

# DESIGN OF A PROSPECTIVE, RANDOMIZED EVALUATION OF AN INTEGRATED NUTRITION PROGRAM IN RURAL VIET NAM \*

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## Abstract

*Few prospective studies of child growth and its determinants take place in programmatic contexts. We evaluated the effect of Save the Children's (SC) community empowerment and nutrition program (CENP) on child growth, care, morbidity, empowerment, and behavioral determinants. This paper describes the research methods of this community – based study. We used a longitudinal, prospective, randomized design. We selected 12 impoverished communes with documented child malnutrition, three comparison, and intervention communes in each of two districts in Phu Tho Province, west of Hanoi. SC taught district trainers in November 1999 to train local health volunteers to implement the 10 month CENP, including situation analysis, positive deviance (PD) inquiry, growth monitoring and promotion, nutrition education and rehabilitation program (NERP), deworming, and monitoring. PD inquiries aim to discover successful care practices in poor households that likely promote well – nourished children. NERPs are neighborhood – based, facilitated group learning sessions where caregivers of malnourished children learn and practice PD and other healthy behaviors. We dewormed all intervention and comparison children. We randomly selected 240 children 5 to 25 months of age (120 intervention and 120 comparison). We gathered information on nutritional status, diet, illness, care, behavioral determinants, empowerment, and program quality, monthly for six months with a re-survey at 12 months.*

*We collected most information through maternal interview but also observed hygiene and program quality, and videotaped feedings at home. Some implementation and research limitations will attenuate CENP impact and measurement of its effectiveness.*

**Key words:** Positive deviance, effectiveness evaluation, child nutrition, Viet Nam, hearth, diet, child – care, malnutrition

## Introduction

The VISION (Viet Nam study to improve outcomes in nutrition) project evaluated the implementation and impact of an integrated nutrition program on the nutritional status, morbidity, and diet of and care for children 5 to 25 months of age at baseline in rural Viet Nam. The ViSION Project involved a partnership among Save the Children/US ([SC] Ha Noi and Westport, Conn., USA), the USAID – funded LINKAGES Project (Washington, D.C.), Emory University Rollins School of Public Health (Atlanta, Ga., USA), and the Research and Training Center for Community Development [RTCCD], Hanoi). The SC Viet Nam field office developed the program model and implemented it through government partners. The LINKAGES project evaluated models for improving complementary feeding. Emory University provided technical assistance for research design, technical support, and analysis. RTCCD implemented the research, and SC headquarters identified the partners and coordinated the effort.

This paper presents the methods and describes the intervention for this 12 – month longitudinal study.

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\* The VISION (Viet Nam study to improve outcomes in nutrition) project evaluated the implementation and impact of an integrated nutrition program on the nutritional status, morbidity, diet of, and care for children 5 to 25 months old in rural Viet Nam, through a partnership among Save the Children/US (hanoi and Westport, Conn., USA), the USAID – funded LINKAGES Project (Washington, D.C.), Emory University's Rollins School of Public Health (Atlanta, Ga., USA), and the Research and Training Center for Community Development (Hanoi, Viet Nam).

## Methods

### Objectives and design

The ViSION project aimed to identify the results and causal pathways of SC's integrated nutrition program, the community empowerment and nutrition program (CENP). Principal aims of the research project included documenting the implementation of all aspects of the CENP, and measuring the impact of the program elements on maternal care behaviors and dietary intakes and growth of children.

We used a longitudinal, prospective, randomized, "probability effectiveness" design[1]. We randomized at the commune level (six intervention and six comparison) and followed a total of 240 children (120 in intervention and 120 in comparison communes at baseline) longitudinally for six months with a re-survey at 12 months. Blinding subjects or data gatherers to the intervention was not feasible.

### Setting and commune selection

The study took place in Phu Tho Province, 98 km northwest of Hanoi. This north central ecological region has the worst child nutrition profile (47% underweight, 46,5% stunted, and 9,9%wasted) in the country\*. The province has 1.3 million rural lowland, midland, and highland inhabitants in thousands of hamlets in 249 communes in eight districts. The main ethnic group is Kinh, the predominant national majority, with some Muong, Dao, San Chay, and San Diu minorities. The population is poor with an average per capita monthly rice production of 17.8 kg \*\*. The area is principally agricultural (rice, tea, palm oil, banana, papaya, eucalyptus) with a tropical climate (average temperature 23.4°C). The province serves as a regional transportation hub for road, rail, and inland water ways and has some industry (fertilizer and paper).\*\*\* There are two rice harvests (May and June and September and October). Diarrhea season is May and June; respiratory infection season is September to December. The rainy season is February to July, and the dry season is August to January.

SC's district selection criteria were no prior SC activity, supportive officials, and a preference for lowland or midland (not highland) ecology to maximize population density. SC selected Thanh Ba and Phu Ninh Districts. SC's commune programming selection criteria were a greater than 30% malnutrition rate (weight- for age Z score less than -2) among children under five years of age; poverty as measured by per capita rice production; and feasibility factors such as at least and food generally available as reported by community leaders. We excluded extremely poor communes, which belonged to the government's "Phase One 10,000 Poorest Communes" and were already targeted by the government for special intervention programs. Commune selection criteria for research sought comparability and minimal contamination between intervention and comparison communes. To minimize confounding, we selected four groups of three communes (two in each district) from the 18 communes (10 in Thanh Ba District and 8 in Phu Ninh District) eligible for programming. The group means or prevalences for childhood malnutrition level, ecology, ethnicity, and distance from district center were as similar as possible ( $P>.05$ ) between each group in a district. We avoided continuous communes, one group from each district, maximizing similarity of background characteristics. Finally, we randomly assigned, by coin toss, one group of six as comparison communes.

The commune profiles were similar (table1) in both study groups. All commune economies were agriculture – based, subsistence and cash crop; only one (#21) was commonly one – trird submerged during July and August. All communes were Kinh ethnicity and had supportive leaders, and none had a food program. Each commune had a commune health center (CHC) with a staff of three to seven, including "doctor's assistants" and nurses. Patients obtained free consultation but paid for treatments. The CHC provided ambulatory and brief observational care. Seriously ill patients were referred to the district hospital, usually in a local vehicle.

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\* UNICEF and National Institute of Nutrition 1998 survey preliminary results, 1999

\*\* The Ministry of Labor, Invalids and Social Affairs categories of food insecurity and poverty: less than 13 kg of rice produced per person per month represents "food deficiency" while less than 20 kg per person per month in lowlands and less than 16 kg per person per month in the less fertile mountainous areas represents "poverty"

\*\*\* Viet Nam sights and tourism, Viet Nam department, 2000

Table 1. Study commune characteristics

Commune No.	Study status	Hamlets (study/total)	Area (hectares)	Total Population	Children Under 5	Childhood Malnutrition Rate (%)	Rice Production (kg per capita/year)	Distance to district center (km)	Ecology: Lowland, Midland, Highland	School: Primary, Junior, High	Electricity, Telephone at Peoples' Committee	CHC Staff <sup>a</sup>
14	Intervention	7/10	1.022	4.433	385	30	257	10	H	P,J	E,	4
15	Intervention	4/12	454	3.597	302	36	262	9	M	P,J	E,T	3
16	Intervention	5/11	654	5.778	461	38	267	7	H	P,J	E,T	2
24	Intervention	8/12	1.168	5.579	950	54	138	5	H	P,J	E,	4
25	Intervention	3/9	1.2	5.438	900	52	248	9	L	P,J	E,T	5
26	Intervention	7/17	1.056	6.692	1.115	53	228	8	L	P	E,T	4
Average		0.48	926	5.253	686	44	233	11				3.7
11	Comparison	3/8	1.077	3.819	329	44	240	20	H	P,J	E	4
12	Comparison	1/7	552	3.966	318	33	258	5	H	P,J	E, T	2
13	Comparison	3/8	580	4.793	482	42	200	7	H	P,J	E, T	4
21	Comparison	3/5	582	2.852	413	52	244	3	H	P,J	E,	3
22	Comparison	10/18	486	6.957	404	48	142	14	L	P,J	E,	5
23	Comparison	8/12	472	6.448	580	49	232	15	L	P,J	E, T	4
Average		0.37	625	4.806	421	45	219	11				3.7

a. Number of doctor's assistants.

The situation analysis included developing a roster of all children less than three years of age, conducting the first growth monitoring and promotion (GMP) session, and conducting the baseline positive deviance inquiry (PDI). The SC staff developed the child roster based on government records from CHCs and official family planning records. The ViSION study team validated these official records with a census in a comparison commune (#21) and found the government records to be 99% complete and accurate.

## Intervention

The intervention consisted of preparatory activities, training, situation analysis, and implementation (table 2). Below we describe the intended intervention as specified in SC's training manuals [2]. A concomitant process evaluation assessed adherence to protocol.

### Preparatory activities

Save the Children approached district and commune officials (June and July 1999) to explain the CENP, obtain permission, evaluate potential program sites, and select actual sites. Upon finalization of the sites, SC assisted local partners to form two district management steering committees (DMSC) and six commune management steering committees (CMSC). The district and commune management steering committees monitored the CENP at their respective levels. The CMSC included the commune people's committee chairman or vice – chair – man, head of the women's union, head of the CHC, and often those responsible for early childhood development and nutrition.

### Training

SC staff conducted a training of trainers in November, 1999 that included two days of management training for provincial, district, and commune partners and an additional five days of implementation training for designated district trainers. These, in turn, trained local health volunteers to implement the 10 – month CENP, including the situation analysis and interventions in their communes.

### Situation analysis

Table 2. CENP components

Preparatory activities (June – July, 1999)	Training (November, 1999)	Situation analysis and implementation (December, 1999 – August, 2000)
Brief provincial, district, commune officials Obtain permission Select districts and communes Formation of provincial management steering committee (PMSC), district management steering committees (DMSC), district facilitator teams (DFT), and commune management steering committees (CMSC)	Training of trainers Management training for PMSC and DMSC Implementation training for DFT and CMSC Training of implementers (health volunteers)	Situation analysis Census of roster development Growth monitoring session #1 Positive deviance inquiry and analysis Implementation Nutrition education and rehabilitation program every month Growth monitoring sessions 2 – 6 every two months Deworming once after CMP 2 Monitoring

### Growth monitoring and promotion sessions

Health volunteers then conducted the first every-two-month commune-level GMP session at which they weighed all children less than 3 years of age on a UNICEP – approved, locally made, Salter 25 kg (0.1kg interval) infant scale (Salter Brecknell Weighing Products, Minneapolis, Minn., USA). At each GMP session, health volunteers plotted weight – for – age on children’s national, combined – sex, “road to health” cards displaying four growth channels: A (“normal”) – standard deviations (SD) or more below the reference median weight – for – age; B (“moderate malnutrition”) less than -2 and -3 SD or more; C (“severe malnutrition”) less than -3 and -4 SD or more; and D (“very severe malnutrition”) less than – 4 SD. Health volunteers counseled about growth, reinforced or introduced good care – giving behavior, and referred ill children or those who failed to gain weight after two CMP sessions (four months) to the community health center for medical evaluation.

### Positive deviance inquiry

The results of the first CMP session and household wealth ranking served to identify children eligible for the PDI. The purpose of the PDI was to identify behaviors that poor families with healthy children (“positive deviant families”) practiced that were different from the norm and likely contributed to the children’s good health. The CENP team grouped children according to nutritional status and age. Then health volunteers and the CMSC members identified those who were very poor and those who were better off based on family per capita rice production, occupation, land, holdings, and possessions. They identified four positive deviant and two negative deviant children per commune. Positive deviant children from poor families and negative deviant children were malnourished (channel C or D) children from better off families. Selection criteria for positive deviant children

included normal nutritional status, not an only child, and 12 to 36 months of age.

SC staff trained district trainers and members of the CMSC in the concepts and methods of the positive deviance approach using the CENP training manual developed by SC [2]. They conducted the PDI with health volunteers by visiting the six families and using a question and observation guider to gather information from family members about child feeding, care and health. The CENP teams also visited the better-off families with malnourished children to identify the causes of their children’s malnutrition and to highlight the lesson that money was neither necessary nor sufficient for child health. District trainers attempted to schedule the PDI to allow observation of a child feeding. They followed a question guide with prompts and took notes. Accompanying health volunteers were encouraged to ask questions. The two district CENP teams organized PDI data from each family, according to SC’s manual and field guide [3], into four categories: demographic information, feeding behaviors, health – seeking behaviors, and caring behaviors.

After the home visits, the CENP team and interested community members convened in an open forum to review the cases and to develop a summary profile for their commune of uncommon behaviors that seemed to contribute to the positive deviant (PD) children’s good nutritional status despite their families’ poverty. The team invited community input to develop a final consensus. The behaviors identified through the PDI informed messages taught at the nutrition education and rehabilitation program (NERP) and GMP sessions to help malnourished children in the commune.

After the situation analysis, the intervention proper consisted of GMP sessions every two months, monthly NERP sessions as long as the number of malnourished children warranted them for up to nine months, deworming after the second GMP session, and internal (i.e., apart from the ViSION evaluation ) monitoring of implementation and nutritional outcomes.

