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Emerging Evidence Lightning Talks

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Food Assistance for Nutrition Evidence Summit
Washington D.C.

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Milk protein and micronutrients added to a school meal improves cognition in Ghanaian children

June 27, 2018

Food Assistance for Nutrition Evidence Summit

Washington D.C.

Dani Van Liefde, Mark Manary, MD

What we know

1 in 5 children receive a school meal

Ghana: Government school feeding program since 2005

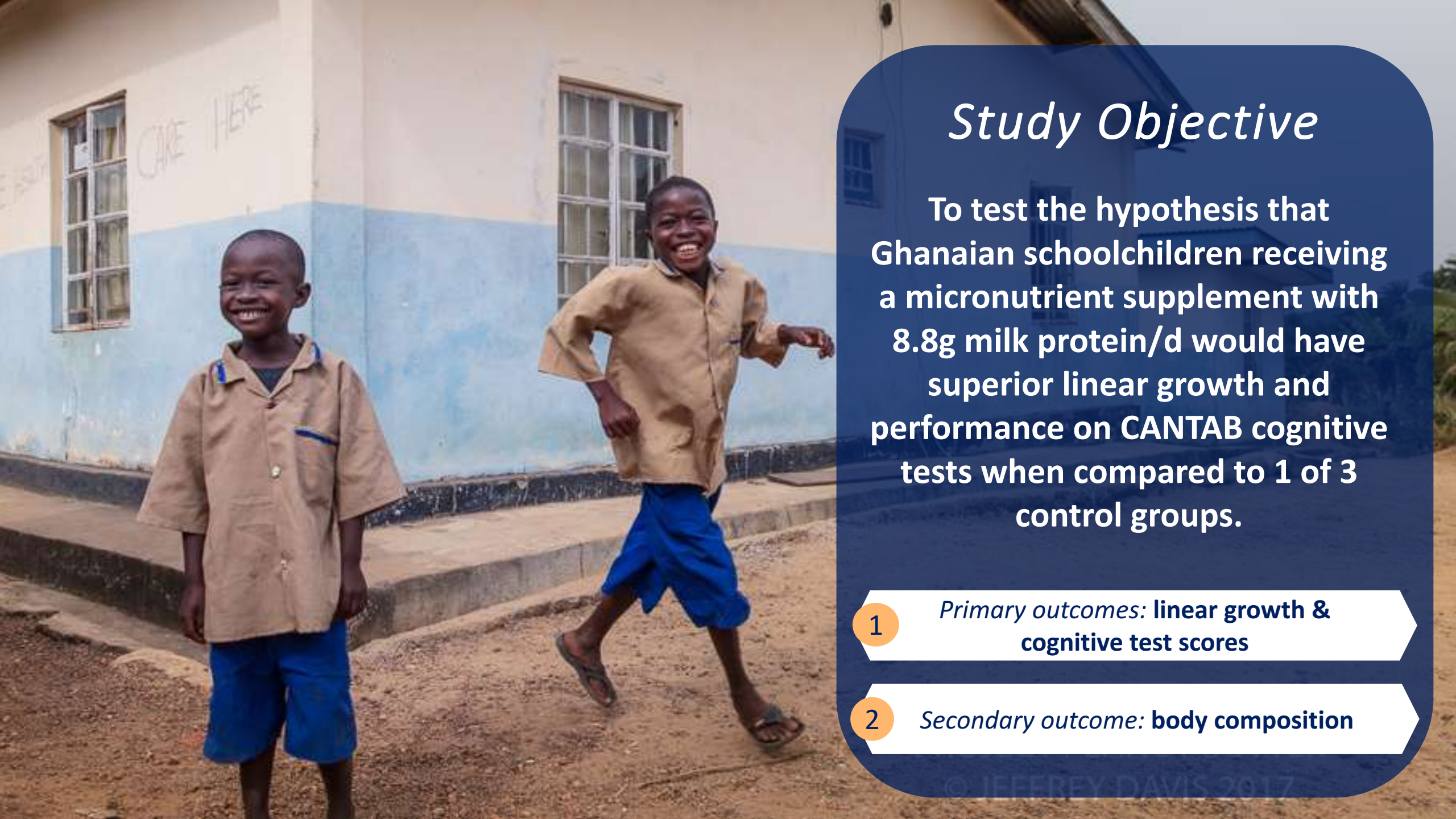
- 1 nutritious meal/day; Covers 38% of school population.
- Costs $0.25/child/day and ~35 million USD/year
- Multisector approach engaging 7 government ministries

In Reality -

- Food is served about 1/3 of the time at participating schools
- No regulation on the foods served – mostly boiled cereal, maize or rice

Benefits of school feeding:

- Increase school attendance, enrollment and alleviates short-term hunger
- Cow's milk in school meal: stimulates weight gain, linear growth, improves nutrition status – mixed results
  - ➢ Effects on cognition?



Study Objective

To test the hypothesis that Ghanaian schoolchildren receiving a micronutrient supplement with 8.8g milk protein/d would have superior linear growth and performance on CANTAB cognitive tests when compared to 1 of 3 control groups.

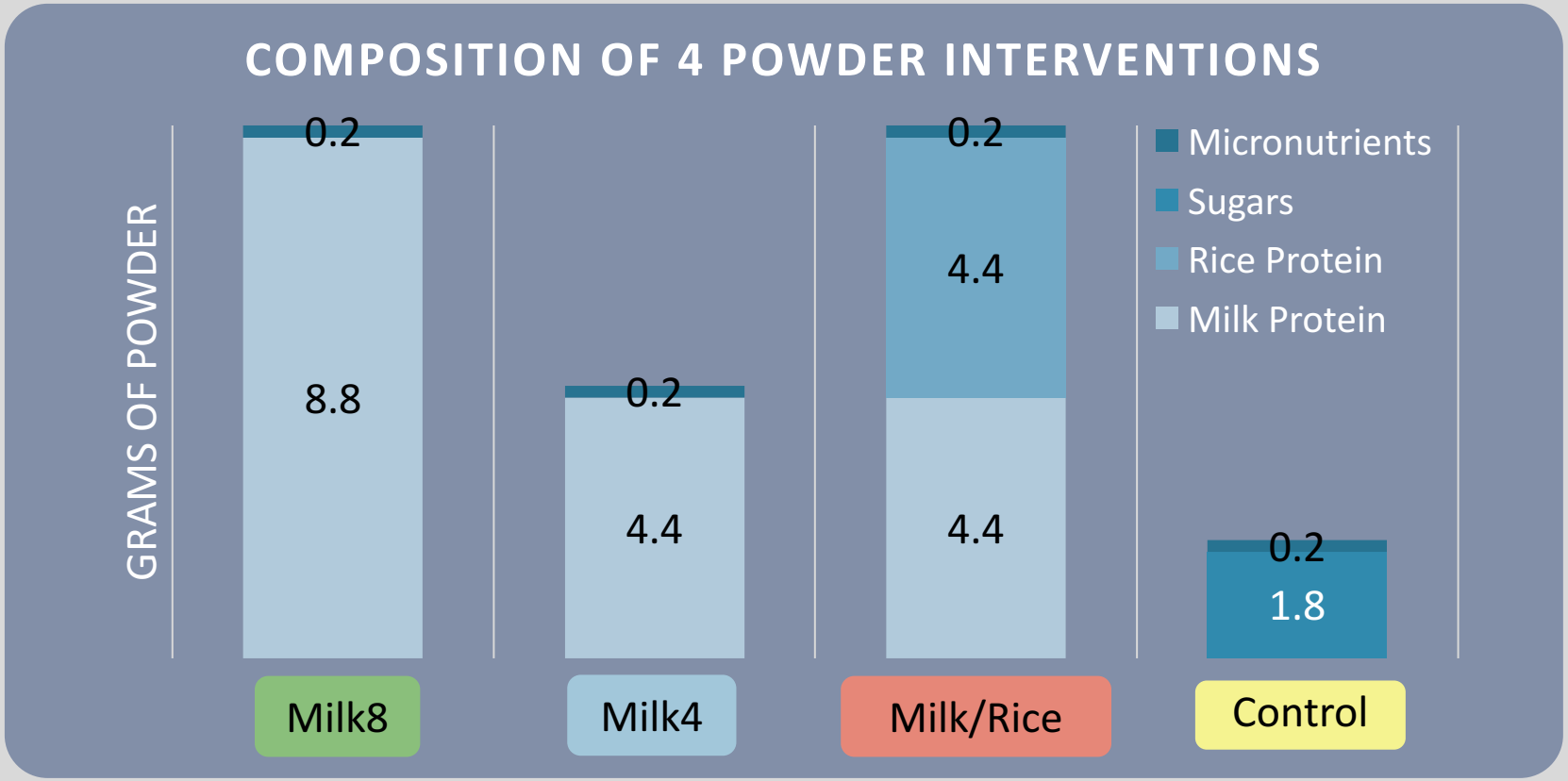
1. *Primary outcomes:* **linear growth & cognitive test scores**
2. *Secondary outcome:* **body composition**

LOCATION: ATEBUBU

PARTICIPANTS

- *Evenly M/F*
- *6-9 years old (average 7.5)*
- *Siblings: 4 average*
- *57% clean water source*
- *51% contained stool disposal*
- ***Only 1 household owned a computer***
- ***Dairy consumption average: 1 day/week average***
- ***Meat consumption average: every 3 days***

Intervention Supplements *by Arla*



- 13 schools, 1400 children
- randomized into 4 color-coded groups
- Breakfast + supplement each school day for 9 months
- Attendance was taken daily; cooks/assistants ensured full consumption of meal.

Assessments: baseline, 4.5 and 9 months

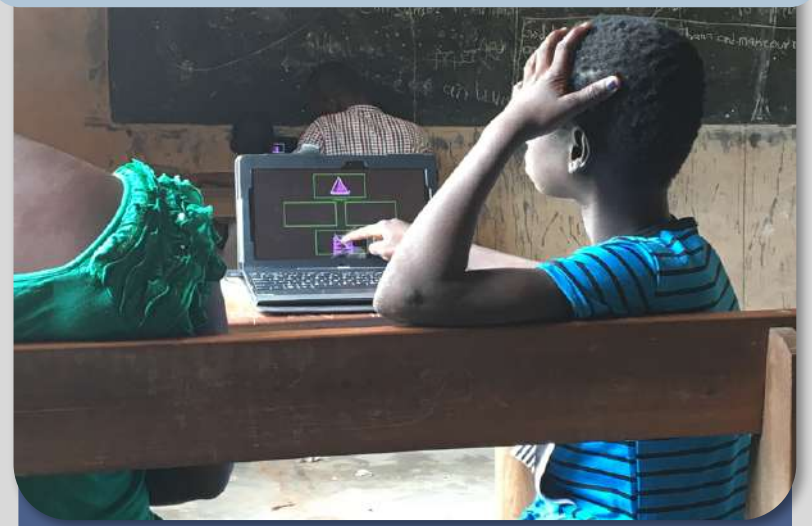
ANTHROPOMETRICS

Measurements:

- Height
- Weight
- MUAC

1 ΔHAZ – 9 months

COGNITION



CANTAB: 5 tests, 13 scores

1. Motor Screening Task (MOT)
2. Big/Little Circle (BLC)
3. **Paired-Associated Learning (PAL)**
4. **Pattern Recognition Memory (PRM)**
5. **Intra/Extradimensional Set Shift (IED)**

1 Δ 13 Scores – 4.5 months

BODY COMPOSITION

RJL Systems Quantum IV Bioelectric Impedance Analyzer

- Fat Mass (FM)
- Fat Free Mass (FFM)
- Lean Dry Mass (LDM)
- Total Body Water (TBW)

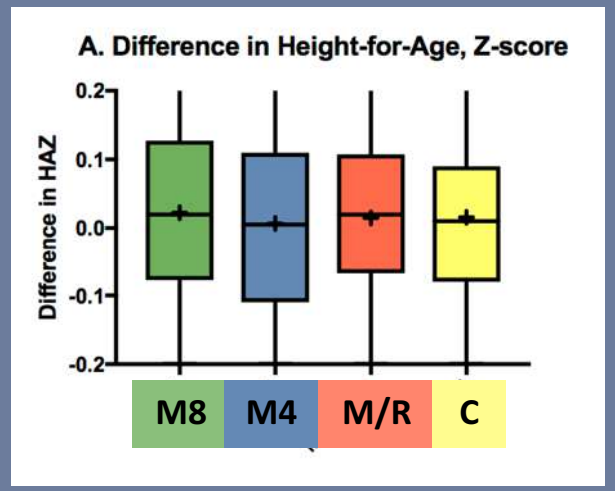
2 ΔFFMI – 9 months

Results

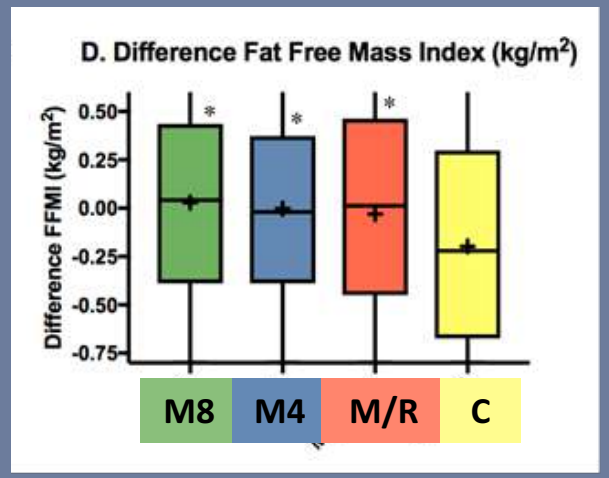
BASELINE: No differences between the 4 supplement groups

Milk8 | Milk4 | Milk/Rice | Control

1 ANTHRO: HAZ ❌



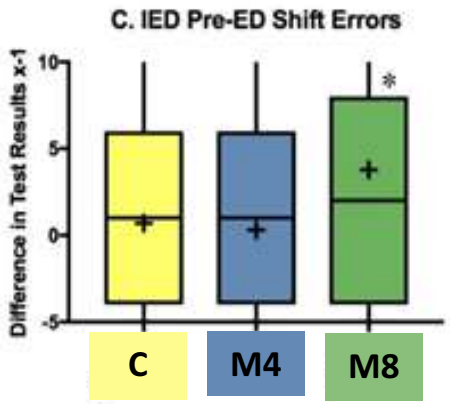
2 BODY COMP: FFMI ✅

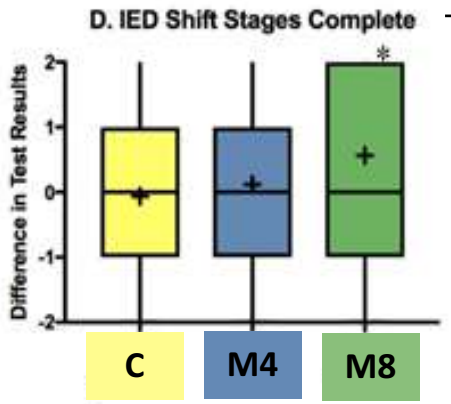


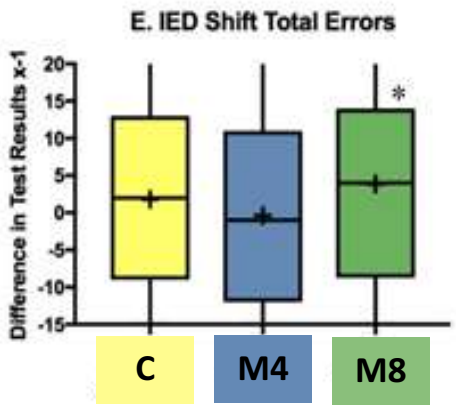
1 COGNITION: CANTAB – PRM and IED Tests ✅

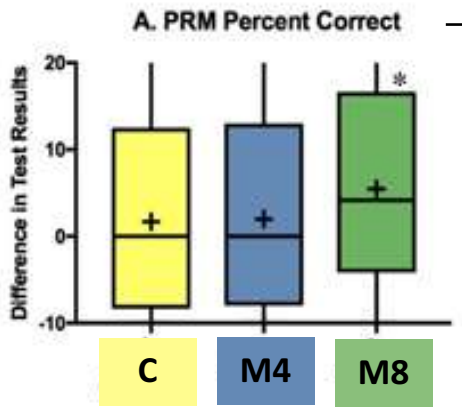
0g Milk vs. 4g Milk vs. 8g Milk

PRM 1/2 tests; IED 3/3 tests

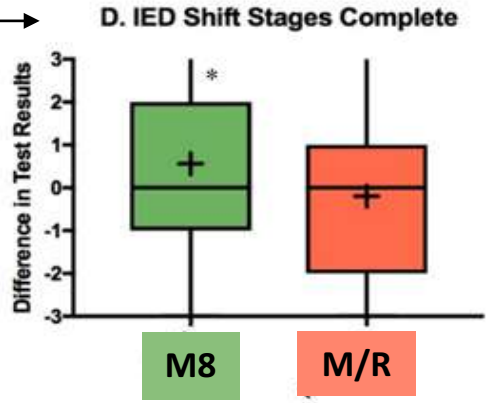


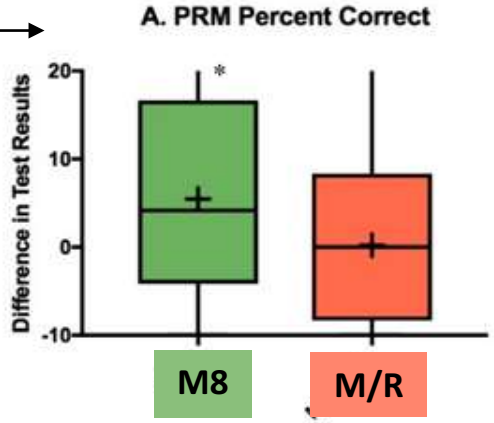






8g Milk vs. 8g Milk/Rice





CONCLUSIONS

Ghanaian school children consuming 8.8g milk protein + micronutrients in a school meal demonstrated…

- Improvement in executive cognitive function at 4.5 months
- No effect on linear growth after 9 months

All groups consuming milk protein led to the accretion of more fat free mass than the control after 9 months.

Supplements cost $0.06

Food Assistance For Nutrition Evidence Summit, June 27-28, 2018, Washington D.C.
Organized by the Food Aid Quality Review (FAQR) Project and United States Agency for International Development (USAID)/Office of Food for Peace (FFP)

Testing Novel Supplementary Food Formulation in Young Children in Rural Villages in Low-Income Country:

Results of RCT in children aged 15 months – 7 years in Guinea-Bissau

Susan B. Roberts, PhD

Director, Energy Metabolism Laboratory
Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University

Professor of Nutrition, Tufts University

Professor of Psychiatry & Scientific Staff Member in Pediatrics, Tufts Medical School

IPHD

GLOBAL FOOD & NUTRITION INC.

Tufts UNIVERSITY

New Supplement Design

- Emphasizes polyphenol-rich ingredients both for potential cognitive effects (neurogenesis, myelination, inflammation) and as source of micronutrients: cocoa, fish oil
- Adds micronutrients as needed to get all micronutrients as close to daily requirements as possible (e.g. 100% RDA iron)
- Protein 22% calories
- Blended preparation approach: prepared in the village from local ingredients plus imported mix of ingredients not available locally

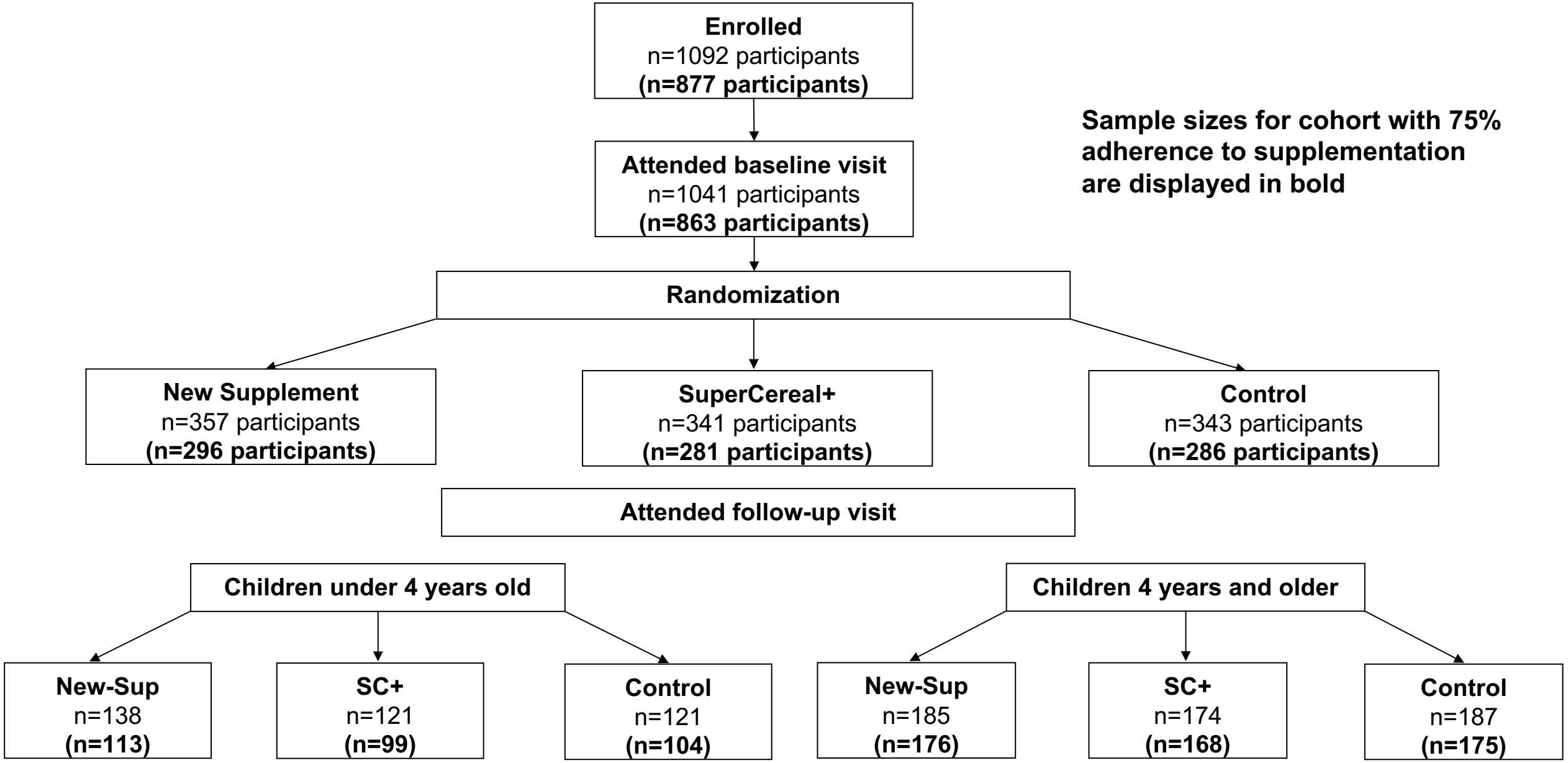
2017 Efficacy Trial

- Based on published pilot that showed significant cognitive benefit (Roberts et al. https://doi.org/10.3945/cdn.117.000885)
- Conducted powered RCT with 3 supplements
- Hypothesis: new supplement will improve cognitive function (primary outcome) as well as body composition, anemia and brain blood flow relative to traditional breakfast in children <4 years who eat most of provided supplement (defined >75%)
- Also compared SuperCereal+ to the traditional breakfast

Protocol

- Randomized controlled trial of 3 supplements 5 d/week for ≈6 months in 10 villages (n=1092 children 15 months to ≈7 years w/ >300 <4 years)
  - Randomization families within villages
  - New-Sup, SuperCereal+ porridge, Control (traditional rice breakfast)
- Outcomes measured at baseline (before supplementation) and 6 months
  - Primary: executive function (working memory) measured by local adaptation of classic Spin-the-Pot test
  - Secondary: growth, hemoglobin, supplement adherence, safety, brain blood flow
- High supplement consumption in all groups (83% New-Sup, 81% SC+, 83% Control, P=0.52)

Consort diagram: overall and 75% supplement adherence cohorts



Sample sizes for cohort with 75% adherence to supplementation are displayed in bold

Descriptive Statistics
Children < 4 years with ≥75% adherence

	New-Sup	SC+	Control	P BL
	Baseline	Baseline	Baseline	
Age (years)	3.0 ± 0.7	2.9 ± 0.7	2.9 ± 0.7	
N (M/F)	120 (63/57)	107 (56/51)	108 (66/42)	
Adherence (%)	90 ± 6	92 ± 5	93 ± 5	
Weight-for-Age Z	-1.29 ± 0.9	-1.22 ± 1.0	-1.33 ± 1.1	
Height-for-age Z	-1.74 ± 1.2	-1.67 ± 1.4	-1.80 ± 1.5	
BMI for age Z	-0.26 ± 1.0	-0.20 ± 1.0	-0.26 ± 1.0	
Hemoglobin (g/dL)	10.3 ± 1.3	9.8 ± 1.4	10.0 ± 1.5	*
% sev/mod anemia	0+32	5+36	1+33	
Lean arm tissue (skinfolds+MUAC)	1.8 ± 1.3	1.9 ± 1.4	1.9 ± 1.4	

Summary:
Multiple benefits for brain and body

- Need to publish results in peer-reviewed journal before public dissemination
- Results in the analysis so far:
  - High rates of consumption – children liked new supplement
  - Beneficial effects on executive function in predefined primary outcome and predefined analyses
    - Related - increase brain blood flow
  - Beneficial effects on anemia (>SC+ or traditional)
  - (Preferentially builds muscle with much less fat deposition c/w SuperCereal+)

Opportunities

- **Identify most active constituents in this multi-component supplement?**
- **Scaling:**
  Use of new supplement in Guinea-Bissau and other low income countries with low baseline nutrition to improve treatment of anemia, muscle loss and cognition?
- **Long-term supplementation:**
  Combine with educational enrichment to demonstrate accelerated learning?

RESEARCH ON FOOD ASSISTANCE FOR NUTRITIONAL IMPACT

FAQR Evidence for Action, Washington DC

June 2018

REFANI

Introduction

Consortium partners:

- Action Against Hunger
- Concern Worldwide (CWW)
- Emergency Nutrition Network (ENN)
- University College London (UCL)

Funding:

- UK aid from the UK Government
- Humanitarian aid from the European Commission

Duration: March 2014 – May 2017

REFANI Research Questions

PRIMARY QUESTION

Can Cash Based Interventions (CBI) protect nutritional status in children (aged 6-59 months) in a range of crisis contexts?

