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Cambodia integrated nutrition, hygiene, and sanitation impact evaluation – endline

Submission date
02/07/2019

Recruitment status
No longer recruiting

Registration date
09/07/2019

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
This study is an impact evaluation of a previously delivered sanitation and nutrition intervention targeting households with children in rural Cambodia. Sanitation and nutrition programming have separately been associated with improved growth in children. This study is intended to measure the effect of a real-world suite of interventions on the outcome of age-adjusted height of children aged 1 – 28 months, both individually and combined.

Who can participate?
Children aged 1 - 28 months and their caregivers who live in one of the pre-selected geographical areas of the study.

What does the study involve?
The study uses the following: (1) anthropometry (length/height and weight of children aged 1 - 28 months; (2) molecular analysis of stool samples to assess carriage of enteric pathogens; (3) a non-invasive measure of anemia based on imaging of fingernails; and (4) other survey data and observational data collected from adult respondents in participating households. The cross-sectional survey is being implemented across four types of villages: (1) control villages where no intervention activities have taken place; (2) villages that have received sanitation programming to encourage construction and use of latrines; (3) villages that have received nutrition programming, including messaging around improved child feeding practices; and (4) villages that have included both the sanitation and the nutrition intervention. The intervention was conceived by the United States Agency for International Development (USAID) and delivered by the non-governmental organization (NGO) Save the Children (StC). These interventions were randomized and delivered 28 - 36 months ago, so the purpose of this study is to measure children born at or following the point of intervention delivery to determine whether child growth (primary outcome: height-for-age Z-score on a continuous scale), anemia, enteric infections, or reported diarrhea differs between the intervention and control groups. The sample size is estimated to be 4,015 children (and their caregivers) to enable comparison of the primary outcome in each intervention group with the control group; the study is not powered to detect differences among the intervention groups.

What are the possible benefits and risks of participating?
There are no direct benefits to trial participants. Indirect benefits include enhancing the evidence base for sanitation and nutrition interventions in rural Cambodia, which may lead to more efficacious programming by government, NGOs, and the private sector. The only risk of participation is loss of time as a result of interacting with the research team. Contact with participating households will be limited to approximately 2 hours or less (1 to 1.5 hours on the first day for a household survey and measurement of the height and weight of the child and up to 30 minutes on the following day for collection of stool sample).

Where is the study run from?
Save the Children, Cambodia.

When is the study starting and how long is it expected to run for?
August 2019 to July 2021.

Who is funding the study?
United States Agency for International Development (USAID).

Who is the main contact?
Dr Joe Brown,
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
110NECHR

Study information

Scientific Title
Cambodia integrated nutrition, hygiene, and sanitation impact evaluation: a randomized, controlled trial of village-scale sanitation, nutrition programming, and combined sanitation and nutrition to improve child linear growth among children aged 1 - 28 months in rural Cambodia.

Study objectives
1. Nutrition interventions increase the practice of key feeding behaviors and consumption of more nutritious foods, which lead to improved child linear growth.
2. Sanitation and hygiene interventions reduce diarrhea and enteric infections and promote gut health, which lead to improved child linear growth.
3. Integrated nutrition and sanitation/hygiene interventions lead to improved child linear growth that is greater than what is achieved when either intervention is delivered individually.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/04/2019, National Ethics Committee for Health Research (Lot #80, Samdach Penn Nouth Blvd (289), Sangkat Boeungkok 2, Khan Tuol Kork, Phnom Penh, Cambodia; +855 12 842 442; sarayvannat@gmail.com), ref: 110NECHR
2. Approved 11/07/2019, Georgia Institute of Technology Institutional Review Board (Office of Research Integrity Assurance, Georgia Institute of Technology, Research Administration Building, 505 10th St NW, Atlanta, GA 30318 USA; +1 404 385 2175; irb@gatech.edu)

Study design
Cross-sectional cluster-randomised study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Growth faltering

Interventions
This is a cross-sectional study that measures children between 1 - 28 months of age across three provinces of rural Cambodia. These areas received a randomized intervention program that was delivered 28 - 36 months preceding our study. Eligible communes within these provinces received one of three interventions or were assigned as control areas. In this cross-sectional study, we are including children who have been born any time after the interventions were delivered and who are now a maximum of 28 months.
1. Community-Led Total Sanitation (CLTS) and support for an enabling environment for sanitation programming in rural areas

2. Baby-Friendly Community Initiative (BFCI), which provides support for poor mothers in providing adequate nutrition for babies, including conditional cash transfer (CCT) and vouchers program
3. The above two interventions combined

This is a study of an intervention delivered 28 - 36 months ago, referred to as the NOURISH program, funded by USAID and managed by Save the Children, an international NGO. NOURISH interventions were focused on four key strategies:
1. Improving community delivery platforms to support improved nutrition through the Baby-Friendly Community Initiative (BFCI),
2. Creating demand for health and sanitation-related practices, services, and products through the use of conditional cash transfers (CCTs), community–led total sanitation (CLTS), vouchers, and Social and Behavioral Change Communication (SBCC)
3. Using the private sector to advance supply of sanitation and nutrition products
4. Building the capacity of government and civil society in nutrition.

The main NOURISH nutrition and WASH interventions (primarily sanitation and hygiene) consisted of demand-creation activities, supply-side support, and capacity building at the village and commune levels, and are further described below. All treatments occurred over 24 months. No data collection was performed by researchers over the intervention period or following interventions. No input on intervention strategies or monitoring was given by researchers.

Nutrition Interventions:
The BFCI for the “first 1,000 days” of life used evidence-based integrated nutrition interventions. Village Health Support Groups (VHSGs), supervised by health workers and Commune Councils for Women and Children (CCWC), improved child care and development at multiple levels: individual, family, and community. Four core activities comprise the community initiative designed to prevent malnutrition:
Village and commune dialogues and events reviewed the growth data of children and link families with technical experts to facilitate access to diverse foods.
VHSGs monitored every child every month. Children who were sick or not growing well were referred to health centers or referral hospitals, as appropriate, and followed up at home after treatment.
VHSGs and Mother Support Group (MSG) members provided tailored interpersonal communication during home visits to promote child care and feeding practices, home hygiene, and proper use of latrines and handwashing stations.
Caregiver peer groups, existing groups in the community such as MSGs, agricultural cooperatives, and women’s savings groups learned about child care and development and fostered an environment of social support for change. Fifteen topics were facilitated once per month within regular group activities, and included hygiene and age-specific care and feeding practices.

SBCC consisted of media and materials to promote key behaviors in health and WASH. The project's SBCC framework was grounded in evidence of what works in social and behavior change and foundational work done by NOURISH in its first year. On the nutrition side, SBCC supported all components of BFCI and was implemented by community change agents (VHSGs and caregiver peer groups).
The VHSG SBCC package included materials that emphasized the national BFCI flipchart, tested materials from other USAID-funded projects (i.e., Cambodia Helping Address Rural Vulnerabilities and Ecosystem Stability [HARVEST], the Rice Field Fisheries Enhancement Project [RFFEP]), and pictorial home visit checklists. To complement the print materials, NOURISH provided short audio messages and counselling videos that contain instructions on issues that

are difficult to explain through discussion (e.g., thickness and amount of food for young children).
The caregiver peer-group SBCC package included a 15-session “first 1,000 days” Care and Protection Learning Session Guide and accompanying short video stories. These sessions had nutrition and WASH topics based on tested materials in Cambodia, together with hands-on experiential activities that weaved in key concepts of community empowerment, women's self-efficacy, and mutual support.
The “first 1,000 days” family SBCC package was centered on a Family Commitment Card enumerating the critical practices and allowing families to prioritize behaviors and visualize successes and gaps. As the Family Card is filled with accomplishments, families were recognized as growth champions with a child book and other incentives to mark accomplishment. A behavior wheel checklist to guide home visits showing health/nutrition and WASH practices supplemented the Family Card.
CCT is a social safety net mechanism for poor “first 1,000 days” families, serving as an incentive for women to access services, practice specific behaviors, and overcome constraints related to poverty. Eligible families (based on poverty status) received up to six payments, for a total of $65 over the first 1,000 days of a child’s life, which were transferred directly into women’s bank accounts after completed use of health and nutrition services.
First transfer: $12.50 at 1 month postpartum. Conditions: At least four antenatal care visits, delivery in a health center, and at least two postnatal care visits.
Remaining five transfers: $10 for the second to fifth transfers and $12.50 for the last transfer over the next 23 months postpartum. Conditions: Monthly monitoring of children’s growth through Growth Monitoring and Promotion at the health centers or in the community, and handwashing station at home.
Integrated Vouchers served as another mechanism to encourage demand and overcome access constraints related to poverty. Vouchers were distributed to poor “first 1,000 days” families in communes where the CCT is implemented, and were redeemable for discounts on three products: water filters ($5 co-payment), two food baskets ($5 co-payment), and latrine materials ($15 co-payment).

Sanitation/Hygiene Interventions:
Community Led Total Sanitation (CLTS) programming aimed to achieve sustained behavior change through the process of community “triggering” leading to spontaneous and long-term abandonment of open defecation practices, conducted in collaboration with the Ministry of Rural Development and provincial and district departments of rural development. In alignment with national Open Defecation Free certification guidelines, CLTS covered entire villages to minimize the risk of fecal-oral contamination for all children. Following CLTS triggering, NOURISH monitored the commitments of families and communities and tracked sanitation progress.