## **Nutrition education and rehabilitation program sessions.**

All channel B, C and D children, i.e., less than -2 WAZ, were referred to NERPs. Health volunteers conducted monthly NERP sessions for 12 days (six days weekly for two weeks) in their hamlets to enable families to both rehabilitate and to sustain the enhanced nutritional status of their malnourished children. In the spirit of “learning by doing”, mothers and caretakers were told to bring a handful of positive deviant foods each day as the “price of admission” to the NERP. Health volunteers taught hygiene, child development, and the preparation and feeding of calorie- and nutrient –dense meals from locally available, affordable foods. They stressed that the “positive deviant” foods brought by participants, such as shrimps, crabs, and greens, were all abundant in the paddies. Participants learned six key “facts for life” [4] messages concerning breastfeeding, food variety, complementary feeding, health care, and taking care of healthy children at home. Key NERP education tools included “food squares” and “clover leaf diagrams”. Food squares listed the four recipes to be prepared and fed to children as extra daily meals during the 12 days. Each included breastmilk, local positive deviant foods (informed by the PDI), and common local sources of energy, protein, and micronutrients (tofu, oil, fish, eggs, etc.). Cloverleaf diagrams showed the commune’s PD behaviors for a “model (i.e., PD) family” under the headings: good food, good child care, and good health care.

On each of the 12 NERP days each participating child received a nutritious meal prepared by two or more caregivers in rotation. The meal was designed as additional to the usual diet, but in practice it may have substituted for another meal [5]. Health volunteers allowed mothers to take home the unconsumed food if the child was reluctant to eat at the NERP session. In addition to mothers’ contributions, the CENP provided funds to the CMSC, according to the baseline level of severe malnutrition, in this case about 1400 VND (US\$0.10) per NERP enrollee per NERP day. The CMSC, in turn, allocated the money to the NERP centers for the purchase of oil, rice, and eggs or tofu. The health volunteers weighed the participating children at entry and at the completion of each two – week NERP session and reviewed the progress of each NERP session with the participant mothers. The CMSC discontinued NERP session when the number of malnourished children made further group rehabilitation inefficient. Thereafter, health volunteers individually made home visits to malnourished children identified through GMP sessions. CENP technical support for NERPs ceased at month nine.

Prior to this CENP in Phu Tho, SC had designed NERPs to enroll only severely malnourished children (<-3Z

weight- for – age). However, the ViSION Project’s baseline showed that the level of malnutrition was lower than official Ministry of Health level (30.0%vs.44.5%, respectively). Thus, this CENP also included moderately malnourished (-2 Z and  $\geq$ -3 Z) children; whereas, prior CENPs graduated severely malnourished children upon achieving moderate malnutrition status. Children graduated from the NERPs in this CENP either by attaining normal nutritional status or by attending four consecutive NERPs with weight gain despite remaining moderately malnourished.

SC provided funds to deworm children under three years of age during or after the second GMP session. IN the absence of a comprehensive national policy, different CMSCs, in dialogue with the DMSC, opted for various regimens, including Hatamintox Pyrantel, 125 to 250 mg for children those 12 to 36 months of age; Pyrantel, 125 mg for those 12 to 23 months of age and Vermox, 500 mg for those 24 to 36 months of age; or Pynatel, 125 mg for those 24 to 35 months of age and 187.5 mg for those 36 months of age. Children in comparison communes were also dewormed.

## **Monitoring**

Health volunteers maintained NERP and GMP rosters and met with the CMSC monthly to report and review progress. A member of the CMSC supervised two to four NERPs, visiting each at least once monthly plus the relevant GMP session , if scheduled. The CMSC reviewed all health volunteers’ hamlet summaries and aggregated the communes’ data, often plotting them on a prominently displayed chart or table in the Peoples Committee headquarters or commune health center. A member of the DMSC visited each program commune monthly during a NERP and GMP session, if scheduled. The DMSC convened a monthly joint meeting with representatives of all CMSCs to review each commune’s financial, GMP and NERP activities. It forwarded summary aggregates to SC monthly during the program and for one year after the end of the CENP.

## **Role of Save the Children**

SC staff worked with government counterparts to select intervention communes, conducted the training of trainers, and advised the training and situation analyses, SC also visited the districts and each commune once or twice during implementation due to the CENP adaptation for moderately malnourished children and the requirement for more health volunteers than usual given the population dispersion . Total program cost was approximately US\$ 12.000 for the six communes.

