

Trial Description

Title

Effectiveness of a nutrition education intervention to improve complementary feeding practices in Malawi: a restricted randomized trial

Trial Acronym

IMCF Malawi

URL of the trial

[---]*

Brief Summary in Lay Language

FAO needs to document the impact of the TIPs approach, capitalise on lessons learnt and refine recommendations to inform the design of future interventions and prioritise resource allocation. However, FAO is not a research institution and has therefore asked the Justus Liebig University to evaluate their TIPs approach within ongoing FAO food security projects i.e. the FAO/FICA project in Malawi. The expected outcome is an assessment of the effectiveness of promoting locally-available and affordable complementary foods to improve infant and young children's nutritional status based on TIPs within FAO food security projects.

Brief Summary in Scientific Language

Malnutrition still remains one of the biggest challenges in developing countries. Children aged 0-23 months are the most vulnerable group with a peak incidence of mortality and morbidity. The promotion of a nutrient-dense diet based on locally available foods is essential to improve the nutritional status of young children. In order to optimize infants and young children's diets, FAO supports the formative research technique "Trials of Improved Practices (TIPs)". TIPs helps to understand families' preferences, capabilities as well as obstacles in improving their complementary feeding practices.

The Malawi Demographic Health Survey 2010 estimated a national stunting prevalence of 47.1%. Results show that stunting increases after six months of age when most children receive complementary feeding. FAO will therefore conduct TIPs in two districts in Malawi followed by a wider dissemination of behaviour change messages. The objective of the research is to evaluate the effectiveness of the behaviour change messages.

Prior to the TIPs, a baseline survey will assess the nutrition security situation of families with children below two years in the FAO project region. The behaviour change communication strategies identified in the TIPs process will be implemented in the prior selected intervention areas by the FAO project. A cross-sectional survey will be conducted by a research team after at least 18 months of intervention evaluating the impact of the intervention by a research team.

The primary outcome parameters to be measured will be mean Height for Age Z-Scores (HAZ). Secondary outcome parameters will be vitamin A deficiency, iron

deficiency and behaviour change. Methods for data collection will include anthropometric measurements, questionnaires, collection of capillary blood, and focus group discussions. Statistical analysis will compare primarily the difference of the mean Height-for-age Z-score in intervention and control areas.

The study is related to IMCF Cambodia.

Organizational Data

- DRKS-ID: **DRKS00003234**
- Date of Registration in DRKS: **2011/08/25**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **119/11 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

Secondary IDs

Health condition or Problem studied

- ICD10: **E45 - Retarded development following protein-energy malnutrition**
- ICD10: **E50.9 - Vitamin A deficiency, unspecified**
- ICD10: **D50.9 - Iron deficiency anaemia, unspecified**

Interventions/Observational Groups

- Arm 1: **FAO/FICA implements activities to improve food security only.**
- Arm 2: **FAO/FICA implements activities to improve food security and in addition nutrition education for behaviour change to improve infant and young child feeding practices.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*

Study Type: **Interventional**

Study Type Non-Interventional: [---]*

Allocation: **Randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

The Height for age Z-Score (HAZ) of children below 2 years will increase if TIPs recommendations and recipes are locally available and accepted.

Secondary Outcome

Anemia (A) among children between 6 and 23 months, defined as hemoglobin level of < 11g/dl, will decrease by 25 %.

Retinol binding protein (RBP) levels will decrease by 15% among children with a C-reactive protein (CRP) level of < 12mg/l.

Prevalence of children with presumed acute respiratory infections and fever (ARI) and diarrhea (D) in the last two weeks prior the survey will decrease by 25%.

There will be differences in knowledge of age-appropriate complementary feeding (KCF) of children between caretakers measured using a knowledge score in interventions and controls.

TIPs formative research generates nutritionally improved, culturally acceptable and affordable recipes which result in improved feeding practices and food intake which will result in a higher dietary diversity score for the children

Countries of recruitment

- **MW Malawi**

Locations of Recruitment



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/08/25**
- Target Sample Size: **2400**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Days**
- Maximum Age: **23 Months**

Additional Inclusion Criteria

Households with children under two years of age

Exclusion criteria

Households with no children under two years of age

Addresses

■ Primary Sponsor

**Justus-Liebig Universität Giessen
Mr. Professor Dr Michael Krawinkel
Wilhelmstr. 20
35392 Giessen
Germany**

Telephone: **06419939048**

Fax: **06419939039**

E-mail: **Krawinkel at fb09.uni-giessen.de**

URL: **http://www.uni-giessen.de/cms/**

■ Contact for Scientific Queries

**Justus-Liebig Universität Giessen
Ms. Dr Irmgard Jordan
Wilhelmstr. 20
35392 Giessen**



Contact for Scientific Queries

Justus-Liebig Universität Giessen

Ms. Dr Irmgard Jordan

Wilhelmstr. 20

35392 Giessen

Germany

Telephone: **06419939038**

Fax: **06419939039**

E-mail: **Irmgard.Jordan at ernaehrung.uni-giessen.de**

URL: **http://www.uni-giessen.de/cms/**

■ Contact for Public Queries

Bunda College of Agriculture, Department of Home Economics and Human Nutrition

Ms. Dr Beatrice Mtimuni

P.O.Box 219

Lilongwe

Malawi

Telephone: /

Fax: [---]*

E-mail: **bmtimuni at bunda.unima.mw**

URL: [---]*

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Food and Agriculture Organization

Viale delle Terme di Caracalla

00153 Rome

Italy

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/09/04**

DRKS-ID: **DRKS00003234**

Date of Registration in DRKS: **2011/08/25**

Date of Registration in Partner Registry or other Primary Registry: [---]*

Trial Publications, Results and other documents

- Trial results **Publication_Breastfeeding and infant's growth**
- Trial results **IMCF Malawi Baseline Report**

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*