Supply-side support (private sector engagement) consisted of collaborating with private and public sector actors to develop locally sensitive market-oriented approaches for the integrated business service centers around “first 1,000 days” products and services. NOURISH encouraged knowledge sharing across small- and medium-sized enterprises (SMEs) as well as utilize existing resource centers and agencies to develop the capacity of SMEs for effective service delivery and to increase their outreach to poor and relatively remote areas. Learning and exposure visits were intended to help enterprises expand their business by diversifying products and services. SBCC for sanitation and hygiene included sanitation campaigns in primary schools.

Intervention Type
Mixed

Primary outcome(s)

Length-for-age/height-for-age Z-score as determined on a continuous scale. The method uses recumbent length mats or stadiometers (for children standing), with triplicate measures being taken. The timepoint is any time between 1 and 28 months of age at this single measurement.

Key secondary outcome(s))

16/01/2020 note on changes to secondary outcome measures as of 22/07/2019: The experimental app-based imaging software for estimation of anemia was removed from beta-testing by the app developer before the start of data collection, so this measure was not able to be included in this study.

Current secondary outcome measures as of 22/07/2019:
1. Caregiver-reported diarrhea in the 7 days preceding the survey (binary). Diarrhea is defined as three or more loose or watery stools – or any stools with blood – in a 24 hour period. Method: questionnaire given to the child's main caregiver.
2. Weight-for-height Z-score, continuous scale. The method uses recumbent length mats or stadiometers (for children standing), with triplicate measures being taken. The timepoint is any time between 1 and 28 months of age at this single measurement.
3. Weight-for-age Z-score, continuous scale. The method uses of recumbent length mats or stadiometers (for children standing), with triplicate measures being taken. The timepoint is any time between 1 and 28 months of age at this single measurement.
4. Stunting (binary). From anthropometry, stunting is defined as at least 2 standard deviations below the WHO reference mean for this population, age-adjusted height or length. The method is use of recumbent length mats or stadiometers (for children standing), with triplicate measures being taken. The timepoint is any time between 1 and 28 months of age at this single measurement.
5. Combined prevalence of the following enteric pathogens (measured as binary for individuals: positive for any of these = 1, negative for any of these = 0). We will use the CDC enteric pathogen TaqMan array card (TAC), designed for the Childhood Health and Mortality Prevention (CHAMPS) Study led by CDC.
6. All cause mortality

Previous secondary outcome measures:
1. Caregiver-reported diarrhea in the 7 days preceding the survey (binary). Diarrhea is defined as three or more loose or watery stools – or any stools with blood – in a 24 hour period. Method: questionnaire given to the child's main caregiver.
2. Weight-for-height Z-score, continuous scale. The method uses recumbent length mats or stadiometers (for children standing), with triplicate measures being taken. The timepoint is any time between 1 and 28 months of age at this single measurement.
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4. Stunting (binary). From anthropometry, stunting is defined as at least 2 standard deviations below the WHO reference mean for this population, age-adjusted height or length. The method is use of recumbent length mats or stadiometers (for children standing), with triplicate measures being taken. The timepoint is any time between 1 and 28 months of age at this single measurement.
5. Anemia. We are using an experimental, image-based measure of blood hemoglobin. Briefly, the method involves capturing an image of the subject's fingernails and indicates anemia (hemoglobin levels <12.5gdL-1) with an accuracy of ±2.4gdL-1. The method is non-diagnostic.
6. Combined prevalence of the following enteric pathogens (measured as binary for individuals:

positive for any of these = 1, negative for any of these = 0). We will use the CDC enteric pathogen TaqMan array card (TAC), designed for the Childhood Health and Mortality Prevention (CHAMPS) Study led by CDC.
7. All cause mortality

Completion date
31/07/2021

Eligibility

Key inclusion criteria
Caregiver respondents:
1. Aged 15 years or above
2. Living in one of the pre-selected geographical areas of the study
3. Has one or more child aged 1 - 28 months at the time of recruitment
4. Caregiver/child dyad is eligible if they have lived in the same location (as primary residence) for the entire life of the child.
5. Khmer language proficiency

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
4124

Key exclusion criteria
Any caregiver or child not meeting inclusion criteria or declining to participate in the study are excluded.

Date of first enrolment
01/08/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Cambodia

Study participating centre
Save the Children - Cambodia
5, Street 242
Sangkat Chaktomuk
Khan Daun Penh
Phnom Penh
Cambodia
12207

Sponsor information

Organisation
United States Agency for International Development (USAID)

ROR
https://ror.org/01n6e6j62

Funder(s)

Funder type
Government

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		28/05/2021	16/08/2022	No	No
Protocol file			16/08/2022	No	No