## VISION project

### Sample

The research team identified children 5 to 25 months of age in the intervention and comparison communes from the government population records. In intervention communes, the CENP team had already weighed all children less than three years of age. In comparison communes, the research team weighed all children less than two years of age. We calculated mean weight – for age Z score (WAZ) for each hamlet and ranked the hamlets by mean WAZ within each commune. Since the SC program stressed rehabilitation of malnourished children, we selected the 34 (of 67) intervention hamlets and the 30 (of 60) comparison hamlets with the highest levels of malnutrition both to capture program impact and to maximize field efficiency. We sorted the eligible children from these hamlets by age and randomly selected children to achieve the desired sample size of 120 intervention and 120 comparison children. We excluded multiple births or children with severe medical problems, such as handicap or measles. We achieved the desired sample without refusal after 20 substitutions for families not at home.

The Ministry of Health used two growth – monitoring charts during the ViSION project. Upon enrollment, field workers gave comparison families a “new” chart (0 – 24 months, channel A vs. non – A) on which they recorded the weights. Although the chart had nutrition messages on the reverse, families were unlikely to read these since the field workers immediately taped them to the wall. When comparison children reached their second birthday, field workers gave them the “old” (0 -60 months, channel A, B, C and D) growth chart, taped it adjacent to the first one, and recorded subsequent weights. The CENP did not provide growth charts to intervention families, but about 20% of intervention families requested a chart, and the field worker provided them the “old” one, taped it to the wall and recorded the weights.

These 240 study children represented the range of nutritional status of children in the study hamlets. Since the NERP, a central CENP intervention, targeted only malnourished children, we augmented the sample during month three of the study with an additional 41 NERP participants from the intervention communes to increase the sample size. We used the following selection criteria: not currently enrolled in the longitudinal study; resident of one of the 34 hamlets in the six intervention communes; attending NERPs according to the latest list available; and age 6.0 to 23.9 months at baseline. We achieved the desired sample after five refusals.

## Data collection

### Forms and equipment

We collected baseline data between December 23, 1999 and January 9, 2000. We used 11 forms (table 3) for gathering information on nutritional status, diet, illness, care, internal determinants of behavior (Knowledge, beliefs, and attitudes including perceived advantages and disadvantages of the behavior, self- efficacy, norms, and skills), , external determinants of behavior (time, father’s role, and maternal nutritional status), and empowerment or the ability to increase control over and to attain better health . During the longitudinal study we used an additional form to gather information on child feeding through video – recording. We developed all questionnaires in English, translated them into Vietnamese, trained field workers in their use, pilot – tested them in Phu Tho Province (but not in the study communes), revised them, re – trained field workers, and back – translated them into English for accuracy. We obtained all measurements on all subjects at baseline, except for videotaped care (obtained on one – half of the sample at either age 12 or 17 months starting two months after baseline) and the market survey (obtained in each of the communes starting four months after baseline). Throughout the study we used an additional group of forms (developed in a similar fashion to the original 11 forms) to evaluate the CENP implementation of the intervention (table 4).

Field workers obtained each anthropometric measurement three times at each measurement period. We used digital reading electronic tare SECA 890 scales (SECA Ltd. Birmingham, UK) precise to 100 g for weight; four – color mid-upper arm circumference tapes precise to 1 mm for mid –upper arm circumference; and Shorr infant/child/adult height measuring boards (Shorr Productions, Olney, Md., USA), precise to 1 mm for maternal heights and recumbent child lengths. Cold weather from December through February precluded undressing children, so we weighed representative clothing items, inventoried the subject’s clothing, calculated the total weight of the clothes, and subtracted this from the otherwise tared children’s weight (mother with partially dressed child versus mother alone [6].

Field workers conducted a 24 – hour dietary recall using photographs and digital reading weighing scales (Soehnle Attache Gram Scales, Montlingen, Switzerland), with 2-kg capacity and 1 – g and 2-g precision for items weighing less than 1 kg and 1 to 2 kg to identify and quantify child food preparations and ingredients [5].

We video – recorded two – hour segments of care timed around a child feeding. We conducted these recordings among a random sub-sample of 119 children when they were either 12 or 17 months old. Subjects were videotaped on two different days seven days apart. We used a

DCR-TRV103 Sony Digital Handycam Camcorder (Sony Corporation, Tokyo, Japan) with two one – hour tapes per encounter. The two – person field team consisted of a photographer and a minute – by-minute activity recorder to facilitate reviewing the video. Field workers encouraged routine activity. If the caregiver – child pair became physically separated beyond the camera frame, we videotaped the child.

### **Informed consent**

The Emory University Human Investigations Committee approved the study. Field workers received written permission from provincial authorities and obtained written informed consent from each study mother or caregiver who was allowed the right to decline to participate without prejudice. Seriously ill children were referred for treatment to the nearest government facility. Field workers provided all study families with a photograph of the child, a pair of socks, and a small bag of laundry detergent as incentives during the study.

### **Logistics**

The two coordinators and nine field workers had one to three years of data collection experience in rural Viet Nam. All were female, 25 to 27 years old, and had bachelor's (n=5) or advanced (n=6) degrees. One team of two to three field workers either monitored CENP implementation, videotaped feedings, or gathered all other data. Logistics permitting, we rotated field workers to balance observer biases.

### **Training and standardization**

All field workers were trained to use all household interview forms. The video team and the household team were trained in the videotaping. Only one team was trained in the CENP process evaluation. Training required 54 days. Each form required multiple rounds of training, practice or field – test, feedback, clarification, and questionnaire refinement, and re-training. The most complex forms, the 24-hour dietary recall and program awareness, required seven rounds. Measurement agreement arose through this iterative process. Standardization occurred by field workers observing role – plays and comparing completed questionnaires with the master trainers' observations. We trained nine field workers and selected the seven who achieved 85% to 100% agreement on 95% to 100% all items on all relevant questionnaires.

### **Supervision quality control**

Coordinators completed 20% of forms simultaneously with the nine field workers during the baseline period to identify and rectify discrepancies. Thereafter, they assessed the field measurements of one field worker per day through simultaneous observation and interview. Field workers were not aware as to when they would be supervised until they arrived at the drop-off point. The coordinators reviewed all forms for completeness and accuracy each evening when they also shared their observations with the data – collection team.

### **Data verification and cleaning**

We used pre-printed labels with identifying data for all forms. We verified data for all forms. We verified data at six points. Before starting the interview, the field worker checked the identification label to ensure that the information on the label corresponded to the family being surveyed. At the end of the interview, the field worker reviewed each form to ensure that all questions had been asked and answered, that the responses were clearly and legibly written on the form, and that no questions were left blank. Coordinators reviewed the quantity and quality of each form every evening. The data manager used a master list of study children and a monthly list of households not contacted to assure that the total expected equaled the total received. Data entry technicians reviewed data for mistakes or illogical presentations. They computerized data through single-entry using a Vietnamese version of Epi –Info, version 6.04[7] with extensive check programs (range, legal values, skips, “must enters, calculations, and unique codes). After data entry, the data manager performed several additional checks, comparing the master list of child codes with codes for each form to confirm completeness, checking for logic between form (i.e., child not losing stature), and checking for outliers of continuous variables with box-and-whisker plots. The data analyst at Emory University reviewed each dataset, evaluating each variable, identifying outliers, and checking each record that had an outlying value.

### **Coverage rates**

Household data collection was nearly complete through six and even 12 months (274[97.2%] and 266 of 282 [94.3%] study children with complete data collection, respectively). CENP monitoring assessed all trainings and PDIs and samples of repetitive interventions, that is NERPs (283/6048 [4.7%] of all NERP days) and GMP weighings (257/9680 [2.7%]).

Table3. Data collection instruments, methods and variables for program impact

Data collection instrument number	Data collection instrument name	Method	Informant	Variables and variable families	Duration to implement (minutes)	Frequency (mo)
1A	Demographic, behavioral determinants, household environment	Interview	Mother	Mother's and father's demographics, education, occupation, income, government group participation Household size, possessions; construction Sanitation, water, fuel, salt Pregnancy, delivery; pregnancy and postpartum diet Child's breastfeeding Child's meal preparation Child care, decisions, care-giver Beliefs, attitudes, self-efficacy, and norms about breast and complementary feeding Daily activities Overall satisfaction with life	35	0,6,12
2A	Child anthropometry and motor milestones	Anthropometry, observation, interview	Child and caregiver	Length, weight, mid-upper arm circumference 23 graded measurements of gross motor function	15	0,1,2,3,4,5,6, 12
2A	Maternal anthropometry	Anthropometry	Mother	Weight, height	5	0,6,12
3A	Child morbidity	Interview	Caregiver	Diarrhea, respiratory, and constitutional symptoms in last 2 weeks by day	5	0,2,4,6,12
3B	Health-seeking behavior for diarrhea	Interview	Caregiver	Breastmilk and complementary feeding by illness day Patterns of care-seeking and treatment by illness day	35	0,2,4,6,12
4A	Hygiene spot observation	Observation	Caregiver and child	Appearance of mother and child Appearance of clothes of mother and child Drinking water container Dish washing tub and dishes Food storage Garbage, animals, human and animal feces, toilet paper, flies	5	0,1,2,3,4,5,6,12
5A	Child 24 – hour recall	Interview	Caregiver	Food, liquids, preparations, ingredients Quantity consumed Breastfeeding episodes	30-60	0,2,4,6,12
6A	Care observation	Videotaping	Caregiver	Two, two – hour continuous videotaped record of child and care – giver, focusing on	120	At age 12 or 17 months



