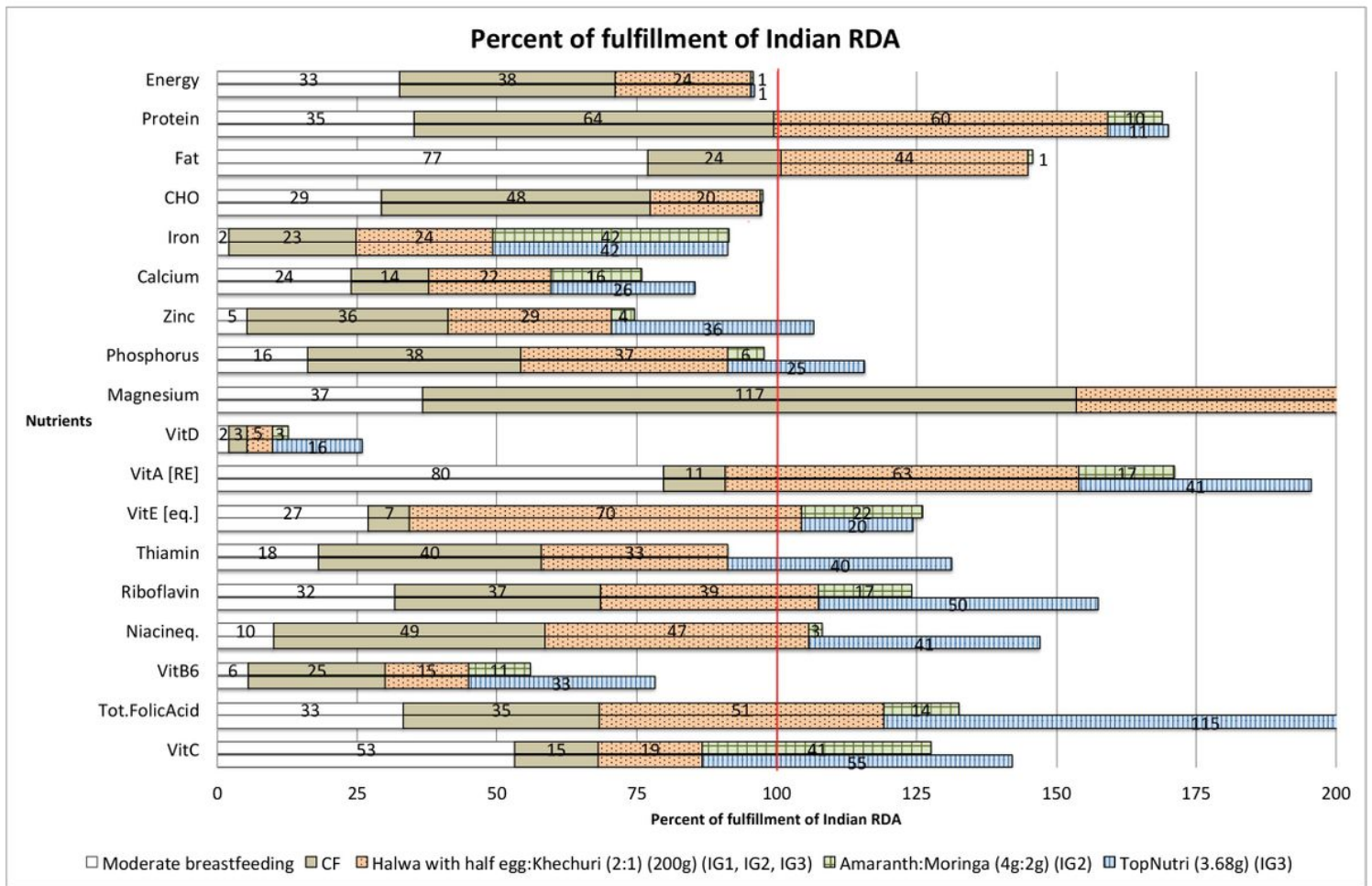Flow chart on enrolment, follow-up and drop-out in the trial

Figure 2

Percent of fulfillment of Indian RDA by assumed moderate frequency of breastfeeding, by complementary feeding (CF) over the day, as well as Halwa:Khechuri (2:1) supplemented with either Amaranthus:Moringa (2:1) leaf powder mixture or an adjusted amount of TopNutri.
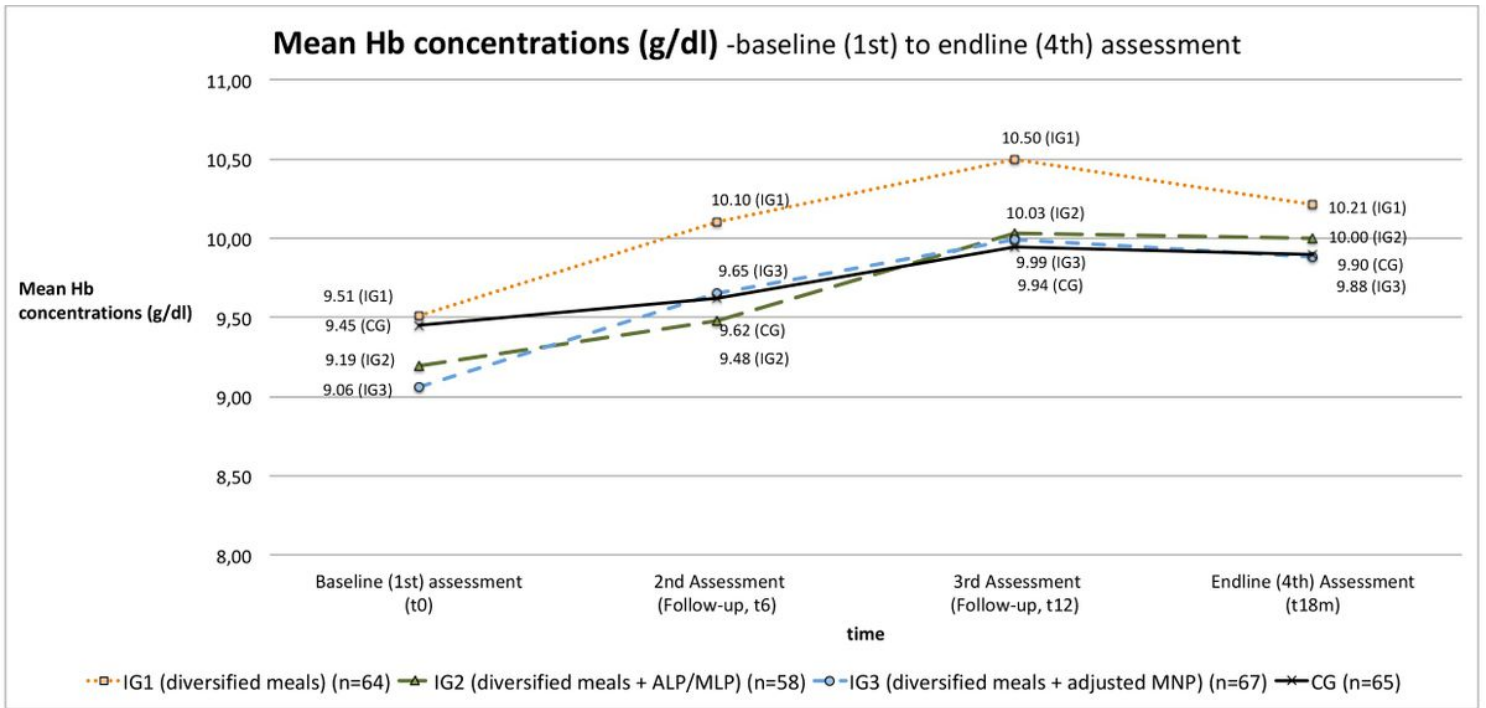
Figure 3

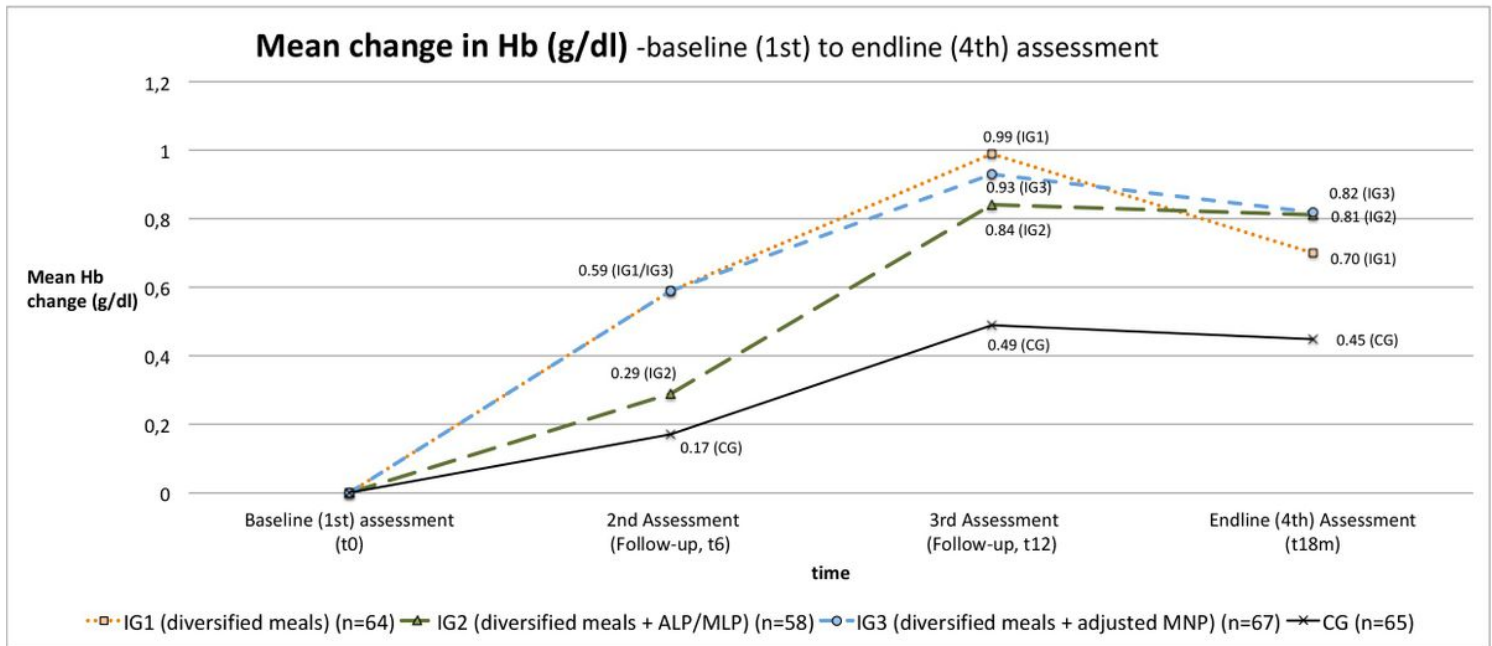Mean Hb concentrations at baseline, 2nd, 3rd, endline assessment (n=254), per study group.

Figure 4

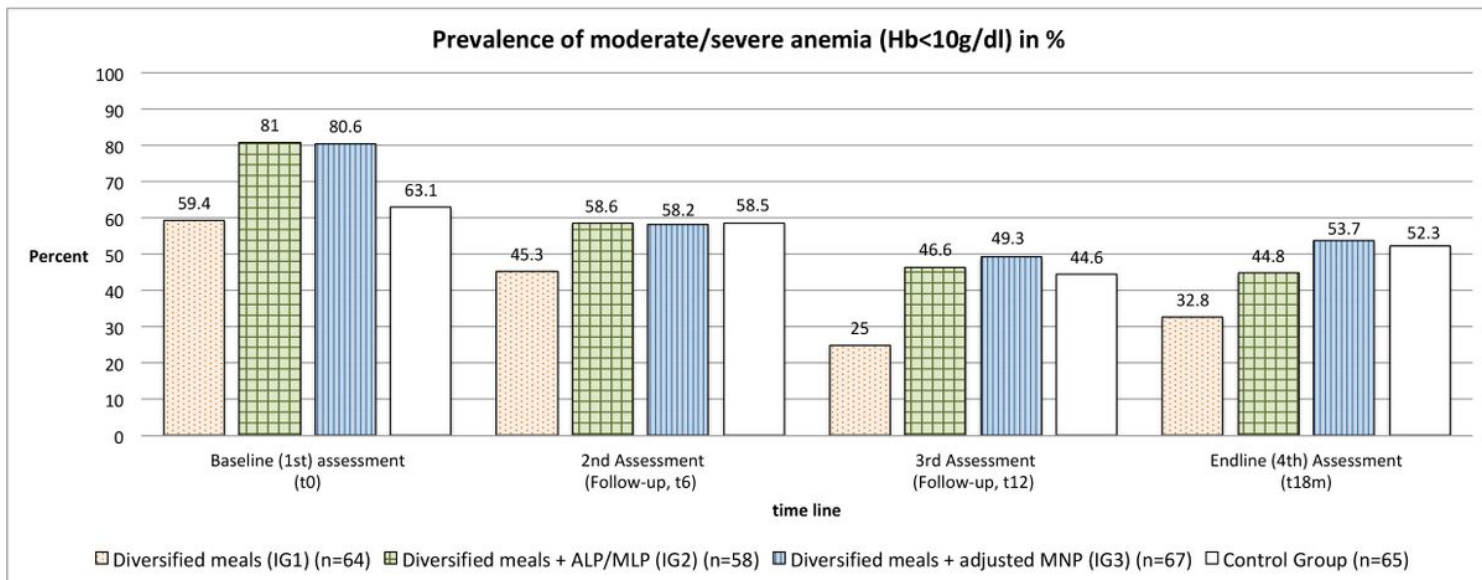Mean changes in Hb concentrations occurred over time (n=254), per study group.

Figure 5

Prevalence of moderate/severe anemia at different assessment points by study group
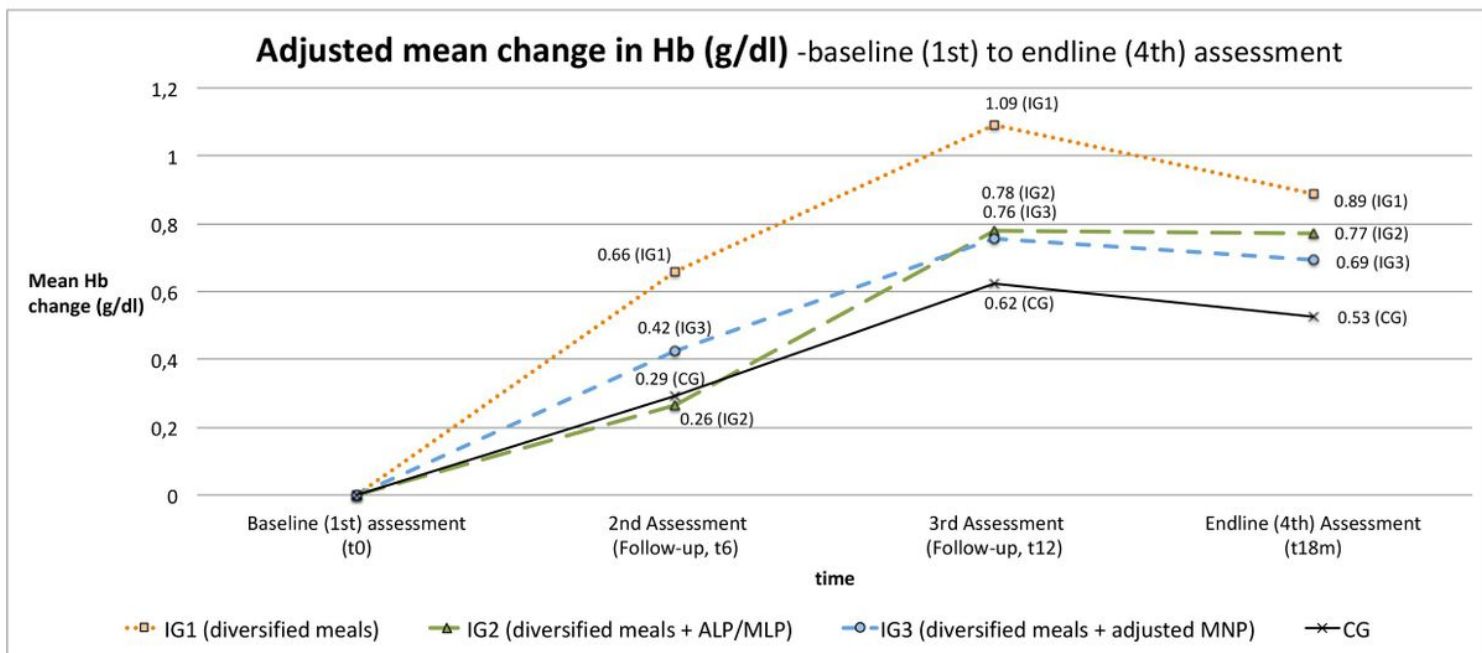
Figure 6

Adjusted mean changes in Hb concentrations occurred over time, per study group (covariates age and Hb at baseline, time between baseline and investigated assessment point, gender).
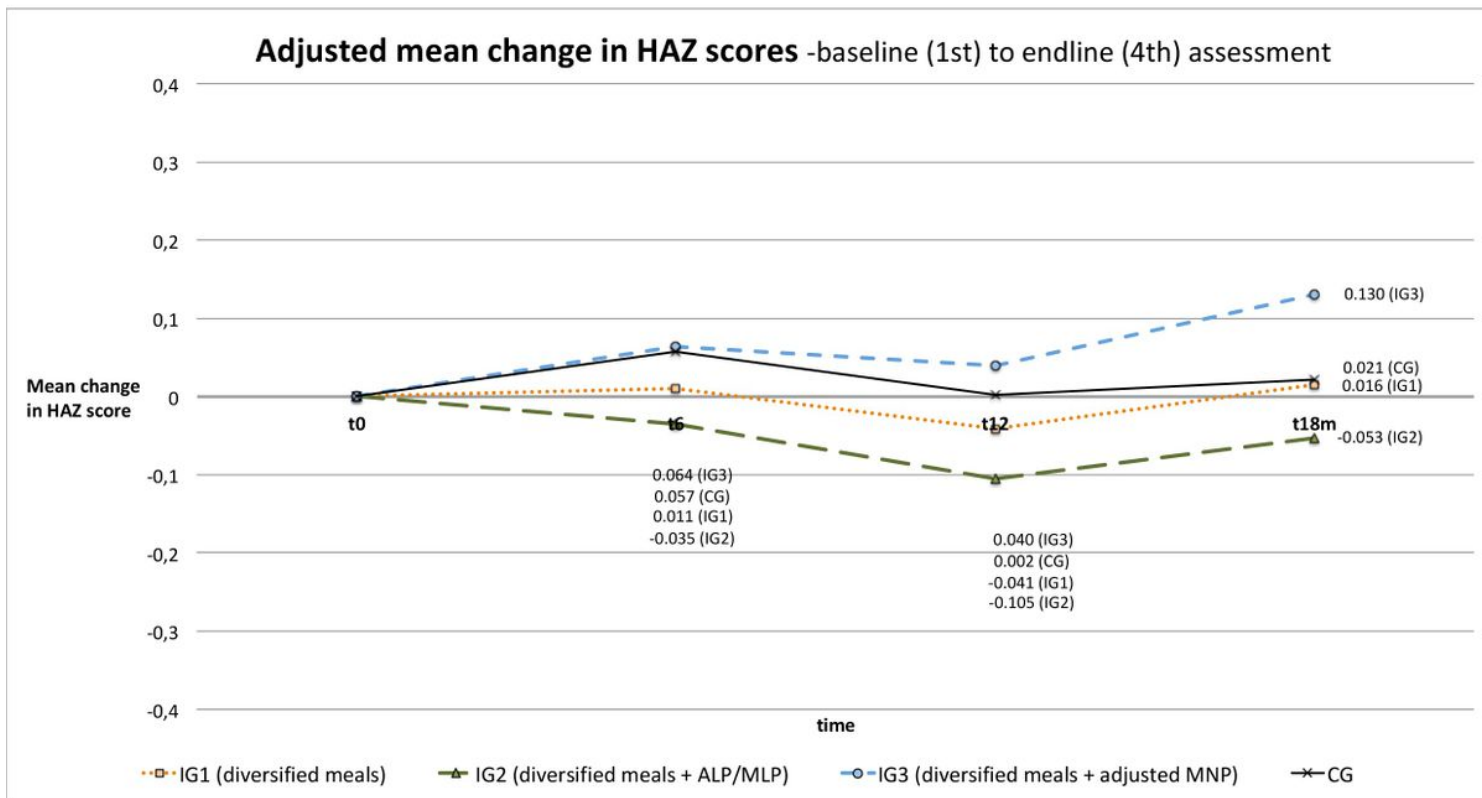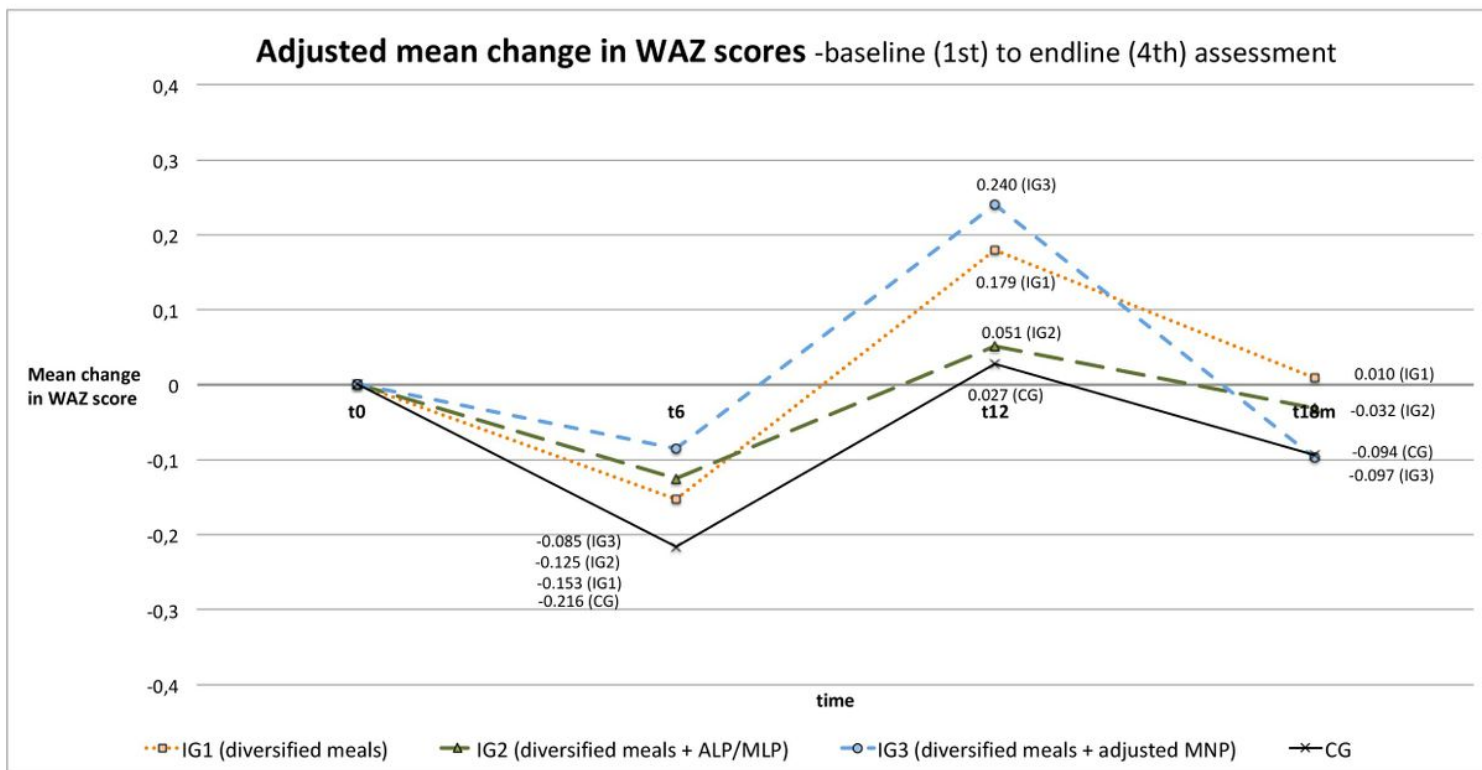
Figure 7

Adjusted mean changes in HAZ scores occurred over time, per study group (covariates age and HAZ scores at baseline, time between baseline and investigated assessment point, gender).
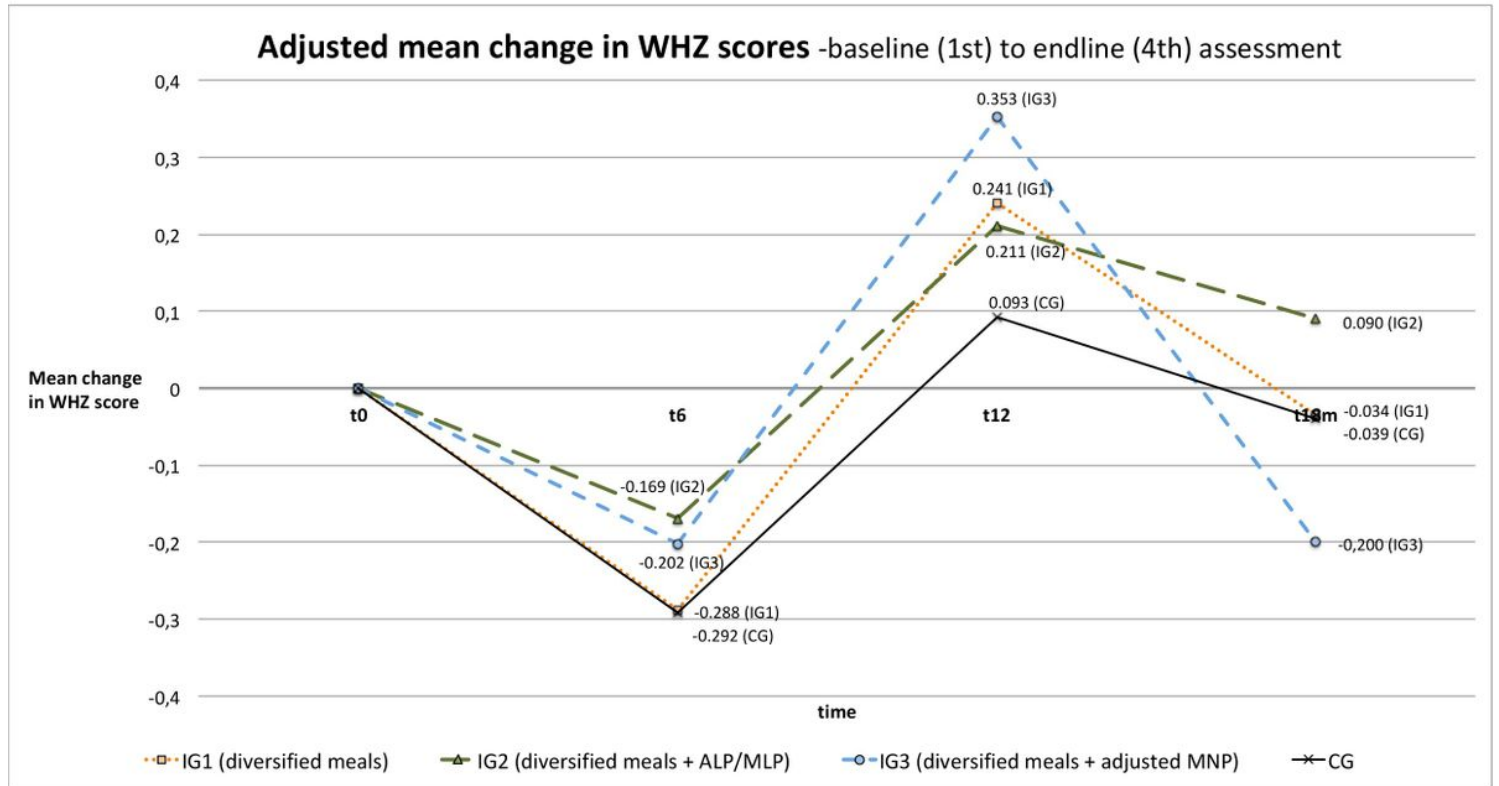

Figure 8

Adjusted mean changes in WAZ scores occurred over time, per study group (covariates age and WAZ scores at baseline, time between baseline and investigated assessment point, gender).

Figure 9

Adjusted mean changes in WHZ scores occurred over time, per study group (covariates age and WHZ scores at baseline, time between baseline and investigated assessment point, gender).
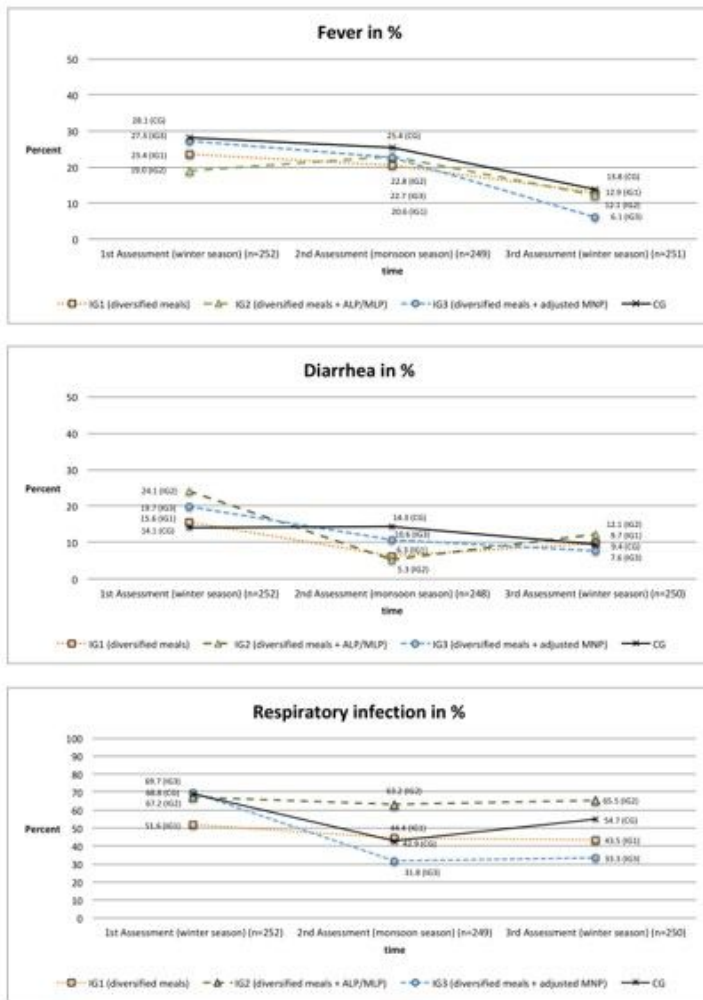
Figure 10

Prevalence of morbidity across different assessment points by study group

Supplementary Files

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- SupFile.docx