REFANI Country Studies

Pakistan

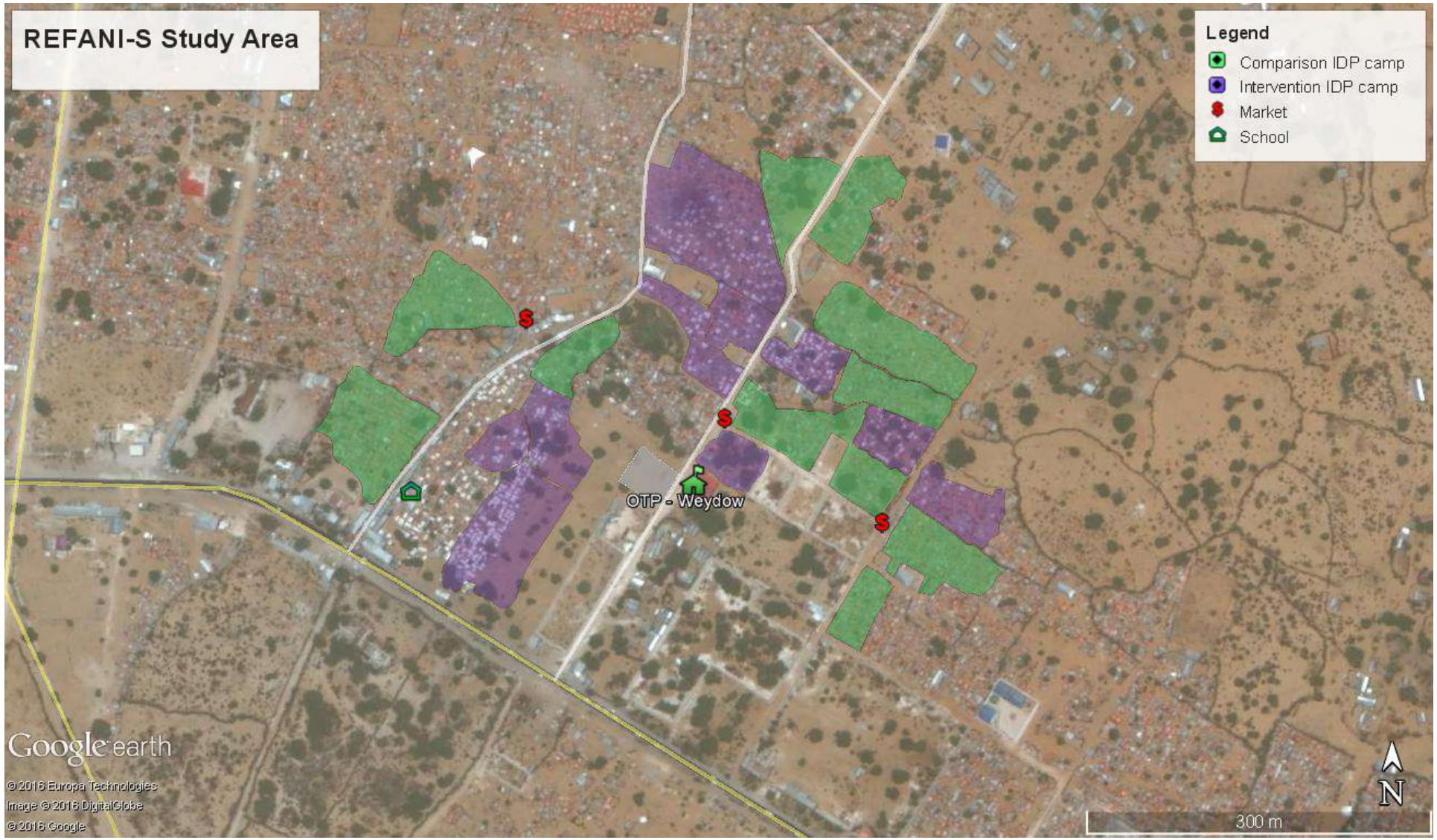
Niger

Somalia

DADU, SINDH PROVINCE

AFGOYE CORRIDOR

TAHOUA DISTRICT


REFANI-S Study Area
Legend
Comparison IDP camp
Intervention IDP camp
Market
School
OTP - Weydow
Google earth
© 2016 Europa Technologies
Image © 2016 DigitalGlobe
© 2016 Google
300 m
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Study Interventions

Study Country and Arm		Type of Cash or voucher transfer	Amount of transfer per month: Local currency	Amount of transfer per month: $US	Duration and dates of distribution programme	Total amount of transfer $US	Target recipient or cash or voucher transfer	Complementary interventions
Niger	Standard Cash	Seasonal unconditional cash transfer	CFA 32,500	58	4 months, Jun-Sep 2015	233	Mothers	4 months supplementary feeding
	Modified Cash	Earlier and longer seasonal unconditional cash transfer	CFA 21,666	39	6 months, Apr-Sep 2015	233	Mothers	4 months supplementary feeding
Pakistan	Control			0	6 months, Jul–Dec 2015	0		WINS
	Standard Cash	Unconditional cash transfer	PKR 1,500	15	6 months, Jul–Dec 2015	88	Mothers	WINS
	Double Cash	Unconditional cash transfer	PKR 3,000	29	6 months, Jul–Dec 2015	175	Mothers	WINS
	Fresh Food Voucher	Voucher transfer	PKR 1,500	15	6 months, Jul–Dec 2015	88	Mothers	WINS
Somalia[1]	Control			0	5 months, May–Oct 2016	0		
	Intervention	Unconditional cash transfer, NFI[2] kits, free piped drinking water		84	5 months, May–Oct 2016	420.00	Mothers	Free drinking water, non-food item kit

Household Results

Study Country & Arm		Household: Household Total Expenditure ($US/30 days)		Household: Household Food Expenditure ($US/30 days)		Household: Household Dietary Diversity Score	
		Baseline mean ± SD	*Intervention effect after 6 months (95% CI)*	*Baseline mean ± SD*	*Intervention effect after 6 months (95% CI)*	*Baseline mean ± SD*	*Intervention effect after 6 months (95% CI)*
Niger	Standard Cash	42.04 ± 26.14		32.12 (28.42, 35.66)		4.0 ± 2.0	
	Modified Cash	42.93 ± 28.38	-2.31 (-8.11, 3.48) P>0.05	34.05 (31.97, 35.97)	-2.38 (-8.45, 3.69) P>0.05	4.2 ± 1.9	0.47 (-1.57, 2.50) P=0.636
Pakistan	Control	77.3 ± 36.1		53.0 (18.3, 70.8)		9.5 ±1.7	
	Standard Cash	70.8 ± 33.6	10.0 (5.4, 14.5) **P<0.001**	38.9 (17.2, 61.3)	9.5 (6.0, 12.9) **P<0.001**	9.2 ±2.0	0.80 (0.57, 1.04) **P<0.001**
	Double Cash	79.0 ± 32.9	4.5 (-0.1, 9.1) P=0.06	48.2 (16.5, 68.2)	8.2 (4.7, 11.7) **P<0.001**	9.5 ±1.5	1.41 (1.18, 1.65) **P<0.001**
	Fresh Food Voucher	73.8 ± 37.3	3.1 (-1.4, 7.7) P=0.18	50.6 (18.2, 69.2)	2.9 (-0.6, 6.3) P=0.10	9.2 ±1.8	0.13 (-0.10, 0.37) P=0.27
Somalia	Control	75.7 ± 37.3		49.0 ± 25.2		6.56 ± 1.5	
	Intervention	92.1 ± 49.1	29.6 (3.5; 55.7) **P=0.028**	68.8 ± 35.1	10.8 (-7.5; 29.0) P=0.20	7.16 ± 1.5	0.99 (0.09; 1.90) **P=0.033**

1 TheHousehold Food Insecurity Access Scale (HFIAS) was also measured in Niger and this showed a significant improvement in household food security in households receiving the modified CTP during the initial 2 months of the transfer when the standard cash arm was not receiving cash (P<0.001 & P=0.0019).