				mealtime Activity log every 60 seconds for sub-sample		
8D	Community empowerment	Interview, open-ended	Health volunteers and mothers	Changes in empowerment domains identified in Viet Nam, including, Knowledge Confidence Community relationships Household decision-making	60	0, 6, 12
9A	Program participation	Interview	Caregiver	Child and mother immunized; child given vitamin A capsule Prior participation in weighing or feeding programs Child and mother's illness and care – seeking in last month Mother's care –seeking for preventive care in last month	7-10	0, 1, 2, 3, 5, 6, 12
10A	Program awareness	Interview	Caregiver	Knowledge of health and nutrition messages and source of knowledge Knowledge of nutrition programs Knowledge of “positive deviant” foods or behaviors and source of knowledge	20	0, 6, 12

Table 4. Data collection methods and variables, and frequency for program implementation

Data collection instrument number	CENP step	Method	Informant	Variables and variable families	Frequency
11A1-1	Training of trainers	Observation	SC trainer	Completion of training topics, interactive training methods, field trips to CMP and NERP sessions	0
11A-2	Training of trainers	Interview	SC trainer	Quality of training, estimation of district trainees' ability, suggestions for improvement, time allotment, estimation of effect of RTCCD field workers	0
11A-3	Training of trainers	Interview	District trainee	Understanding of the two central tenets of CENP (PD and mothers' contributions)	0
11B-1	Census training	Interview	District trainer	Satisfaction with training, estimation of commune trainees' ability, suggestions for improvement	0
11B-2	Census training	Observation	District trainer	Age calculation, calendar use, form completion, report completion	0
11C-1	GMP training	Observation	District trainer	Community group involvement, weighing, plotting, counseling, report completion	0
11C-2	GMP implementation	Observation	Health volunteer	Community group involvement, weighing coverage by age	0,2,4,6,8

				group	
11C-3	GMP training	Interview	District trainer	Satisfaction with training, estimation of commune trainees' ability, time allotment, suggestion for improvement	0
11C-4	GMP implementation	Validation	Health volunteer	Re-weigh the first ~5 children	0
11D-1	PDI training	Observation	District trainer	Household selection, PDI data gathering methods, PDI analysis categorization	0
11D-2	PDI training	Interview	District trainer	Satisfaction with training, estimation of commune trainees' ability, time allotment, suggestions for improvement	0
11D-3	PDI training	Interview	SC supervisor	Satisfaction with training, estimation of commune trainees' ability, time allotment, suggestion for improvement	0
11D-1	PDI implementation	Observation	District trainer and Health volunteer	Interview methods, adherence to question guide, probing, time spent, scheduling visit around child feeding, # families visited; categorization of findings, use of valid data, enthusiasm	0
11D-4	PDI implementation	Interview	SC supervisor	Satisfaction with implementation, estimation of commune trainees' performance, validity of household selection criteria, time allotment, suggestion for improvement	0
11E-1	NERP training	Observation	District trainer	Completion of training topics (health education messages, encouraging mothers' contributions, NERP report), estimation of trainees' knowledge	0
11E-2	NERP training	Interview	District trainer	Satisfaction with training, estimation of commune trainees' understanding, time allotment, suggestion for improvement	0
11E-3	NERP implementation	Observation	Health volunteer	Health message, mothers' contribution and participation in food preparation, mothers' and children's hygiene, health volunteers' weighing, attendance	1-6,8
11E-4	NERP implementation	Interview	Caregivers	Attendance, enthusiasm, contribution, cooking, child diet, knowledge of rationale for participation, suggestions for improvement	1-6,8
11E-5	NERP training	Interview	SC supervisor	Satisfaction with training, estimation of district trainers' ability, estimation of health volunteers' ability, time allotment, suggestions for improvement Use of "food squares" and "clover diagrams"	0
11E-6	NERP implementation	Observation	Health volunteer	Availability and price of positive deviant and other foods	3,5,6,8
11E-7	NERP implementation	Interview	Food vendor	Treatment protocol, distribution method	3-6,8
11F	Deworming	Interview	Health worker		3

## Analysis and statistical issues

Sample size was calculated by the expected impact (nutritional status as a continuous and categorical variable) and intermediate outcomes (behavior change) as informed by findings of Mackintosh et al. [8] and Sternin et al.[9]. It was estimated that sample sizes of 200 children (100 intervention and 100 comparison) would allow measuring a 10% increase in the mean number of meals fed per day, a 25% increase in the mean number of snacks fed per day, and a 40% decrease in the rate of malnutrition. Sample size was inflated by 20% to 240 to allow for drop – outs, missing data, refusals, and errors.

