Improving child nutrition and development through community based childcare centres in Malawi

Recruitment status No longer recruiting	Prospectively registered		
	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

Plain English summary of protocol

Background and study aims

Malawi ranks 73rd out of 104 countries on the Global Hunger Index (a tool used to describe the state of countries' hunger situation), due to the high rate of malnutrition and stunted growth in children. It is also one of the most committed countries to improving nutrition, ranking 3rd on the Hunger and Nutrition Commitment Index (which ranks governments on their commitment to tackling hunger). It has been found that 94% of rural residents and 38% of urban residents are involved in farming to some extent, mainly in small farms. This type of farm mainly focuses on growing maize and a range of other crops. Analyses of the food consumption patterns from the Malawi Integrated Household Survey (IHS) found that although diets are dominated by maize, a range of nutritious foods are being consumed. Overall however, these diets are not balanced enough to meet the nutritional requirements for growth and development. This study is looking at a nutrition and agriculture education program. The aim of this study is to find out whether this program can help to improve the diets, health, nutrition and development of young children and their households in rural areas of Malawi.

Who can participate?

Children aged 0-5 years living in the catchment areas of participating Community-Based Childcare Centers and their caregivers

What does the study involve?

Communities are randomly allocated to one of two groups. Community-Based Childcare Centers (CBCCs) in the first group are supported by the Save the Children's Early Childhood Development (ECD) program, which is offered as standard by the government. Community-Based Childcare Centers (CBCCs) in the first group are supported by the Save the Children's Early Childhood Development (ECD) program which has been combined with a nutrition and agriculture education program. This involves training for caregivers on nutrition and health, as well as education about nutritious food production and meal preparation.

What are the possible benefits and risks of participating? Participants may benefit from improved diets which are likely to improve their healthy growth and development. The main risks involve issues related to inappropriate food management and preparation. Training activities are provided to reduce this risk however.

Where is the study run from?

The study is run from Save the Children Malawi and takes place in 60 Community-Based Childcare Centers (CBCCs) in the Zomba district (Malawi)

When is the study starting and how long is it expected to run for? September 2015 to December 2016

Who is funding the study?

This work was supported by a Nutrition Embedding Evaluation Program (NEEP) grant from PATH, funded by the UK Government's Department for International Development

Who is the main contact? Dr Aulo Gelli

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

The Nutrition Embedded Evaluation Program Impact Evaluation (NEEP-IE) study: a cluster randomised controlled trial designed to evaluate the impact of a childcare centre-based integrated nutrition and agriculture intervention on the diets, nutrition and development of young children in Malawi

Acronym

NEEP-IE

Study objectives

The aim of this study is to evaluate whether the provision of a childcare centre-based integrated package of nutrition and agriculture interventions (including nutritious food production and behaviour change communication related to food intake, care and hygiene practices) improve the diets, health, nutrition and development of young children and their households in rural areas of Malawi.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. National Commission for Science and Technology (Malawi), 12/11/2015, ref: NCST/RTT/2/6
- 2. International Food Policy Research Institute IRB (Washington, DC), 26/03/2015, ref: IRB00007490

Study design

Cluster randomised control trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Low quality diets, poor nutrition and health status

Interventions

Sixty community-based childcare centres (CBCCs) in rural communities around Zomba district (Malawi) arerandomly assigned to one of two treatment arms

Control group: CBCCs are supported by Save the Children's ECD program with no nutrition or agricultural support.

Intervention group: CBCCs are supported by Save the Children's ECD program with an integrated nutrition and agricultural intervention for nine months. The integrated nutrition and agriculture intervention is aimed at improving the diets, feeding, health and hygiene knowledge and practices in households with infants and young children. This will include promoting optimal feeding and caring practices through parenting groups; engaging parents, adolescents and other adults in the community in the planning and preparation of meals for children within CBCCs; improving agricultural production of nutritious foods and food diversification by using CBCC gardens as a learning site for communities; forming Village Savings and Loans groups to help communities save and access funds to purchase supplies for the CBCC garden and CBCC meals or to start new home gardens; and by organising farmers into collectives to increase their purchasing and selling power. The training materials and approaches used will draw on existing materials developed and validated.

Follow up for all participants involves completion of a household survey and child and caregiver assessments at 9 months. Following collection of the follow up measures, participants in the control group are given the opportunity to take part in the intervention.

Intervention Type

Behavioural

Primary outcome measure

- 1. Dietary intake is measured though 24 hour caregiver recall at baseline and 12 months
- 2. Childcare practices are assessed through caregiver recall compared to the WHO IYCF definitions at baseline and 12 months
- 3. Pre-school enrolment and attendance is measured over 7 days through caregiver recall at baseline and 12 months
- 4. Household food production is measured through recall of previous harvest at baseline and 12 months

Secondary outcome measures

- 1. Child's nutrition status is measured through anthropometry (weight-for-age, height-for-age, weight-for-age z-scores and MUAC) at baseline and 12 months
- 2. Child development is measured through the Malawi Development Assessment Tool z-scores (fine motor, gross motor, language and social domains) at baseline and 12 months

Overall study start date

01/09/2015

Completion date

31/12/2016

Eligibility

Kev inclusion criteria

Child inclusion criteria:

- 1. Aged 0-5 years
- 2. Living in the catchment area of the targeted preschool
- 3. Provision of informed consent from parent or guardian

Caregiver inclusion criteria: Caregiver to a participating child.

Participant type(s)

All

Age group

Mixed

Sex

Both

Target number of participants

The study population is expected to include approximately 1300 children and 1200 caregivers.

Key exclusion criteria

- 1. Child, parent or guardian unwilling to participate in the study
- 2. Child known to have a chronic medical condition which will affect participation in the CBCC in the long run

Date of first enrolment

01/09/2016

Date of final enrolment

15/10/2016

Locations

Countries of recruitment

Malawi

Study participating centre Save the Children Malawi

Zomba Office Opposite Emmanuel International Office Private Bag 66 Zomba Malawi

Sponsor information

Organisation

PATH

Sponsor details

2201 Westlake Ave #200 Seattle United States of America WA 98121

Sponsor type

Charity

ROR

https://ror.org/02ycvrx49

Funder(s)

Funder type

Government

Funder Name

Department for International Development

Alternative Name(s)

Department for International Development, UK, DFID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal by December 2018.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

IPD is available upon reasonable request to the International Food Policy Research Institute (ifpri-data@cgiar.org).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	19/06/2017		Yes	No
Results article	results	01/10/2018		Yes	No
Results article	results	01/02/2020	10/08/2020	Yes	No