2 NM – not measured

Diet Diversity in Children

		Individual Dietary Diversity Score		*Recent*
		Baseline	*6-month intervention effect (95% CI)*[2]	*Baseline prevale*
Niger	Standard Cash	2.3 ± 1.3		27.5 (18.0,
	Modified Cash	2.5 ± 1.3	-0.03 (-0.59, 0.52) P=0.904	31.5 (26.8,
Pakistan	Control	7.5 ± 2.0		82.5 (79.8,
	Standard Cash	7.0 ± 1.9	0.59 (0.39, 0.79) **P<0.001**	75.9 (73.0,
	Double Cash	7.1 ± 2.0	0.73 (0.53, 0.93) **P<0.001**	80.7 (77.8,
	Fresh Food Voucher	7.2 ± 1.9	0.43 (0.23, 0.63) **P=0.001**	78.9 (76.0,
Somalia	Control	2.37 ± 0.97		68.5 (63.0,
	Intervention	2.95 ±1.03	0.57 (0.04, 1.10) **P=0.036**	74.3 (62.2;

1 Intervention effects are shown as the change in the mean or proportion (difference in differe
2 A 2-week recall period was used in Pakistan and a 4-week recall period was used in Niger and Somalia.

Primary Outcomes: Children

Study Country & Arm	
Niger	Standard Cash
	Modified Cash
	Control
Pakistan	Standard Cash
	Double Cash
	Fresh Food Voucher
Somalia	Control
	Intervention

Secondary Outcomes: Children

		Stunting (HAZ <-2)		
		Baseline prevalence	*6-month intervention effect*	*12-month intervention effect*
Niger	Standard Cash	36.6% (33.0, 40.3)		
	Modified Cash	34.8% (30.6, 39.3)	OR 1.33 (0.97, 1.84) P=0.078	NM
Pakistan	Control	51.7% (48.2-55.1)		
	Standard Cash	50.9% (47.6-54.2)	OR 0.36 (0.22, 0.59) **P<0.001**	OR 0.54 (0.36, 0.81) **P=0.003**
	Double Cash	46.5% (43.0-(49.9)	OR 0.39 (0.24, 0.64) **P<0.001**	OR 0.53 (0.35, 0.82) **P=0.004**
	Fresh Food Voucher	54.9% (51.5-58.3)	OR 0.41 (0.25, 0.67) **P<0.001**	OR 0.48 (0.31, 0.73) **P=0.001**
Somalia	Control	45.4% (36.4, 54.2)		NM
	Intervention[1]	55.5% (44.6, 65.9)	-0.16% (-7.61, 7.29) P=0.9	NM

Conclusions and Recommendations

- The combined findings indicate that cash and voucher transfers are *only effective* at reducing *acute malnutrition* in *some contexts* and the effect size may be small.
- This finding is consistent with the existing literature from development contexts and is unsurprising given the multiple causes of malnutrition and the fact that only some of these risk factors are likely to improve following short term cash or voucher transfers to individuals.
- The Pakistan study found compelling evidence that cash and voucher transfers can increase mean HAZ and *reduce stunting, with moderate effect sizes*.

Conclusions and Recommendations

- CBI are a useful tool in humanitarian response but they will not usually be adequate, *by themselves*, to achieve humanitarian nutrition and health objectives.
- Important drivers of health and nutrition outcomes, including access to vaccination, WASH infrastructure, and access to curative nutrition and health services, are unlikely to be removed by cash transfers to individual beneficiaries in most contexts, and will continue to require direct, sector-specific interventions.
- Research in difficult humanitarian contexts is important and possible, given donor support and strong partnerships.

Impact of food supplements on fat-free mass, hemoglobin, iron status, and inflammation in children with moderate acute malnutrition: a 2x2x3 factorial randomized trial in Burkina Faso

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UNIVERSITY OF TAMPERE
SCHOOL OF MEDICINE
DEPARTMENT FOR INTERNATIONAL HEALTH

Treatfood Project – Burkina Faso

- Objective: to assess the impact on weight gain, body composition (measured with D2O) and Hb status of:

  Corn-soy blend vs. lipid based supplements (LNS)

  Milk vs. soy as protein source

  dehulled soy vs. soy isolates
- Settings: ALIMA project, Province du Passoré, Burkina Faso
- Subjects: 6-23 months children with MAM:
  - MUAC 115-125mm or WHZ >-3 <-2

Trial registration: ISRCTN42569496

Fabiansen C et al. PLoS Med. 2017 Sep 11;14(9):e1002387

Study design

Matrix	Soy quality	Milk (% of protein) 0	20	50
R → CSB	Dehulled	A	B	C
	Isolate	D	E	F
R → LNS	Dehulled	G	H	I
	Isolate	J	K	L

All supplements provided 500 kcal; all had the same mineral vitamin premix

Results (1)

	Matrix	Soy quality	Milk protein (%)	
	LNS vs CSB	Isolate vs dehulled	20% vs 0%	50% vs 0%
FFMI (kg/m²)	**0·083 (0·003; 0·163)**	0·038 (-0·042; 0·118)	**0·097 (-0·002; 0·196)**	**0·049 (-0·047; 0·146)**
FMI (kg/m²)	0·052 (-0·024; 0·127)	-0·003(-0·078; 0·073)	**-0·085 (-0·178; 0·008)**	**-0·064 (-0·155; 0·028)**
FFM (g)	37 (-10; 84)	24 (-23; 71)	40 (-18; 99)	29 (-28; 87)
FM (g)	28 (-12; 67)	1 (-38; 40)	-41 (-90; 8)	-30 (-77; 18)
Weight (g)	**75 (32; 119)**	**36 (-8; 79)**	9 (-45; 63)	20 (-33; 73)
Length (cm)	0·03 (-0·05; 0·11)	0·02 (-0·07; 0·1)	0·03 (-0·08; 0·13)	0·07 (-0·03; 0·17)
Weight-height Z	**0·11 (0·04; 0·17)**	0·05 (-0·01; 0·11)	0 (-0·07; 0·08)	0·01 (-0·07; 0·09)
Knee-heel (mm)	0·4 (-0·2; 1)	0 (-0·6; 0·6)	**0·6 (-0·2; 1·3)**	**0·7 (-0·052; 1·4)**
MUAC (mm)	**1 (0·5; 1·6)**	0·3 (-0·24; 0·85)	0·5 (-0·2; 1)	0·2 (-0·5; 0·9)
Triceps (mm)	**0·16 (0·06; 0·25)**	0·06 (-0·04; 0·16)	-0·05 (-0·18; 0·07)	-0·09 (-0·21; 0·03)

- LNS increased fat-free mass accretion relative to CSB
- Soy isolate had no main effect. If beneficial, only in LNS
- Milk only marginally significantly increased FFMI and knee-heel length

Results (2)

- LNS vs CSB
  - Hemoglobin: 3 (1; 4) g/L
  - Serum ferritin: 4.3 (6.6; 12.3) µg/L
  - Serum sTfr: -1.0 (-1.4; -0.6) mg/L
- Soy quality
  - No effects
- Milk content
  - No effects

- LNS increased iron status and haemoglobin relative to CSB
- Soy isolate had no main effect.
- Milk had no effect

Note: LNS also had an effect on inflammation markers

Cichon B et al, Am J Clin Nutr. 2018 Feb 1;107(2):278-286.

Discussion: main effect (1)

Children gained predominantly fat free mass (93.5%), like well nourished children of the same age, even when they received lipid based supplements

Higher-fat free mass index with LNS

Muscle, a major component of fat-free mass protective against chronic diseases by improving insulin sensitivity

Concern re. an increased risk of obesity and chronic diseases with LNS and other food supplements in MAM children not supported by these data

Discussion: main effect (2)

LNS lead to significantly higher weight gain and higher fat free mas index; consistent with previous studies

No clear effect of milk compared to soy:

- **No dose effect relationship**
- **Not consistent with previous studies on SAM children**
- **Mechanism of the usual effect of milk products unknown:**
  - **AA profile ?**
  - **Protein level ?**

No effect of soy isolates compared to dehulled soy:
High nutrient / phytate ratio ? No effect on mineral absorption ?

Discussion (3): Hb, iron and inflammation

LNS led to significantly higher Hb concentration

All markers of iron status suggest improvement

Explanation: better acceptability ? Less sharing ? Better absorption with a vitamin C effect ? Less antinutrients ?

Effect of LNS on inflammation markers:
Explanation: increased infection ? No evidence; no difference in malaria diagnostic; increased iron and LA intake ?

Acknowledgements:

Took part in this study:

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And the Burkina Faso team:

93 project staff

~ 300 CHW

Lower cost efficacious RUTF

made in developing countries

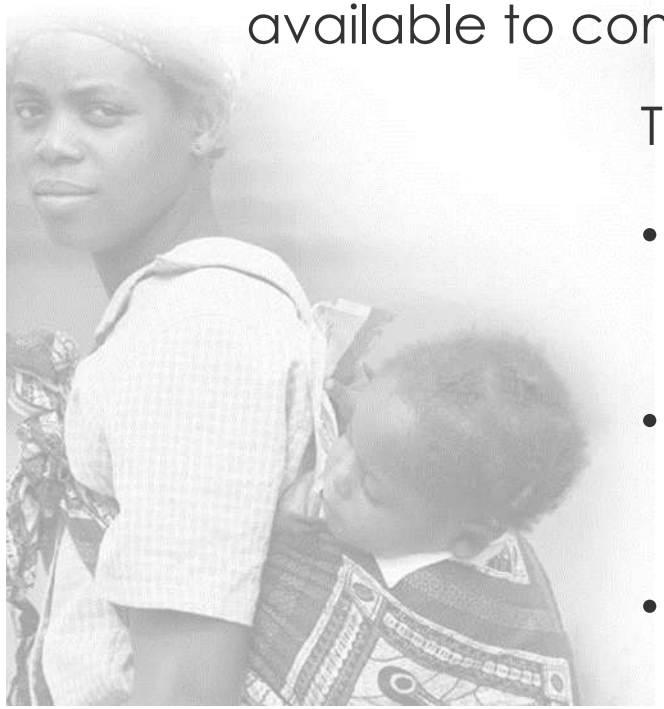
Steve Collins
Valid Nutrition

Our Mission

VALID NUTRITION

Breaking the mould and driving evidence-based change

We exist to make effective affordable and appealing nutrition available to consumers in developing countries - at scale.



To do things differently we must:

- Offer **better and less costly nutritional products**
- **Source and manufacture in developing countries**
- Treat recipients as proactive clients & **focus on "demand" not just "supply"**

Soya, Maize, Sorghum (SMS)- RUTF with Amino Acid

Three arm non-inferiority individually randomized controlled efficacy trial

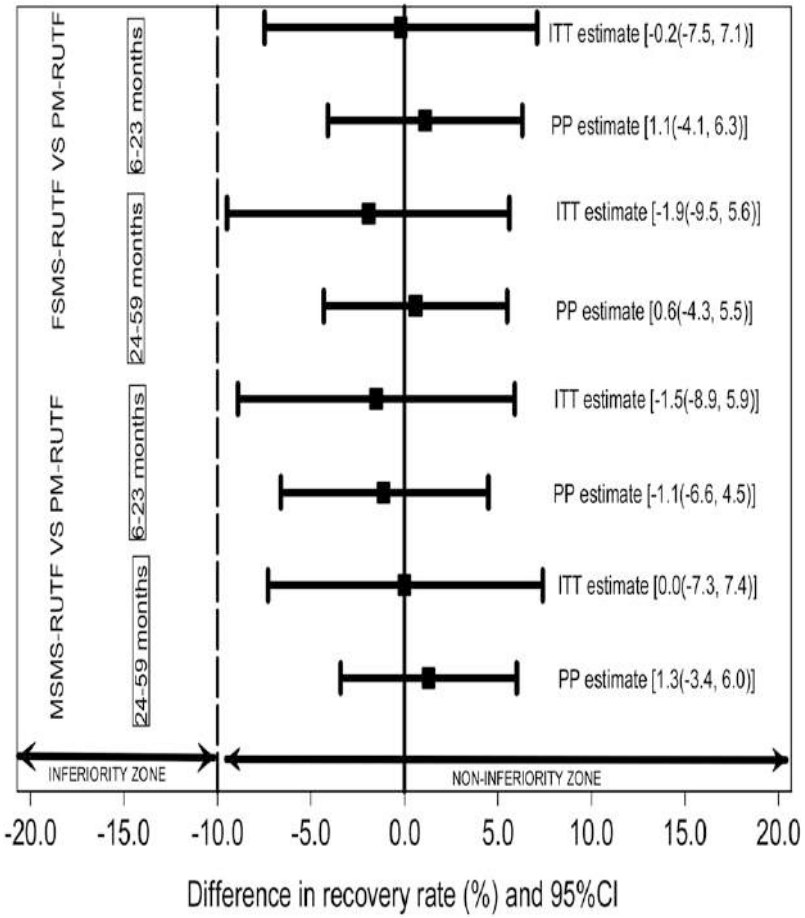
Bahwere et al. Am J Clin Nutr. 2017 Oct;106(4):1100-1112.

No Milk	9.3% milk	25% milk
ITT analyses = **433** (262/171)	**ITT analyses**=**420** (253/167)	**ITT analyses**=**446** (280/166)
PP analysis	**PP analysis**	**PP analysis**
cure rate=360 (211/149)	cure rate=355 (205/150)	cure rate=380 (229/151)
Defaulters excluded n=73 (51/22)	Defaulters excluded n=65 (48/17)	Defaulters excluded n=66 (51/15)
Weight gain & LOS=340 (196/144)	Weight gain & LOS=330 (186/144)	Weight gain & LOS=353 (210/143)
Not cured excluded n=93 (66/27)	Not cured excluded n=90 (67/23)	Not cured excluded n=93 (70/23)