Detailed information on variable creation and analytical approaches is outside the scope of this paper. In brief, we converted all data to primary and secondary variables using standard approaches. For anthropometry, for example, standard computerized algorithms were used to average 2 or 3 of the repeated anthropometric measures to obtain a single height, length, mid –upper arm circumference, and weight at each age. These anthropometric values were then used to create indices using Epi – Info 6.0- weight – for – age, weight – for – length, and length – for –age. Additional information on variable construction and the analysis of growth [10], dietary [5], and morbidity variables [11] are presented elsewhere in this volume.

## Discussion

This paper provides a detailed description of the implementation of the CENP, a complex integrated nutrition program in Viet Nam, and describes the rigorous methods to evaluate it. This is one of a few efforts of this kind. Most large – scale, detailed evaluations have been “efficacy trials” rather than full – scale effectiveness studies [12,13]. Moreover, effectiveness trials typically have not involved randomization [12].

## Implementation

SC succeeded in teaching district Ministry of Health partners to train local implementers to conduct a complex set of intervention: CMP, PDI, and NERP. Despite the implementers’ characteristic enthusiasm, some field realities prompt caution. The CENP is designed as a rehabilitation model for lowland, densely populated communes with high levels of severe malnutrition. Neither condition prevailed in the selected districts, which were drawn from a pool of similar districts with minimal non – governmental organizational activity and a SC commitment to introduce the program. Political support in Phu Tho province for district and commune selection was more restrained than in earlier iterations.

These communes also had baseline levels of malnutrition that were far less than officially reported. In response, SC recommended including moderately malnourished children in the NERPs and revised graduation criteria, a modification that had been contemplated but not tested. Thus, compared to children in prior CENPs, these intervention children were more likely to be enrolled in and slower to graduate from NERPs. Meanwhile, NERP implementation deviated from protocol in that daily contributions were not the norm, and home – delivered meals were common, perhaps because the population was dispersed, or caregivers were less concerned about moderate malnutrition than they would have been about severe malnutrition. It is possible that this and other local adaptations may have been implemented earlier in other settings without the knowledge of SC.

## Research methods

The ViSION project trained its field research team to exacting standards of data collection . The RTCCD team then identified and enrolled intervention and comparison households, repeated caregiver interviews and unobtrusive observations of households and CENP implementation, mastered a new qualitative method, videotaping, achieved nearly complete data collection, and maintained exemplary data management. ON the other hand, no research effort is watertight. The effect of repeated household visits remains unknown. The potential bias of demonstrating atypical behavior for the video camera is real, but can be reduced by restricting analysis to the second hour or even the second day when videotaping was less novel. The ethical requirement to provide caregivers of all comparison and some intervention children with a growth chart, which included nutritional messages. Was unavoidable and may have mitigated detecting the impact of the CENP because comparison caregivers gained nutritional knowledge. Similarly, the detergent incentive may have influenced hygiene or other health outcomes in both groups. Likewise, to isolate the effect of the CENP apart from its deworming component, we dewormed all study children , and this might have improved the health and nutrition of the comparison children. We added 41 children who were attending the NERPs from month three. Interpreting their baseline and change may be difficult, given their late start; however, they were not included in most analyses to date. In addition, we decided to explore home care and care- seeking only for diarrhea, but its prevalence at baseline in December was trivial, so demonstrating change may be challenging. Finally, while no-governmental organization activity was nil at the baseline, three communes (two intervention and one comparison received additional nutritional inputs. On balance, the above factors are likely to have moderately attenuated differences between intervention

and comparison children. All listed program factors would reduce CENP's impact. Similarly, our provision of certain items (growth charts and detergent) to families in the comparison communes for ethical reasons would tend to improve some outcomes in comparison communes.

In summary, this evaluation documents the difference between CENP protocol and implementation and the effectiveness of the implementation in a challenging field setting. While the implementation may be similar to previous iterations, the effectiveness may be somewhat less, given the challenging field conditions and changes to protocol. Our thorough understanding of the CENP implementation allows us to better interpret its effect and thus the potential of PD – informed programs.

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