

Small quantity lipid-based nutritional supplementation and measles vaccination coverage in children aged 6–23 months: a pragmatic cluster-randomized trial

In the format provided by the
authors and unedited

Supplementary data

Supplementary table 1: Supplemental characteristics of survey participants at baseline and at endline

	Baseline		Endline	
	Control arm N = 796 ¹	NutriVax arm N = 801 ¹	Control arm N = 801 ¹	NutriVax arm N = 803 ¹
Sociodemographic characteristics				
Child with siblings from the same mother	710 (89%)	703 (88%)	720 (90%)	717 (89%)
If yes, number of living siblings	4 [2 - 5]	3 [2 - 5]	4 [2 - 6]	4 [2 - 6]
Father as survey respondent	60 (8%)	65 (8%)	17 (2%)	10 (1%)
Other family member as survey respondent	10 (1%)	11 (1%)	10 (1%)	10 (1%)
Clinical characteristics				
Non-bloody diarrhoea	50 (6%)	45 (6%)	8 (1%)	8 (1%)
Malaria (suspected)	47 (6%)	32 (4%)	12 (1%)	9 (1%)
Respiratory infection	5 (1%)	2 (0%)	5 (1%)	3 (0%)
Upper respiratory infection (e.g. cold, otitis)	18 (2%)	21 (3%)	18 (2%)	3 (0%)
Vomiting	11 (1%)	8 (1%)	0 (0%)	1 (0%)
Dehydration	10 (1%)	7 (1%)	1 (0%)	0 (0%)
Deworming over the last 6 months	294 (37%)	281 (35%)	175 (22%)	215 (27%)
Mother characteristics				
Native language				
Kanuri	353(44%)	314(39%)	360(45%)	382(48%)
Hausa	239(30%)	288(36%)	275(34%)	234(29%)
Fulani	152(19%)	141(18%)	102(13%)	106(13%)
Other	51(6%)	58(7%)	63(8%)	81(10%)
Mother alive	791 (99%)	797 (100%)	798 (100%)	801 (100%)
If alive, age in years	30 [25 - 35]	30 [25 - 35]	30 [25 - 35]	30 [25 - 35]
If alive, she can read or write	218 (28%)	183 (23%)	302 (38%)	230 (29%)
If alive, main activity:				
Housewife	641(81%)	666(83%)	635(80%)	651(81%)
Farmer	64 (8%)	66 (8%)	66 (8%)	78 (10%)
Shopkeeper or trader	30 (4%)	23 (3%)	43 (5%)	20 (2%)
Employed in the private sector	10 (1%)	4 (1%)	1 (0%)	3 (0%)
Public agent	9 (1%)	9 (1%)	0 (0%)	3 (0%)
Not working or looking for work	3 (0%)	1 (0%)	4 (1%)	4 (0%)
Other	35 (4%)	29 (4%)	49 (6%)	42 (5%)
If alive, Marital status:				
Married or civil union	785 (99%)	786 (99%)	787 (99%)	792 (99%)
Widowed	5 (1%)	3 (0%)	5 (1%)	6 (1%)
Separated/Divorced	1 (0%)	8 (1%)	6 (1%)	3 (0%)
Father characteristics				
Native language				
Kanuri	367 (46%)	314 (39%)	379 (47%)	371 (46%)
Hausa	227 (29%)	297 (37%)	265 (33%)	244 (30%)
Fulani	139 (17%)	129 (16%)	82 (10%)	97 (12%)
Other	62 (8%)	61 (8%)	74 (9%)	91 (11%)
Father alive	788 (99%)	794 (99%)	795 (99%)	797 (99%)
If alive, age in years	40 [37 - 50]	40 [35 - 50]	43 [36 - 50]	40 [35 - 50]
If alive, he can read or write	346 (44%)	305 (38%)	456 (57%)	400 (50%)
If alive, main activity:				
Farmer	498 (63%)	564 (71%)	500 (63%)	556 (70%)
Trader or shopkeeper	75 (10%)	58 (7%)	86 (11%)	64 (8%)
Public agent	81 (10%)	62 (8%)	26 (3%)	26 (3%)
Driver	44 (6%)	39 (5%)	55 (7%)	52 (7%)
Employed in the private sector	44 (6%)	28 (4%)	19 (2%)	12 (2%)
Not working or looking for work	14 (2%)	11 (1%)	13 (2%)	7 (1%)
Other	32 (4%)	32 (4%)	96 (12%)	80 (10%)
Vaccination characteristics				
Caregivers declaring that not all recommended vaccines were received by their child	324 (41%)	336 (42%)	375 (47%)	312 (39%)
Reason for the child not having received all recommended vaccines				
Mother too busy	77/324 (24%)	81/336 (24%)	105/375 (28%)	71/312 (23%)
Family problem, including illness of mother	51/324 (16%)	50/336 (15%)	46/375 (12%)	35/312 (11%)
Fear of side effects	49/324 (15%)	64/336 (19%)	16/375 (4%)	23/312 (7%)
Place of immunization too far from home	46/324 (14%)	55/336 (16%)	43/375 (11%)	52/312 (17%)
No faith in immunization	32/324 (10%)	38/336 (11%)	35/375 (9%)	17/312 (5%)
Long wait	26/324 (8%)	21/336 (6%)	38/375 (10%)	52/312 (17%)
Child too ill to be brought	18/324 (6%)	21/336 (6%)	25/375 (7%)	5/312 (2%)
Vaccines not available in the health centre	12/324 (4%)	5/336 (1%)	3/375 (1%)	3/312 (1%)
Time of immunization inconvenient	9/324 (3%)	5/336 (1%)	48/375 (13%)	73/312 (23%)

Rumors	9/324 (3%)	17/336 (5%)	12/375 (3%)	8/312 (3%)
Place and/or time of immunization unknown	9/324 (3%)	8/336 (2%)	10/375 (3%)	3/312 (1%)
Child too ill to be given immunization	4/324 (1%)	2/336 (1%)	5/375 (1%)	2/312 (1%)
Other	29/324 (9%)	28/336 (8%)	52/375 (14%)	42/312 (13%)

Footnote to Supplementary table 1: ¹Data are n (%) or median [Q1 - Q3].

Supplementary table 2: Baseline and endline characteristics by Local Government Area

	Baseline		Endline	
	Nguru N = 799 ¹	Karasuwa N = 798 ¹	Nguru N = 799 ¹	Karasuwa N = 805 ¹
Sociodemographic characteristics				
Age, months	17[14 - 20]	16[14 - 19]	17[15 - 20]	16[14 - 20]
12-15 months	284 (36%)	288(36%)	224(28%)	283(35%)
16-23 months	515 (64%)	510 (64%)	575 (72%)	521 (65%)
Male child	400 (50%)	398 (50%)	400 (50%)	401 (50%)
Child with siblings from the same mother	711 (89%)	702 (88%)	722 (90%)	715 (89%)
If yes, number of living siblings	3[2 - 5]	4[2 - 5]	4[2 - 6]	4[2 - 6]
Mother as survey respondent	733 (92%)	715 (90%)	786 (98%)	766 (95%)
Father as survey respondent	57 (7%)	68 (9%)	4 (1%)	23 (3%)
Other family member as survey respondent	7 (1%)	14 (2%)	7 (1%)	13 (2%)
Survey respondent trained in Family MUAC ^a	230 (29%)	286 (36%)	326 (41%)	333 (41%)
Clinical characteristics				
Chronic disease declared	9 (1%)	20 (3%)	16 (2%)	19 (2%)
Hospitalization declared in the last 3 months	16 (2%)	25 (3%)	21 (3%)	20 (2%)
Notion of fever in the last 24h	2 (0%)	21 (3%)	34 (4%)	48 (6%)
Current morbidity ^s	62 (8%)	139 (17%)	30 (4%)	30 (4%)
Non-bloody diarrhoea	31 (4%)	64 (8%)	8 (1%)	8 (1%)
Malaria (suspected)	14 (2%)	65 (8%)	12 (2%)	9 (1%)
Respiratory infection	0 (0%)	7 (1%)	0 (0%)	8 (1%)
Upper respiratory infection (e.g. cold, otitis)	20 (3%)	19 (2%)	14 (2%)	7 (1%)
Vomiting	1 (0%)	18 (2%)	1 (0%)	0 (0%)
Dehydration	1 (0%)	16 (2%)	0 (0%)	1 (0%)
Deworming over the last 6 months	248 (31%)	327 (41%)	165 (21%)	225 (28%)
Nutritional characteristics				
MUAC, mm	132[124 - 141]	133[125 - 141]	134[126 - 142]	134[127 - 142]
MUAC <115 mm	37 (5%)	48 (6%)	34 (4%)	37 (5%)
MUAC, mm [115-124]	164 (21%)	132 (17%)	120 (15%)	128 (16%)
Nutritional oedema	7 (1%)	8 (1%)	7 (1%)	14 (2%)
Acute malnutrition	205 (26%)	184 (23%)	156 (20%)	168 (21%)
Severe acute malnutrition	43 (5%)	53 (7%)	40 (5%)	48 (6%)
Child currently breastfed	480 (60%)	525 (66%)	554 (69%)	547 (68%)
Child currently receiving RUTF	14 (2%)	44 (6%)	34 (4%)	67 (8%)
Child currently receiving RUSF	6 (1%)	27 (3%)	13 (2%)	42 (5%)
SQ-LNS ever received at PHCC	-	-	209(26%)	210(26%)
Vaccination characteristics				
Vaccine card retention	350 (44%)	352 (44%)	516 (65%)	510 (63%)
Not all recommended vaccines received	341 (43%)	319 (40%)	334 (42%)	353 (44%)
Reason for the child not having received all recommended vaccines:	341 (43%)	319 (40%)	333 (42%)	353 (44%)
Mother too busy	28/341 (8%)	73/319 (23%)	29/334 (9%)	66/353 (19%)
Family problem, including illness of mother	58/341 (17%)	43/319 (13%)	37/334 (11%)	44/353 (12%)
Fear of side effects	25/341 (7%)	22/319 (7%)	50/334 (15%)	40/353 (11%)
Place of immunization too far from home	56/341 (16%)	57/319 (18%)	25/334 (7%)	14/353 (4%)
No faith in immunization	9/341 (3%)	5/319 (2%)	47/334 (14%)	74/353 (21%)
Long wait	21/341 (6%)	18/319 (6%)	13/334 (4%)	17/353 (5%)
Child too ill to be brought	8/341 (2%)	18/319 (6%)	12/334 (4%)	8/353 (2%)
Vaccines not available in the health centre	5/341 (1%)	12/319 (4%)	4/334 (1%)	9/353 (3%)
Time of immunization inconvenient	109/341 (32%)	49/319 (15%)	94/334 (28%)	82/353 (23%)
Rumors	4/341 (1%)	2/319 (1%)	3/334 (1%)	4/353 (1%)
Place and/or time of immunization unknown	24/341 (7%)	46/319 (14%)	22/334 (7%)	30/353 (8%)
Child too ill to be given immunization	6/341 (2%)	11/319 (3%)	4/334 (1%)	2/353 (1%)
Other	17/341 (5%)	40/319 (13%)	50/334 (15%)	44/353 (12%)
Most important reported reason:				
Mother too busy	27/341 (8%)	58/319 (18%)	27/334 (8%)	57/353 (16%)
Family problem, including illness of mother	52/341 (15%)	37/319 (12%)	36/334 (11%)	40/353 (11%)
Fear of side effects	23/341 (7%)	19/319 (6%)	44/334 (13%)	34/353 (10%)
Place of immunization too far from home	47/341 (14%)	44/319 (14%)	17/334 (5%)	12/353 (3%)
No faith in immunization	7/341 (2%)	3/319 (1%)	37/334 (11%)	57/353 (16%)
Long wait	20/341 (6%)	15/319 (5%)	12/334 (4%)	14/353 (4%)
Child too ill to be brought	5/341 (1%)	6/319 (2%)	5/334 (1%)	2/353 (1%)
Vaccines not available in the health centre	4/341 (1%)	8/319 (3%)	3/334 (1%)	8/353 (2%)

	Baseline		Endline	
	Nguru N = 799 ¹	Karasuwa N = 798 ¹	Nguru N = 799 ¹	Karasuwa N = 805 ¹
Time of immunization inconvenient	106/341 (31%)	47/319 (15%)	79/334 (24%)	58/353 (16%)
Place and/or time of immunization unknown	4/341 (1%)	2/319 (1%)	3/334 (1%)	3/353 (1%)
Rumors	23/341 (7%)	34/319 (11%)	17/334 (5%)	27/353 (8%)
Child too ill to be given immunization	6/341 (2%)	11/319 (3%)	4/334 (1%)	2/353 (1%)
Other	17/341 (5%)	35/319 (11%)	50/334 (15%)	40/353 (11%)
Household characteristics				
Household size	7[5 - 10]	7[5 - 10]	7[5 - 10]	7[5 - 9]
Number of years living in this settlement	17[9 - 26]	20[10 - 27]	14[7 - 25]	14[8 - 20]
Distance Settlement-PHCC, km	6.0[4.0 - 10.0]	8.0[0.0 - 15.0]	5.0[3.0 - 9.5]	10.0[1.0 - 16.0]
0-5km	368 (46%)	304 (39%)	447 (56%)	276 (35%)
6-10km	270 (34%)	156 (20%)	208 (26%)	177 (22%)
11-15km	48 (6%)	128 (16%)	48 (6%)	64 (8%)
>15km	111 (14%)	196 (25%)	96 (12%)	272 (34%)
Settlements directly served by PHCC for immunization	606 (76%)	618 (79%)	527 (66%)	597 (74%)
Mother characteristics				
Native language				
Hausa	371(46%)	156(20%)	337(42%)	172(21%)
Fulani	130(16%)	163(20%)	82(10%)	126(16%)
Kanuri	258(32%)	409(51%)	316(40%)	426(53%)
Other	40(5%)	69(9%)	64(8%)	80(10%)
Mother alive	796 (100%)	792 (99%)	795 (99%)	804 (100%)
If alive, age in years	30[25 - 35]	30[25 - 35]	30[25 - 35]	30[25 - 35]
If alive, she can read or write	278 (35%)	123 (16%)	345 (43%)	187 (23%)
If alive, main activity:				
Housewife	680(85%)	627(79%)	619(78%)	667(83%)
Farmer	43(5%)	87(11%)	71(9%)	73(9%)
Employed in the private sector	10 (1%)	4 (1%)	1 (0%)	3 (0%)
Trader or shopkeeper	30 (4%)	23 (3%)	39 (5%)	24 (3%)
Not working or looking for work	3 (0%)	1 (0%)	6 (1%)	2 (0%)
Public agent	10 (1%)	8 (1%)	1 (0%)	2 (0%)
Other	21 (3%)	43 (5%)	58 (7%)	33 (4%)
If alive, marital status:				
Married or civil union	785 (99%)	786 (99%)	781 (98%)	798 (99%)
Widowed	4 (1%)	4 (1%)	6 (1%)	5 (1%)
Separated/Divorced	6 (1%)	3 (0%)	8 (1%)	1 (0%)
Father characteristics				
Native language				
Hausa	366 (46%)	158 (20%)	340 (43%)	169 (21%)
Fulani	115 (14%)	153 (19%)	64 (8%)	115 (14%)
Kanuri	266 (33%)	415 (52%)	318 (40%)	432 (54%)
Other	51 (6%)	72 (9%)	77 (10%)	88 (11%)
Father alive	789 (99%)	793 (99%)	793 (99%)	799 (99%)
If alive, age in years	40[37 - 50]	40[35 - 50]	43[37 - 50]	42[35 - 50]
If alive, he can read or write	350 (44%)	301 (38%)	491 (62%)	365 (46%)
If alive, main activity:				
Farmer	412(52%)	650(82%)	416(52%)	640(80%)
Driver	62 (8%)	21 (3%)	73 (9%)	34 (4%)
Employed in the private sector	58 (7%)	14 (2%)	18 (2%)	13 (2%)
Trader or shopkeeper	96 (12%)	37 (5%)	102 (13%)	48 (6%)
Not working or looking for work	13 (2%)	12 (2%)	9 (1%)	11 (1%)
Public agent	103 (13%)	40 (5%)	39 (5%)	13 (2%)
Other	46 (6%)	18 (2%)	136 (17%)	40 (5%)

Footnote to Supplementary table 2:

¹Data are n (%) or median [Q1 - Q3]. MUAC=mid-upper-arm circumference. PHCC= Primary Health Care Center; RUSF=ready-to-use supplementary food.

RUTF=ready-to-use therapeutic food. SQ-LNS=small-quantity lipid-based nutrient supplement. x Family MUAC refers to training sessions where mothers and caregivers are taught how to use MUAC bracelets and check for nutritional oedema to detect acute malnutrition in their children at home.

⁵Current morbidity refers to presenting at least one of the following conditions: non-bloody diarrhoea, Malaria (suspected), respiratory infection, upper respiratory infection (e.g. Cold, Otitis), vomiting, dehydration

Acute malnutrition is definition is defined as MUAC<125 or edema.

Severe acute malnutrition is defined as MUAC<115 mm or oedema

Supplementary table 3: Baseline and endline characteristics by sex

	Baseline		Endline	
	Boy N = 798 ¹	Girl N = 795 ¹	Boy N = 801 ¹	Girl N = 801 ¹
Sociodemographic characteristics				
Age, months	17[14 - 20]	17[14 - 20]	17[14 - 20]	17[14 - 20]
12-15 months	290(36%)	281(35%)	250(31%)	256(32%)
16-23 months	508(64%)	514(65%)	551(69%)	545(68%)
Child with siblings from the same mother	705(88%)	705(89%)	719(90%)	717(90%)
If yes, number of living siblings	3[2 - 5]	4[2 - 6]	4[2 - 6]	4[2 - 6]
Mother as survey respondent	727(91%)	717(90%)	768(96%)	783(98%)
Father as survey respondent	59(7%)	66(8%)	17(2%)	10(1%)
Other family member as survey respondent	12(2%)	9(1%)	13(2%)	7(1%)
Survey respondent trained in Family MUAC ^a	251(31%)	262(33%)	346(43%)	312(39%)
Clinical characteristics				
Chronic disease declared	14(2%)	15(2%)	16(2%)	19(2%)
Hospitalization declared in the last 3 months	17(2%)	24(3%)	19(2%)	22(3%)
Notion of fever in the last 24h	13(2%)	10(1%)	42(5%)	40(5%)
Current morbidity ^s	108(14%)	93(12%)	36(4%)	24(3%)
Non-bloody diarrhoea	51(6%)	44(6%)	11(1%)	5(1%)
Malaria (suspected)	45(6%)	34(4%)	15(2%)	6(1%)
Respiratory infection	4(1%)	3(0%)	4(0%)	4(0%)
Upper respiratory infection (e.g. cold, otitis)	19(2%)	20(3%)	10(1%)	11(1%)
Vomiting	12(2%)	7(1%)	0(0%)	1(0%)
Dehydration	7(1%)	10(1%)	1(0%)	0(0%)
Deworming over the last 6 months	275(35%)	298(37%)	193(24%)	197(25%)
Nutritional characteristics				
MUAC, mm	133[125 - 142]	132[125 - 140]	134[128 - 142]	134[126 - 142]
MUAC <115 mm	44(6%)	41(5%)	31(4%)	40(5%)
MUAC, mm [115-124]	139(17%)	157(20%)	112(14%)	136(17%)
Nutritional oedema	10(1%)	5(1%)	11(1%)	10(1%)
Acute malnutrition	191(24%)	198(25%)	146(18%)	178(22%)
Severe acute malnutrition	53(7%)	43(5%)	40(5%)	48(6%)
Child currently breastfed	502(63%)	501(63%)	558(70%)	542(68%)
Child currently receiving RUTF	30(4%)	28(4%)	47(6%)	54(7%)
Child currently receiving RUSF	18(2%)	15(2%)	31(4%)	24(3%)
SQ-LNS ever received at PHCC	-	-	205(26%)	214(27%)
Immunization characteristics				
Vaccine card retention	347(43%)	354(45%)	503(63%)	522(65%)
Not all recommended vaccines received	326(41%)	331(42%)	332(42%)	355(44%)
Reason for the child not having received all recommended vaccines:	326(41%)	331(42%)	332(41%)	354(44%)
Mother too busy	47/341 (14%)	54/319 (17%)	42/334 (13%)	53/353 (15%)
Family problem, including illness of mother	55/341 (16%)	46/319 (14%)	44/334 (13%)	37/353 (10%)
Fear of side effects	20/341 (6%)	27/319 (8%)	49/334 (15%)	41/353 (12%)
Place of immunization too far from home	60/341 (18%)	53/319 (17%)	16/334 (5%)	23/353 (7%)
No faith in immunization	9/341 (3%)	5/319 (2%)	57/334 (17%)	64/353 (18%)
Long wait	21/341 (6%)	18/319 (6%)	14/334 (4%)	16/353 (5%)
Child too ill to be brought	14/341 (4%)	12/319 (4%)	9/334 (3%)	11/353 (3%)
Vaccines not available in the health centre	7/341 (2%)	10/319 (3%)	6/334 (2%)	7/353 (2%)
Time of immunization inconvenient	71/341 (21%)	84/319 (26%)	85/334 (25%)	91/353 (26%)
Rumors	1/341 (0%)	5/319 (2%)	4/334 (1%)	3/353 (1%)
Place and/or time of immunization unknown	40/341 (12%)	30/319 (9%)	28/334 (8%)	24/353 (7%)
Child too ill to be given immunization	7/341 (2%)	10/319 (3%)	6/334 (2%)	0/353 (0%)
Other	36/341 (11%)	21/319 (7%)	42/334 (13%)	52/353 (15%)
Most important reported reason:				
Mother too busy	36(11%)	49(15%)	38(11%)	46(13%)
Family problem, including illness of mother	50(15%)	39(12%)	41(12%)	35(10%)
Fear of side effects	19(6%)	23(7%)	43(13%)	35(10%)
Place of immunization too far from home	47(14%)	44(13%)	13(4%)	16(5%)
No faith in immunization	6(2%)	4(1%)	42(13%)	52(15%)
Long wait	18(6%)	17(5%)	13(4%)	13(4%)
Child too ill to be brought	5(2%)	6(2%)	3(1%)	4(1%)
Vaccines not available in the health centre	5(2%)	7(2%)	4(1%)	7(2%)
Time of immunization inconvenient	70(21%)	80(24%)	63(19%)	74(21%)
Place and/or time of immunization unknown	1(0%)	5(2%)	3(1%)	3(1%)
Rumors	31(10%)	26(8%)	25(8%)	19(5%)
Child too ill to be given immunization	7(2%)	10(3%)	6(2%)	0(0%)
Other	31(10%)	21(6%)	39(12%)	51(14%)
Household characteristics				
Household size	7[5 - 10]	7[5 - 10]	7[5 - 10]	7[5 - 10]
Number of years living in this settlement	17[9 - 26]	20[10 - 27]	13[7 - 20]	15[8 - 25]

	Baseline		Endline	
	Boy N = 798 ¹	Girl N = 795 ¹	Boy N = 801 ¹	Girl N = 801 ¹
Distance Settlement-PHCC, km	8.0[2.0 - 14.0]	8.0[2.0 - 14.0]	8.0[2.4 - 14.0]	6.0[3.0 - 14.0]
0-5km	330(42%)	340(43%)	348(44%)	375(47%)
6-10km	201(25%)	224(28%)	192(24%)	191(24%)
11-15km	89(11%)	87(11%)	55(7%)	57(7%)
>15km	170(22%)	136(17%)	199(25%)	169(21%)
Settlements directly served by PHCC for immunization	618(78%)	603(77%)	556(69%)	566(71%)
Mother characteristics				
Native language				
Kanuri	273(34%)	253(32%)	251(31%)	258(32%)
Hausa	135(17%)	157(20%)	104(13%)	103(13%)
Fulani	334(42%)	331(42%)	378(47%)	364(45%)
Other	55(7%)	54(7%)	68(8%)	76(9%)
Mother alive	792(99%)	792(100%)	798(100%)	800(100%)
If alive, age, years	30[25 - 35]	30[25 - 35]	30[25 - 35]	30[25 - 35]
If alive, she can read or write, yes	205(26%)	195(25%)	260(33%)	271(34%)
If alive, main activity:				
Housewife	647(82%)	656(83%)	662(83%)	623(78%)
Farmer	72(9%)	58(7%)	66(8%)	78(10%)
Employed in the private sector	7(1%)	7(1%)	0(0%)	4(1%)
Trader or shopkeeper	26(3%)	27(3%)	26(3%)	37(5%)
Not working or looking for work	3(0%)	1(0%)	4(1%)	4(1%)
Public agent	9(1%)	9(1%)	1(0%)	2(0%)
Other	29(4%)	35(4%)	39(5%)	52(7%)
If alive, marital status:				
Married or civil union	781(99%)	786(99%)	788(99%)	790(99%)
Widowed	6(1%)	2(0%)	5(1%)	6(1%)
Separated/Divorced	5(1%)	4(1%)	5(1%)	4(1%)
Father characteristics				
Native language				
Hausa	277(35%)	246(31%)	252(31%)	256(32%)
Fulani	122(15%)	145(18%)	90(11%)	89(11%)
Kanuri	333(42%)	346(44%)	381(48%)	369(46%)
Other	65(8%)	58(7%)	78(10%)	87(11%)
Father alive	788(99%)	790(99%)	796(99%)	795(99%)
If alive, age in years	40[35 - 50]	42[36 - 50]	42[35 - 50]	43[36 - 50]
If alive, he can read or write	311(40%)	338(43%)	418(53%)	437(55%)
If alive, main activity:				
Farmer	533(68%)	526(66%)	534(67%)	521(66%)
Driver	43(5%)	40(5%)	55(7%)	52(7%)
Employed in the private sector	36(5%)	35(4%)	12(2%)	19(2%)
Trader or shopkeeper	71(9%)	62(8%)	67(8%)	83(10%)
Not working or looking for work	11(1%)	14(2%)	10(1%)	10(1%)
Public agent	63(8%)	80(10%)	25(3%)	27(3%)
Other	30(4%)	34(4%)	93(12%)	83(10%)

Footnote to Supplementary table 3:

¹Data are n (%) or median [Q1 - Q3].

MUAC=mid-upper-arm circumference. PHCC= Primary Health Care Center; RUSF=ready-to-use supplementary food. RUTF=ready-to-use therapeutic food.

SQ-LNS=small-quantity lipid-based nutrient supplement.

^aFamily MUAC refers to training sessions where mothers and caregivers are taught how to use MUAC bracelets and check for nutritional oedema to detect acute malnutrition in their children at home.

[§]Current morbidity refers to the presence of at least one of the following conditions: non-bloody diarrhoea, malaria (suspected), respiratory infection, upper respiratory infection (e.g. cold, otitis), vomiting, dehydration

Acute malnutrition is defined as a MUAC of less than 125 mm or the presence of nutritional edema.

Severe acute malnutrition is defined as a MUAC of less than 115 mm or the presence of nutritional oedema

Supplementary Table 4: Difference in Differences (DiD) analysis showing DiD mean boot for main and secondary outcomes

	OR	95% CI	p-value	DiD pp	DiD mean boot pp	95% CI pp	p-value
Primary outcome confirmed by card							
MCV1	2.39	1.76–3.25	<0.0001	20.1	20.0	13.7 to 26.5	< 0.0001
Secondary outcomes confirmed by card							
Vaccine card retention	2.25	1.68–3.02	<0.0001	17.8	17.8	11 to 24.3	< 0.0001
Timeliness MCV1	2.00	1.42–2.81	<0.0001	13.6	13.6	7.7 to 19.6	< 0.0001
MCV2 >15 months	2.14	1.34–3.46	<0.0001	12.1	12.1	5.4 to 18.7	< 0.0001
Pentavalent 3	2.42	1.8–3.25	<0.0001	20.4	20.2	13.6 to 26.8	< 0.0001
Meningitis	2.39	1.76–3.25	<0.0001	20.0	19.9	13.4 to 26.3	< 0.0001
Zero-dose [/]	0.47	0.35–0.63	<0.0001	-17.0	-17.0	-23.7 to -10.5	< 0.0001
Zero-dose [/] and acute malnourished	0.49	0.3–0.8	<0.0001	-4.3	-4.3	-8.8 to 0.1	0.0528
Secondary outcomes confirmed by card or recall							
MCV1	1.96	1.47–2.63	<0.0001	15.1	15.0	8.3 to 22	< 0.0001
Timeliness MCV1	1.73	1.24–2.4	<0.0001	11.7	11.7	5.7 to 17.7	< 0.0001
MCV2 >15months	1.50	1.01–2.24	0.0120	7.6	7.6	0.3 to 15.1	0.0408
Pentavalent 3	2.06	1.54–2.76	<0.0001	16.6	16.5	9.8 to 23.1	< 0.0001
Yellow fever	2.14	1.6–2.86	<0.0001	17.3	17.3	10.6 to 24	< 0.0001
Fully vaccinated	1.64	1.19–2.25	<0.0001	9.9	9.9	3.9 to 16	0.0016
Zero-dose [/]	0.47	0.34–0.66	<0.0001	-12.5	-12.4	-18.6 to -6.3	< 0.0001
Zero-dose (Nigerian NPI)	0.42	0.29–0.6	<0.0001	-11.7	-11.7	-17.2 to -6.2	< 0.0001
Zero-dose [/] and acute malnourished	0.33	0.18–0.59	<0.0001	-4.5	-4.5	-8.3 to -0.9	0.0176
Vitamin A received	1.79	1.34–2.39	<0.0001	13.6	13.6	7 to 20.1	0.0004

Footnote to Supplementary table 4

OR= odd ratio, CI= confidence interval, DiD= difference in difference; pp= percentage point

All estimates were obtained from the same mixed-effects difference-in-differences model.

OR = cluster-specific odds ratio derived from the arm × period interaction in a mixed-effects logistic regression including arm, period, their interaction, and cluster-level baseline coverage as fixed effect, with cluster as a random intercept. 95% CIs are from profile likelihood and p-values from likelihood ratio tests.

DiD pp = absolute difference in model-predicted probabilities × 100, with 95% CIs and p-values derived from parametric bootstrap.

DiD mean boot presented only for verifying the robustness of the bootstrap (it's the average of the DiD calculated across all bootstrap replicates); Percentile confidence interval estimated by parametric bootstrap (5000 iterations) based on the fitted mixed-effects model; $\square$ two-sided bootstrap p-value for $H_0: DiD = 0$, based on the proportion of bootstrap replicates crossing zero.

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

[/] Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition. Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b. £Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card.

BCG: Bacillus Calmette-Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

\$Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

Supplementary table 5: Characteristics of participants in the NutriVax arm at endline stratified by SQ-LNS uptake

	Endline	
	Received SQ-LNS N = 386 ¹	Did not receive SQ-LNS N = 417 ¹
Sociodemographic characteristics		
Age (months)	17 [14 - 20]	17 [14 - 20]
12-15 months	127 (33%)	125 (30%)
16-23 months	259 (67%)	292 (70%)
Male child	191 (49%)	203 (49%)
Child with siblings from the same mother	349 (90%)	368 (88%)
If yes, number of living siblings	4 [2 - 6]	4 [2 - 6]
Mother as survey respondent	377 (98%)	404 (97%)
Father as survey respondent	4 (1%)	6 (1%)
Other family member as survey respondent	3 (1%)	7 (2%)
Survey respondent trained in Family MUAC ^a	202 (52%)	143 (34%)
Clinical characteristics		
Chronic disease declared	7 (2%)	10 (2%)
Hospitalization declared in the last 3 months	10 (3%)	7 (2%)
Notion of fever in the last 24h	28 (7%)	17 (4%)
Current morbidity ^s	10 (3%)	11 (3%)
Non-bloody diarrhoea	3 (1%)	5 (1%)
Malaria (suspected)	4 (1%)	5 (1%)
Respiratory infection	2 (1%)	1 (0%)
Upper respiratory infection (e.g. cold, otitis)	1 (0%)	2 (0%)
Vomiting	0 (0%)	1 (0%)
Dehydration	0 (0%)	0 (0%)
Deworming over the last 6 months	121 (31%)	94 (23%)
Nutritional characteristics		
MUAC, mm	134 [125 - 142]	133 [126 - 141]
MUAC <115 mm	15 (4%)	28 (7%)
MUAC, mm [115-124]	77 (20%)	57 (14%)
Nutritional oedema	3 (1%)	7 (2%)
Acute malnutrition	94 (24%)	85 (20%)
Severe acute malnutrition	18 (5%)	32 (8%)
Child currently breastfed	259 (67%)	282 (68%)
Child currently receiving RUTF	4 (1%)	38 (9%)
Child currently receiving RUSF	2 (1%)	14 (3%)
Vaccination characteristics		
Vaccine card retention	330 (85%)	222 (53%)
Not all recommended vaccines received	114 (30%)	198 (47%)
Reason for the child not having received all recommended vaccines:		
Mother too busy	7/114 (6%)	45/198 (23%)
Family problem, including illness of mother	31/114 (27%)	42/198 (21%)
Fear of side effects	31/114 (27%)	40/198 (20%)
Place of immunization too far from home	21/114 (18%)	31/198 (16%)
No faith in immunization	19/114 (17%)	16/198 (8%)
Long wait	3/114 (3%)	20/198 (10%)
Child too ill to be brought	2/114 (2%)	15/198 (8%)
Vaccines not available in the health centre	3/114 (3%)	2/198 (1%)
Time of immunization inconvenient	0/114 (0%)	8/198 (4%)
Rumors	1/114 (1%)	2/198 (1%)
Place and/or time of immunization unknown	1/114 (1%)	1/198 (1%)
Child too ill to be given immunization	1/114 (1%)	2/198 (1%)
Other	21/114 (18%)	21/198 (11%)
Most important reported reason:		
Mother too busy	6/114 (5%)	40/198 (20%)
Family problem, including illness of mother	21/114 (18%)	31/198 (16%)
Fear of side effects	19/114 (17%)	31/198 (16%)
Place of immunization too far from home	21/114 (18%)	23/198 (12%)
No faith in immunization	18/114 (16%)	16/198 (8%)
Long wait	3/114 (3%)	14/198 (7%)
Child too ill to be brought	2/114 (2%)	13/198 (7%)
Vaccines not available in the health centre	2/114 (2%)	2/198 (1%)
Time of immunization inconvenient	0/114 (0%)	4/198 (2%)
Place and/or time of immunization unknown	1/114 (1%)	1/198 (1%)
Rumors	1/114 (1%)	1/198 (1%)
Child too ill to be given immunization	1/114 (1%)	2/198 (1%)
Other	19/114 (17%)	20/198 (10%)
Household characteristics		

	Endline	
	Received SQ-LNS N = 386 ¹	Did not receive SQ-LNS N = 417 ¹
Household size	7 [5 - 10]	7 [5 - 9]
Number of years living in this settlement	15 [8 - 25]	12 [7 - 20]
Distance Settlement-PHCC in km	6.0 [0.0 - 14.0]	8.0 [4.0 - 14.0]
0-5km	189 (49%)	182 (44%)
6-10km	89 (23%)	103 (25%)
11-15km	31 (8%)	33 (8%)
>15km	77 (20%)	99 (24%)
Settlement directly served by PHCC for immunization services	269 (70%)	262 (63%)
Mother characteristics		
Native language		
Kanuri	103(27%)	131(31%)
Hausa	52(13%)	54(13%)
Fulani	179(46%)	203(49%)
Other	52(13%)	29(7%)
Mother alive	386 (100%)	415 (100%)
If alive, age, years	30 [25 - 35]	30 [25 - 35]
If alive, she can read or write, yes	111 (29%)	119 (29%)
If alive, main activity:		
Housewife	312(81%)	339(82%)
Farmer	38 (10%)	40 (10%)
Employed in the private sector	2 (1%)	1 (0%)
Trader or shopkeeper	10 (3%)	10 (2%)
Not working or looking for work	2 (1%)	2 (0%)
Public agent	1 (0%)	2 (0%)
Other	21 (5%)	21 (5%)
If alive, marital status:		
Married or civil union	381 (99%)	411 (99%)
Widowed	2 (1%)	4 (1%)
Separated/Divorced	3 (1%)	0 (0%)
Father characteristics		
Native language		
Hausa	106 (27%)	138 (33%)
Fulani	51 (13%)	46 (11%)
Kanuri	169 (44%)	202 (48%)
Other	60 (16%)	31 (7%)
Father alive	384 (99%)	413 (99%)
If alive, age in years	40 [35 - 50]	42 [36 - 50]
If alive, he can read or write	203 (53%)	197 (48%)
If alive, main activity:	286 (74%)	270 (65%)
Farmer	21 (5%)	31 (8%)
Driver	4 (1%)	8 (2%)
Employed in the private sector	26 (7%)	38 (9%)
Trader or shopkeeper	7 (2%)	0 (0%)
Not working or looking for work	10 (3%)	16 (4%)
Public agent	30 (8%)	50 (12%)

Supplementary table 5: ¹Data are n (%) or median [Q1 - Q3].

MUAC=mid-upper-arm circumference. PHCC= Primary Health Care Center; RUSF=ready-to-use supplementary food. RUTF=ready-to-use therapeutic food.

SQ-LNS=small-quantity lipid-based nutrient supplement.

^aFamily MUAC refers to training sessions where mothers and caregivers are taught how to use MUAC bracelets and check for nutritional oedema to detect acute malnutrition in their children at home.

[§]Current morbidity refers to the presence of at least one of the following conditions: non-bloody diarrhoea, malaria (suspected), respiratory infection, upper respiratory infection (e.g. cold, otitis), vomiting, dehydration.

Supplementary Table 6: Cluster-level analysis of primary and secondary outcome in the NutriVax arm at endline stratified by SQ-LNS uptake

	Endline				
	Received SQLNS N = 386 ¹	Did not receive SQLNS N = 417 ¹	OR*	95% CI**	p-value [□]
Primary outcome confirmed by card					
MCV1	283 (73.3%)	161 (38.6%)	4.26	(3.11–5.85)	<0.0001
Secondary outcomes confirmed by card					
Vaccine card retention	330 (85.5%)	222 (53.2%)	4.98	(3.53–7.09)	<0.0001
Timeliness of MCV1	190 (49.2%)	101 (24.2%)	2.99	(2.17–4.13)	<0.0001
MCV2, age≥15 months	100 (25.9%)	52 (12.5%)	2.90	(1.94–4.39)	<0.0001
Pentavalent 3	316 (81.9%)	192 (46.0%)	5.03	(3.61–7.06)	<0.0001
Meningitis	274 (71.0%)	160 (38.4%)	3.74	(2.75–5.11)	<0.0001
Zero-dose [/]	63 (16.3%)	206 (49.4%)	0.21	(0.15–0.29)	<0.0001
Zero-dose [/] and malnourished*	18 (4.7%)	30 (7.2%)	0.70	(0.37–1.28)	0.2463
Secondary outcomes confirmed by card or recall					
MCV1	313 (81.1%)	237 (56.8%)	3.13	(2.25–4.4)	<0.0001
Timeliness of MCV1	197 (51.0%)	119 (28.5%)	2.58	(1.89–3.52)	<0.0001
MCV2, age≥15 months	105 (27.2%)	60 (14.4%)	2.66	(1.8–3.96)	<0.0001
Pentavalent 3	325 (84.2%)	209 (50.1%)	5.13	(3.65–7.29)	<0.0001
Yellow fever	308 (79.8%)	230 (55.2%)	3.04	(2.19–4.24)	<0.0001
Fully vaccinated [‡]	174 (45.1%)	102 (24.5%)	2.52	(1.84–3.48)	<0.0001
Zero-dose [/]	28 (7.3%)	123 (29.5%)	0.18	(0.12–0.28)	<0.0001
Zero-dose (Nigerian NPI) ^{\$}	13 (3.4%)	98 (23.5%)	0.12	(0.06–0.21)	<0.0001
Zero-dose [/] and malnourished	6 (1.6%)	20 (4.8%)	0.33	(0.12–0.79)	0.0122
Vitamin A received	253 (65.5%)	172 (41.2%)	2.32	(1.71–3.15)	<0.0001

Footnote to Supplementary table 6

¹ Data are n (%)

*Cluster-specific odds ratios (OR) from a mixed-effects logistic regression including SQLNS and the cluster-level baseline immunization proportion as fixed effects, with cluster as a random intercept.

** from profile likelihood

□ p-value from likelihood ratio test

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

[/] Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition.

Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b.

Malnourished = MUAC of less than 125 mm or the presence of nutritional edema.

[‡]Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card.

BCG: Bacillus Calmette-Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

^{\$}Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

Supplementary Table 7: Main and secondary outcomes at endline by Local Government Area and by arm

	Nguru		Karasuwa	
	Control arm N = 400 ¹	NutriVax arm N = 399 ¹	Control arm N = 401 ¹	NutriVax arm N = 404 ¹
Primary outcome confirmed by card				
MCV1	169 (42.3%)	211 (52.9%)	161 (40.1%)	233 (57.7%)
Sensitivity analyses of primary outcome				
MCV1 among children aged <20 months	141 (44.2%)	146 (50.3%)	115 (36.5%)	179 (56.6%)
Secondary outcomes confirmed by card				
Vaccine card retention	248 (62.0%)	268 (67.2%)	226 (56.4%)	284 (70.3%)
Timeliness of MCV1	97 (24.3%)	120 (30.1%)	101 (25.2%)	171 (42.3%)
MCV2, age ≥ 15 months	62 (21.8%)	88 (30.2%)	48 (18.4%)	64 (24.6%)
Pentavalent 3	197 (49.3%)	239 (59.9%)	203 (50.6%)	269 (66.6%)
Meningitis	164 (41.0%)	210 (52.6%)	159 (39.7%)	224 (55.4%)
Zero-dose [/]	169 (42.3%)	140 (35.1%)	180 (44.9%)	129 (31.9%)
Zero-dose [/] and malnourished*	28 (7.0%)	22 (5.5%)	36 (9.0%)	26 (6.4%)
Zero-dose [/] and severely malnourished**	7 (1.8%)	8 (2.0%)	12 (3.0%)	7 (1.7%)
Secondary outcomes confirmed by card or recall				
MCV1	238 (59.5%)	272 (68.2%)	199 (49.6%)	278 (68.8%)
Timeliness of MCV1	117 (29.3%)	136 (34.1%)	105 (26.2%)	180 (44.6%)
MCV2, age ≥ 15 months	125 (22.9%)	165 (29.9%)	51 (19.5%)	67 (25.8%)
MCV2	84 (21.0%)	104 (26.1%)	55 (13.7%)	75 (18.6%)
Pentavalent 3	223 (55.8%)	257 (64.4%)	208 (51.9%)	277 (68.6%)
Yellow fever	227 (56.8%)	262 (65.7%)	191 (47.6%)	276 (68.3%)
Fully vaccinated [£]	125 (31.3%)	118 (29.6%)	109 (27.2%)	158 (39.1%)
Zero-dose [/]	98 (24.5%)	74 (18.5%)	136 (33.9%)	77 (19.1%)
Zero-dose (Nigerian NPI) ^{\$}	64 (16.0%)	54 (13.5%)	113 (28.2%)	57 (14.1%)
Zero-dose [/] and malnourished*	19 (4.8%)	9 (2.3%)	32 (8.0%)	17 (4.2%)
Zero-dose [/] and severely malnourished**	5 (1.3%)	5 (1.3%)	10 (2.5%)	7 (1.7%)
Vitamin A received	154 (38.5%)	196 (49.1%)	157 (39.2%)	229 (56.7%)

Footnote to Supplementary table 7¹ Data are n (%)

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

[/] Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition.

Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b.

* Malnourished = MUAC of less than 125 mm or the presence of nutritional edema.

** Severely malnourished = MUAC of less than 115 mm or the presence of nutritional oedema.

MUAC=mid-upper-arm circumference.

£ Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card.

\$ Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

BCG: Bacillus Calmette-Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

Supplementary Table 8: Main and secondary outcomes at baseline and at endline by Local Government Area

	Baseline		Endline	
	Nguru N = 799 ¹	Karasuwa N = 798 ¹	Nguru N = 799 ¹	Karasuwa N = 805 ¹
Primary outcome confirmed by card				
MCV1	211 (26.4%)	227 (28.4%)	380 (47.6%)	394 (48.9%)
Sensibility analyses of primary outcome				
MCV1 among children aged <20 months	156 (26.9%)	177 (28.5%)	287 (47.1%)	294 (46.6%)
Secondary outcomes confirmed by card				
Vaccine card retention	350 (43.8%)	352 (44.1%)	516 (64.6%)	510 (63.4%)
Timeliness of MCV1	133 (16.6%)	147 (18.4%)	217 (27.2%)	272 (33.8%)
MCV2, age ≥ 15 months	81 (15.7%)	46 (9.0%)	150 (26.1%)	112 (21.5%)
Pentavalent 3	272 (34.0%)	304 (38.1%)	436 (54.6%)	472 (58.6%)
Meningitis	205 (25.7%)	216 (27.1%)	374 (46.8%)	383 (47.6%)
Zero-dose [/]	474 (59.3%)	454 (56.9%)	309 (38.7%)	309 (38.4%)
Zero-dose [/] and malnourished*	126 (15.8%)	106 (13.3%)	50 (6.3%)	62 (7.7%)
Zero-dose [/] and severely malnourished**	29 (3.6%)	37 (4.6%)	15 (1.9%)	19 (2.4%)
Secondary outcomes confirmed by card or recall				
MCV1	403 (50.4%)	400 (50.1%)	510 (63.8%)	477 (59.3%)
Timeliness of MCV1	149 (18.6%)	160 (20.1%)	253 (31.7%)	285 (35.4%)
MCV2, age ≥ 15 months	156 (30.3%)	114 (22.4%)	172 (29.9%)	118 (22.6%)
MCV2	171 (21.4%)	131 (16.4%)	188 (23.5%)	130 (16.1%)
Pentavalent 3	308 (38.5%)	346 (43.4%)	480 (60.1%)	485 (60.2%)
Yellow fever	386 (48.3%)	386 (48.4%)	489 (61.2%)	467 (58.0%)
Fully vaccinated [£]	190 (23.8%)	197 (24.7%)	243 (30.4%)	267 (33.2%)
Zero-dose [/]	259 (32.4%)	277 (34.7%)	172 (21.5%)	213 (26.5%)
Zero-dose (Nigerian NPI) ^{\$}	188 (23.5%)	209 (26.2%)	118 (14.8%)	170 (21.1%)
Zero-dose [/] and acute malnourished	77 (9.6%)	73 (9.1%)	28 (3.5%)	49 (6.1%)
Zero-dose [/] and severely malnourished**	19 (2.4%)	29 (3.6%)	10 (1.3%)	17 (2.1%)
Vitamin A received	374 (46.8%)	436 (54.6%)	350 (43.8%)	386 (48.0%)

Footnote to Supplementary table 8:
¹ Data are n (%)

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

[/] Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition.

Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b.

* Malnourished = MUAC of less than 125 mm or the presence of nutritional edema.

** Severely malnourished = MUAC of less than 115 mm or the presence of nutritional oedema.

MUAC=mid-upper-arm circumference.

£ Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card.

\$ Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

BCG: Bacillus Calmette-Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

Supplementary Table 9: Main and secondary outcomes at baseline by sex and by arm

	Boy		Girl	
	Control arm N = 393 ¹	NutriVax arm N = 405 ¹	Control arm N = 400 ¹	NutriVax arm N = 395 ¹
Primary outcome confirmed by card				
MCV1	111 (28.2%)	105 (25.9%)	127 (31.8%)	95 (24.1%)
Sensitivity analyses of primary outcome				
MCV1 among children aged <20 months	91 (30.0%)	74 (25.1%)	100 (32.7%)	68 (23.1%)
Secondary outcomes confirmed by card				
Vaccine card retention	186 (47.3%)	161 (39.8%)	197 (49.3%)	157 (39.7%)
Timeliness of MCV1	64 (16.3%)	68 (16.8%)	82 (20.5%)	66 (16.7%)
MCV2, age ≥ 15 months	40 (15.6%)	21 (8.4%)	34 (12.7%)	32 (13.0%)
Pentavalent 3	155 (39.4%)	134 (33.1%)	157 (39.3%)	129 (32.7%)
Meningitis	105 (26.7%)	98 (24.2%)	125 (31.3%)	93 (23.5%)
Zero-dose [†]	217 (55.2%)	248 (61.2%)	216 (54.0%)	244 (61.8%)
Zero-dose [†] and malnourished*	51 (13.0%)	66 (16.3%)	46 (11.5%)	69 (17.5%)
Zero-dose [†] and severely malnourished**	18 (4.6%)	20 (4.9%)	13 (3.3%)	15 (3.8%)
Secondary outcomes confirmed by card or recall				
MCV1	197 (50.1%)	198 (48.9%)	206 (51.5%)	201 (50.9%)
Timeliness of MCV1	67 (17.0%)	80 (19.8%)	87 (21.8%)	75 (19.0%)
MCV2, age ≥ 15 months	140 (26.6%)	130 (26.1%)	63 (23.6%)	73 (29.6%)
MCV2	86 (21.9%)	63 (15.6%)	74 (18.5%)	79 (20.0%)
Pentavalent 3	168 (42.7%)	159 (39.3%)	172 (43.0%)	154 (39.0%)
Yellow fever	191 (48.6%)	185 (45.7%)	202 (50.5%)	193 (48.9%)
Fully vaccinated [£]	97 (24.7%)	93 (23.0%)	113 (28.3%)	84 (21.3%)
Zero-dose [†]	130 (33.1%)	143 (35.3%)	127 (31.8%)	135 (34.2%)
Zero-dose (Nigerian NPI) ^{\$}	91 (23.2%)	109 (26.9%)	89 (22.3%)	107 (27.1%)
Zero-dose [†] and malnourished*	34 (8.7%)	47 (11.6%)	28 (7.0%)	41 (10.4%)
Zero-dose [†] and severely malnourished**	15 (3.8%)	15 (3.7%)	8 (2.0%)	10 (2.5%)
Vitamin A received	193 (49.1%)	206 (50.9%)	209 (52.3%)	201 (50.9%)

Footnote to Supplementary table 9:

¹ Data are n (%)

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

[†] Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition.

Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b.

* Malnourished = MUAC of less than 125 mm or the presence of nutritional edema.

** Severely malnourished = MUAC of less than 115 mm or the presence of nutritional oedema.

MUAC=mid-upper-arm circumference.

£ Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card.

\$ Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

BCG: Bacillus Calmette-Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

Supplementary Table 10: Main and secondary outcomes at endline by sex and by arm

	Boy		Girl	
	Control arm N = 407 ¹	NutriVax arm N = 394 ¹	Control arm N = 392 ¹	NutriVax arm N = 409 ¹
Primary outcome confirmed by card				
MCV1	170 (41.8%)	218 (55.3%)	159 (40.6%)	226 (55.3%)
Sensitivity analyses of primary outcome				
MCV1 among children aged <20 months	132 (40.4%)	161 (53.5%)	123 (40.2%)	164 (53.8%)
Secondary outcomes confirmed by card				
Vaccine card retention	235 (57.7%)	268 (68.0%)	238 (60.7%)	284 (69.4%)
Timeliness of MCV1	93 (22.9%)	146 (37.1%)	104 (26.5%)	145 (35.5%)
MCV2, age ≥ 15 months	54 (19.8%)	72 (25.9%)	56 (20.6%)	80 (29.3%)
Pentavalent 3	200 (49.1%)	248 (62.9%)	199 (50.8%)	260 (63.6%)
Meningitis	169 (41.5%)	214 (54.3%)	153 (39.0%)	220 (53.8%)
Zero-dose/	182 (44.7%)	138 (35.0%)	166 (42.3%)	131 (32.0%)
Zero-dose/ and malnourished*	31 (7.6%)	22 (5.6%)	33 (8.4%)	26 (6.4%)
Zero-dose/ and severely malnourished**	11 (2.7%)	7 (1.8%)	8 (2.0%)	8 (2.0%)
Secondary outcomes confirmed by card or recall				
MCV1	227 (55.8%)	274 (69.5%)	209 (53.3%)	276 (67.5%)
Timeliness of MCV1	103 (25.3%)	161 (40.9%)	118 (30.1%)	155 (37.9%)
MCV2, age ≥ 15 months	125 (22.9%)	165 (29.9%)	63 (23.2%)	88 (32.2%)
MCV2	69 (17.0%)	87 (22.1%)	70 (17.9%)	92 (22.5%)
Pentavalent 3	213 (52.3%)	261 (66.2%)	217 (55.4%)	273 (66.7%)
Yellow fever	217 (53.3%)	264 (67.0%)	200 (51.0%)	274 (67.0%)
Fully vaccinated [£]	117 (28.7%)	134 (34.0%)	116 (29.6%)	142 (34.7%)
Zero-dose/	121 (29.7%)	77 (19.5%)	112 (28.6%)	74 (18.1%)
Zero-dose (Nigerian NPI) ^{\$}	91 (22.4%)	53 (13.5%)	85 (21.7%)	58 (14.2%)
Zero-dose/ and malnourished*	26 (6.4%)	13 (3.3%)	25 (6.4%)	13 (3.2%)
Zero-dose/ and severely malnourished**	10 (2.5%)	5 (1.3%)	5 (1.3%)	7 (1.7%)
Vitamin A received	157 (38.6%)	200 (50.8%)	153 (39.0%)	225 (55.0%)

Footnote to Supplementary table 10:

¹ Data are n (%)

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

/ Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition.

Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b.

* Malnourished = MUAC of less than 125 mm or the presence of nutritional edema.

** Severely malnourished = MUAC of less than 115 mm or the presence of nutritional oedema.

MUAC=mid-upper-arm circumference.

£ Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card.

\$ Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

BCG: Bacillus Calmette-Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

Supplementary Table 11: Distance in kilometers between settlements and primary health care centres (PHCCs) by Local Government Area (LGA)

LGA	Number of settlements	Mean distance in kilometers	standard deviation of distance	Median distance in kilometers	IQR of distance	<5km	6-10km	11-15km	>15km	Settlements directly served by PHCC for immunization
Baseline										
Nguru	50	7.8	6.0	6	4 – 10	46%	34%	6%	14%	76%
Karasuwa	50	9.5	8.8	8	0.2 – 15.5	38%	20%	16%	26%	78%
Total	100	8.6	7.6	8	2 – 14	42%	27%	11%	20%	77%
Endline										
Nguru	50	7	5.7	5	3.2 – 9.1	56%	26%	6%	12%	66%
Karasuwa	50	11	10.1	10	1.1 – 16	34%	22%	8%	34%	74%
Total	100	9	8.4	7	2.9 – 14	45%	24%	7%	23%	70%

Supplementary Table 12: Distance in kilometers between settlements and primary health care centres (PHCCs) at baseline by Local Government Area (LGA), arm and cluster

LGA	Arm	Ward	Number of settlements	Mean distance in kilometers	standard deviation of distance	Median distance in kilometers	IQR of distance	<5km	6-10km	11-15km	>15km	Settlements directly served by PHCC for immunization
Nguru	Control	Balanguwa	5	16.0	4.0	18.0	14 – 18	0%	20%	20%	60%	100%
Nguru	Control	Bulabulin	5	7.6	3.3	8.0	8 – 10	20%	80%	0%	0%	100%
Nguru	Control	Dumsai	5	6.8	3.7	7.0	6 – 10	20%	80%	0%	0%	60%
Nguru	Control	Ngarbi	5	5.2	3.0	6.0	2 – 8	40%	60%	0%	0%	40%
Nguru	Control	Sabon Garin Kanuri	5	3.6	1.5	4.0	2 – 5	100%	0%	0%	0%	100%
Nguru	NutriVax	Afunori	5	8.0	8.6	8.0	2 – 8	40%	40%	0%	20%	40%
Nguru	NutriVax	Dabule	5	12.0	8.0	14.0	10 – 14	20%	20%	40%	20%	100%
Nguru	NutriVax	Hausari	5	3.0	1.9	3.0	3 – 4	100%	0%	0%	0%	80%
Nguru	NutriVax	Maja Kura	5	10.8	7.2	8.0	5 – 18	40%	20%	0%	40%	80%
Nguru	NutriVax	Tsohon Nguru	5	4.6	0.9	4.0	4 – 5	80%	20%	0%	0%	60%
Karasuwa	Control	Bilal Jawa	5	11.6	12.4	10.0	0 – 20	40%	20%	0%	40%	60%
Karasuwa	Control	Garin Gawo	5	11.0	7.2	13.0	8 – 16	20%	20%	20%	40%	100%
Karasuwa	Control	Jajeri	5	11.2	2.3	12.0	10 – 12	0%	40%	60%	0%	80%
Karasuwa	Control	Jajimaji	5	1.9	1.3	1.2	1 – 2.3	100%	0%	0%	0%	100%
Karasuwa	Control	Waro	5	12.8	14.7	14.0	0 – 14	40%	0%	40%	20%	80%
Karasuwa	NutriVax	Fajiganari	5	7.6	5.0	8.0	8 – 8	20%	60%	20%	0%	100%
Karasuwa	NutriVax	Gasma	5	8.4	8.5	8.0	0 – 16	40%	20%	0%	40%	60%
Karasuwa	NutriVax	Karasuwa Galu	5	15.6	11.3	16.0	14 – 16	20%	0%	20%	60%	80%
Karasuwa	NutriVax	Karasuwa Garin Guna	5	11.0	7.8	10.0	8 – 18	20%	40%	0%	40%	40%
Karasuwa	NutriVax	Wachakal	5	4.0	6.9	0.0	0 – 4	80%	0%	0%	20%	80%

Supplementary Table 13:

Distance in kilometers between settlement and primary health care centres (PHCCs) at endline by Local Government Area (LGA), arm and cluster

LGA	Arm	Ward	Number of settlements	Mean distance in kilometers	standard deviation of distance in kilometers	Median distance in kilometers	IQR of distance	<5km	6-10km	11-15km	>15km	Settlements directly served by PHCC for immunization
Nguru	Control	Balanguwa	5	11.8	7.9	14.0	4 – 18	40%	0%	20%	40%	80%
Nguru	Control	Bulabulin	5	6.6	3.8	8.0	3 – 10	40%	60%	0%	0%	100%
Nguru	Control	Dumsai	5	11.4	6.9	14.0	8 – 16	20%	20%	20%	40%	40%
Nguru	Control	Ngarbi Sabon	5	4.4	2.6	4.0	2 – 6	60%	40%	0%	0%	20%
Nguru	Control	Garin Kanuri	5	3.4	0.9	4.0	3 – 4	100%	0%	0%	0%	100%
Nguru	NutriVax	Afunori	5	6.8	5.9	6.0	4 – 8	40%	40%	0%	20%	60%
Nguru	NutriVax	Dabule	5	11.6	9.5	10.0	8 – 14	20%	40%	20%	20%	60%
Nguru	NutriVax	Hausari	5	3.6	1.1	4.0	3 – 4	100%	0%	0%	0%	80%
Nguru	NutriVax	Maja Kura	5	4.5	3.4	4.0	4 – 5	80%	20%	0%	0%	80%
Nguru	NutriVax	Tsohon Nguru	5	5.6	1.5	5.0	5 – 6	60%	40%	0%	0%	40%
Karasuwa	Control	Bilal Jawa	5	11.6	12.4	10.0	0 – 20	40%	20%	0%	40%	60%
Karasuwa	Control	Garin Gawo	5	9.0	6.2	10.0	6 – 13	20%	40%	20%	20%	100%
Karasuwa	Control	Jajeri	5	14.8	7.8	10.0	10 – 20	0%	60%	0%	40%	80%
Karasuwa	Control	Jajimaji	5	1.9	1.3	1.3	1 – 2.4	100%	0%	0%	0%	100%
Karasuwa	Control	Waro	5	18.4	15.7	18.0	6 – 32	20%	0%	0%	60%	60%
Karasuwa	NutriVax	Fajiganari	5	8.4	5.7	8.0	8 – 10	20%	60%	0%	20%	100%
Karasuwa	NutriVax	Gasma	5	8.4	8.5	8.0	0 – 16	40%	20%	0%	40%	60%
Karasuwa	NutriVax	Karasuwa Galu	5	15.6	11.3	16.0	14 – 16	20%	0%	20%	60%	80%
Karasuwa	NutriVax	Karasuwa Garin Guna	5	15.4	12.5	14.0	10 – 19	20%	20%	20%	40%	40%
Karasuwa	NutriVax	Wachakal	5	6.4	7.9	2.0	0 – 14	60%	0%	20%	20%	60%

Supplementary Table 14: Cluster level analysis of the main and secondary outcomes with non-adjusted p-values and with adjusted p-value for secondary outcomes only

Cluster-specific OR	OR*	95% CI**	p-value [□]	p-value_adj [§]
Primary outcome confirmed by card				
MCV1	2.08	(1.3–3.35)	0.0040	
Sensitivity analyses of primary outcome				
MCV1 Age<20	2.11	(1.25–3.59)	0.0074	
MCV1 (covariate-adjusted) ¹	2.18	(1.35–3.56)	0.0028	
MCV1 (covariate-adjusted) ²	2.08	(1.30–3.35)	0.004	
Secondary outcomes confirmed by card				
Vaccine card retention	2.09	(1.36–3.23)	0.0019	0.0108
Timeliness MCV1	1.78	(1.1–2.91)	0.0225	0.0294
MCV2 >15 months	1.69	(0.99–2.92)	0.0551	0.0626
Pentavalent 3	2.16	(1.38–3.41)	0.0018	0.0108
Meningitis	2.00	(1.26–3.21)	0.0056	0.0194
Zero-dose [∇]	0.50	(0.33–0.75)	0.0017	0.0108
Zero-dose [∇] and malnourished	0.45	(0.19–1.02)	0.0552	0.0626
Secondary outcomes confirmed by card or recall				
MCV1	1.93	(1.19–3.15)	0.0097	0.0198
Timeliness MCV1	1.70	(1.09–2.67)	0.0220	0.0294
MCV2 >15months	1.50	(0.93–2.45)	0.0885	0.0940
Pentavalent 3	1.97	(1.22–3.23)	0.0083	0.0198
Yellow fever	2.04	(1.26–3.33)	0.0057	0.0194
Fully vaccinated [£]	1.39	(0.86–2.25)	0.1674	0.1674
Zero-dose [∇]	0.50	(0.31–0.83)	0.0088	0.0198
Zero-dose (Nigerian NPI) ^{\$}	0.48	(0.28–0.85)	0.0136	0.0231
Zero-dose and acute malnourished	0.30	(0.13–0.72)	0.0105	0.0198
Vitamin A received	1.82	(1.12–2.96)	0.0180	0.0278

Footnotes to Supplementary table 14

*Cluster-specific OR estimated by mixed-effects logistic regression (NutriVax amr vs control amr) **from profile likelihood [□]p-value from likelihood ratio test

§ Adjusted p-values for multiple comparisons among secondary endpoints using the Benjamini–Hochberg procedure to control the false discovery rate at 5%;; p-values <0.05 considered statistically significant. The primary endpoint was tested separately.

1 Adjusted on the following variables: distance in kilometres between settlement and primary health care centre (PHCC) at endline and the binary variable of whether settlement directly deserved by PHCC for immunization at endline

2 Adjusted on the following variable: Local Government Areas

MCV1= first dose of measles-containing-vaccine. MCV2= second dose of measles-containing-vaccine.

Timeliness of MCV1 is defined as receipt of the first measles vaccine dose within one month one month of a child's 9-month birthday.

/Zero-dose: children who had not received any pentavalent vaccines according to WHO/GAVI definition.

Pentavalent vaccine protects against diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type b.

Malnourished = MUAC of less than 125 mm or the presence of nutritional edema.

£Fully vaccinated refers to children with BCG, pentavalent-3, PCV-3, OPV-3, at least one dose of measles, yellow fever confirmed by card or recall and IPV-2, meningitis confirmed by card. BCG: Bacillus Calmette–Guérin; OPV: Oral Polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; IPV: Inactivated Polio vaccine.

\$Zero-dose (Nigerian NPI) refers to children with no BCG, no pentavalent-1, no PCV-1, no OPV-1, no MCV1, no Yellow fever confirmed by card or recall and no IPV1, no Meningitis confirmed by card.

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1, 2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{1,2}	See table 2	2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	22
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	22
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Non-relevant
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	26
	4b	Settings and locations where the data were collected		4, 23
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	24
Outcomes	6a	Completely defined pre-specified primary and	Whether outcome measures pertain to the cluster level, the	4, 26

		secondary outcome measures, including how and when they were assessed	individual participant level or both	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		26
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	27
	7b	When applicable, explanation of any interim analyses and stopping guidelines		Non applicable
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		22-23
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	5, 22-23
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	23
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	22

	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	22
	10c	From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	29
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	23
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account 27-28
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	27-28
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome 5
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members 5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5

	14b	Why the trial ended or was stopped		Not relevant
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Page 5; Table 1 page 18-19; table 2 page 20
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Page 5; Figure 1 page 16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Page 5-6 and Extended Data table 7 and Extended Data table 10
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		5-7; figure 2 page 17 and table 3 page 21
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		6-7
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ³)		7
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and		7-10

considering other relevant evidence			
Other information			
Registration	23	Registration number and name of trial registry	2, 32
Protocol	24	Where the full trial protocol can be accessed, if available	23, 28
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts^{1,2} to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	Identification of study as cluster randomised
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	yes
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	yes
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both
Outcome	Clearly defined primary outcome for this report	Whether the primary outcome pertains to the cluster level, the individual participant level or both
Randomization	How participants were allocated to interventions	How clusters were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	Number of clusters randomized to each group
Recruitment	Trial status ¹	
Numbers analysed	Number of participants analysed in each group	Number of clusters analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results at the cluster or individual participant level as applicable for each primary outcome
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

¹ Relevant to Conference Abstracts

REFERENCES

- ¹ Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283
- ² Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20
- ³ Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.