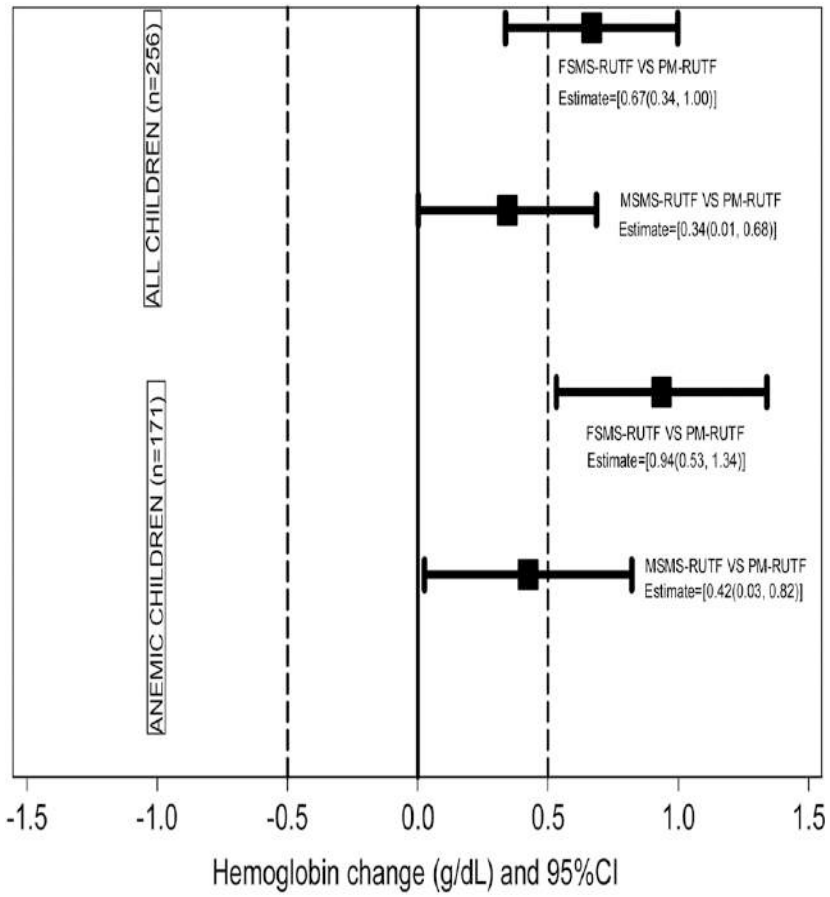
Numbers in each analysis - Total (< 24 months / >= 24 months)

More efficacious products

Recovery rates equivalent to Peanut Milk recipe RUTF



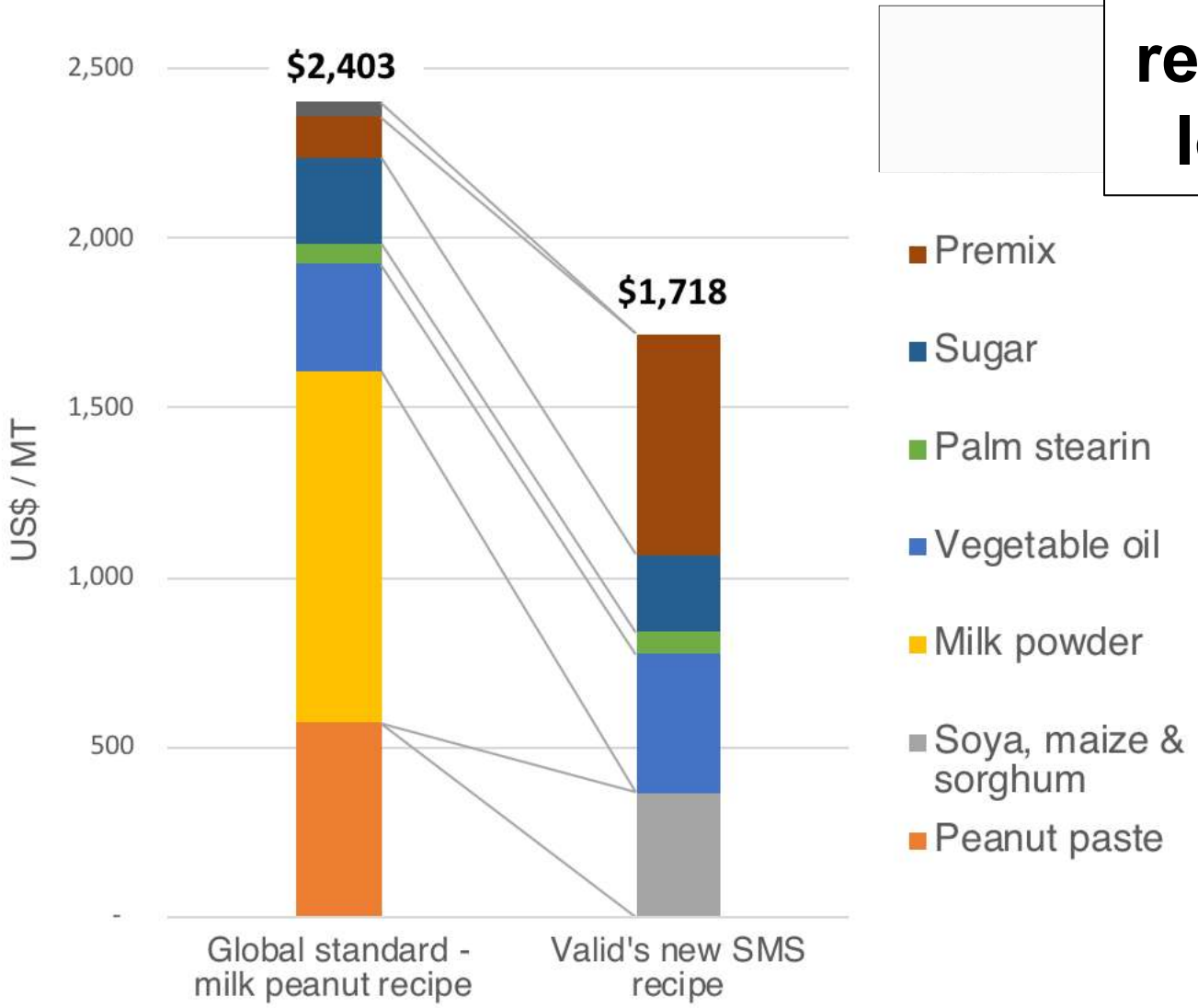
Treatment of anaemia superior to Peanut Milk recipe RUTF



Source: Am J Clin Nutr. **2017 Oct;106(4):1100-1112.**

Cost comparison Soya Maize Sorghum RUTF Vs standard milk peanut RUTF

Lower cost recipes using local crops



Source: Valid Nutrition 2017

Other benefits of Soya Maize Sorghum RUTF compared to the standard milk peanut RUTF

- **Easier and safer to manufacture and use**
  - Reduced aflatoxin risk from peanuts
  - Decreased risk of allergic reaction to peanuts amongst users
  - Decreased costs and working capital requirements for manufacture in developing countries
  - No issues with lactose intolerance
- **Decreased carbon foot print and enhanced sustainability**
  - Use of plant origin ingredients grown in developing countries
  - Few food miles for production and use
- 10% lower sugar content

Agricultural diversity & sustainability

Economic empowerment

Recipes using local crops

Valid's Model

Lower cost more efficacious products

Thank you for listening