

Operational research for Ethiopia Integrated Nutrition Project (EINP)

Submission date 30/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/11/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/11/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Malnutrition in children is a huge public health issue in Ethiopia and can negatively affect achievement in school, brain development, and productivity at work later in life. Thus to address this issue, appropriately designed nutrition interventions are important. We designed a community-based nutrition project called Ethiopia Integrated Nutrition Project (EINP), which includes three types of nutrition programs: 1) Community-based Participatory Nutrition Education (CPNE): providing 2 weeks of intensive nutrition education sessions to undernourished children and their mothers including cooking demonstrations with locally available foods, nutrition message discussion, hand washing practices, and a follow-up visit, 2) Essential Nutrition Action (ENA) activity: brief nutrition information sharing by voluntary community health workers or a community group once a month, and 3) Community-based Management of Acute Malnutrition (CMAM): providing therapeutic and supplementary foods to moderately or severely malnourished children. This study aims to find out the effectiveness of EINP in improving the childrens growth and the caregivers' feeding practices.

Who can participate?

Babies aged 6 to 12 months and their mothers living in the participating districts of Ethiopia can take part.

What does the study involve?

The districts are randomly divided into intervention and control groups. In the intervention area, the CPNE program, the ENA activity and the CMAM program will be conducted concurrently, and in the control area only the ENA activity and the CMAM program will be implemented. Undernourished children and their caregivers will receive the CPNE program, the ENA activity will target all mothers with children under two years old, and moderately or severely undernourished children will be admitted to the CMAM program.

What are the possible benefits and risks of participating?

While the potential benefits of participation are minimal, the risks associated with participation are also negligible. The time commitment for participation is less than one hour per interview. Participants may feel bored during the survey.

Where is the study run from?

Habro district, West Hararghe zone, and Melka Bello district, East Hararghe zone, Ethiopia.

When is the study starting and how long is it expected to run for?

September 2012 to December 2014.

Who is funding the study?

1. World Vision Korea (Korea)
2. Korea International Cooperation Agency (KOICA) (Korea)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effectiveness evaluation of community-based nutrition program in improving child growth and feeding practices in rural Eastern Ethiopia: a clustered randomized trial

Study objectives

To examine the effectiveness of the CPNE program integrated with the ENA and CMAM programs in reducing the prevalence of stunting, underweight and wasting and improving

height-for-age, weight-for-age and weight-for-height Z scores among children aged 6 to 24 months

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oromya Regional Health Bureau (ORHB), Ethiopia, 27/08/2012, ref. BEFO/AH/UTR/1-84/29021

Study design

Clustered randomized trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Child undernutrition

Interventions

Community-based Participatory Nutrition Education (Behavior Change Communication form), Community-based Management of Acute Malnutrition, and Essential Nutrition Action activity (nutrition counselling)

In the intervention area, the CPNE program, the ENA activity and the CMAM program will be conducted concurrently, and in the control area, the ENA activity and the CMAM program will be implemented only. Target children differ by type of intervention. Undernourished children and their caregivers will receive the CPNE program by project staff, the ENA activity will be given to all mothers with children under two years old as much as trained volunteers can visit households, and moderately or severely undernourished children will be admitted to the CMAM program. Besides we attempted to measure differences in child growth such as z-scores at whole the community level considering all children at 6 to 24 months of age not specifically at individual children level who directly receive interventions. Since the above programs, especially the CPNE program and the ENA activity, are publicly conducted in communities, we wanted to measure the direct and indirect effects of the interventions together.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Length-for-age
2. Weight-for-age
3. Weight-for-length z scores
4. Prevalence of stunting, wasting and being underweight

Children 6 to 12 months of age are measured by trained anthropometrists from the time of enrollment, at every 3 months, for five times, for their height with locally manufactured measuring boards nearest to 0.1 cm and weight with electronic weighing scales to nearest 0.01 kg. For example, a child whose age is 9 months old at enrollment will be measured at 9, 12, 15, 18, and 21 months old.

Secondary outcome measures

Complementary feeding practices such as dietary diversity and feeding frequency, and hand washing practices

Mothers will be asked at the same timepoints that the primary outcomes are measured about her feeding and hygienic practices, e.g. how and what she fed child in the last 24 hours, and when she washed her hands by enumerators, through household visits.

Overall study start date

01/09/2012

Completion date

31/12/2014

Eligibility**Key inclusion criteria**

Infants 6 to 24 months of age

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

2064

Key exclusion criteria

N/A

Date of first enrolment

01/09/2012

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

Ethiopia

United States of America

Study participating centre

W2501, 615 N. Wolfe Street,

Baltimore

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Sponsor information

Organisation

World Vision Korea (Korea)

Sponsor details

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Sponsor type

Research organisation

Website

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Funder(s)

Funder type

Government

Funder Name

World Vision Korea (E197814) (Korea)

Funder Name

Korea International Cooperation Agency (KOICA) (Korea)

Alternative Name(s)

KOICA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration