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The WinFood Intervention Study: the effects of improved complementary foods on nutrition and health among Cambodian infants and children

Submission date 24/02/2011	**Recruitment status** No longer recruiting
Registration date 25/03/2011	**Overall study status** Completed
Last Edited 04/06/2015	**Condition category** Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The WinFood Intervention Study: the effects of improved complementary foods on nutrition and health among Cambodian infants and children, a randomised, single-blind study

Acronym
WinFood

Study objectives
Improved complementary foods based on locally available traditional ingredients will improve the nutritional and health status of Cambodian infants and children

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethics Committee for Health Research (NECHR), Cambodia, 22/10/2010, ref: Version No 1 dated 28-05-2010

Study design
Randomised single-blind study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Infants at risk of undernutrition

Interventions
Four different pre-cooked complementary food supplements given as a porridge daily from 6-15 months of age (6-8 months: 50 g, 9-12 months: 75 g, 13-15 months: 125 g)
1. WinFood CF: rice and two highly-nutritious fish and one spider species
2. WinFood Light: rice and a common fish species plus vitamin-mineral premix
3. Corn-Soy-Blend Plus (CSB+)
4. Corn-Soy-Blend Plus Plus (CSB++).
Food class (1 & 2) are the experimental and food class (3 & 4) are the control interventions

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Changes in fat-free body mass (deuterium dilution) and iron status (serum ferritin and transferrin receptors) from baseline (age 6 months) until the end of the 9 month intervention

Key secondary outcome(s))
Changes in:
1. Ponderal and linear growth
2. Physical activity (using an accelerometer, actigraph)
3. Motor milestones (questionnaire, clinic visits)

4. Morbidity
5. Haemoglobin concentration (using Haemocue)
6. Serum concentrations of acute phase proteins [C-reactive protein (CRP) and a-acid glycoprotein(AGP)], insulin-like growth factor (IGF)-1 and zinc
7. Whole blood fatty acid composition

Measured from baseline (age 6 months) until the end of the 9 month intervention

Completion date
10/02/2012

Eligibility

Key inclusion criteria
Children who are 6 months old and have a weight-for-height z-score > -3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Sex
All

Key exclusion criteria
1. Weight-for-height z-score < -3
2. Bilateral pitting oedema
3. Haemoglobin (Hb) < 80 g/L
4. Clinical signs of vitamin A deficiency (xerosis or Bitot spots). These children will be referred for treatment.

Date of first enrolment
07/03/2011

Date of final enrolment
10/02/2012

Locations

Countries of recruitment
Cambodia

Denmark

Study participating centre
Rolighedvej 30
Frederiksberg
Denmark
1958

Sponsor information

Organisation
University of Copenhagen (Denmark)

ROR
https://ror.org/035b05819

Funder(s)

Funder type
Government

Funder Name
Danish Ministry of Foreign Affairs (Denmark) - Danish International Development Agency (Danida) (ref: 57-08-LIFE)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No
Results article	results	01/04/2015		Yes	No